PREVALENCE OF GALLSTONES IN THE BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER, DIET AND BODY MASS INDEX.

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Thesis submitted in full compliance with the requirements for the Masters in Technology Degree in the Department of Radiography and the Durban University of Technology.

Except for quotations specifically indicated in the text and such help as I have acknowledged, this thesis is wholly my own work, and has not been submitted for any qualification at any other institution.

25/04/07
DATE

I, the undersigned approve the final submission of this thesis:

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DEDICATION

This thesis is dedicated to the father (late) Nkosinomusa and uncle (late) Bhekizitha. They instilled the sense of learning in me since I was very small. It is unfortunate that they cannot be here to share this joy.

This thesis is also dedicated to the following people:

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ABSTRACT

PURPOSE

This study aimed at determining and evaluating the prevalence of gallstones in the Black population of District 28 (D28) in relation to age, gender, diet and body mass index (BMI) in order to identify people at high risk and advise them so that they can avoid the complications and decrease the morbidity rate.

Blacks are thought to have increased prevalence of gallstones but there has been no systematic evaluation of its prevalence in D28.

METHODS AND MATERIALS

389 Black people from D28 were selected from referrals (for many different radiological examinations) coming to the X-ray and ultrasound departments. Some of the respondents were staff members who also met the selection criteria for the study.

An interview was conducted at Ngwelezane hospital using a structured questionnaire on health, social and diet history of the respondents. All information was entered into the data sheet. All respondents were then scanned using Mid-range ultrasound machines to establish the presence of gallstones and this information was thereafter documented on the data sheet.

SPSS version 11.5 (SPSS Inc, Chicago, Ill) was used for data analysis. Prevalence and 95% confidence intervals were calculated using the Epitable module of Epi Info version 6.04 (CDC, 2001). Pearson's Chi square tests were

used to assess associations between categorical variables and gall stones. Logistic regression analysis was applied to assess the independent effects of multiple risk factors on the development of gall stones. Backwards elimination method based on likelihood ratios was used with entry and exit probabilities set at 0.05 and 0.1 respectively.

RESULTS

The overall prevalence of gall stones in the sample was 26.74% (95% CI 22.51 to 31.30). It was lowest in the youngest age group (which was less than 20 years) (13.3%). The age-specific prevalence increased until the 41-50 age group (33.3%), but thereafter there was a slight decrease to 24.4% in the 51-60 group. The over 60 year group had a high prevalence of 33.3%. There was no significant association between the age group and gallstones (p=0.192), although a slight trend was demonstrated.

There was a slightly higher prevalence of gall stones in the females (28.1%) than in the males (22.3%), although the difference was not statistically significant (p=0.269).

Consuming plant protein was protective for developing gall stones (OR = 0.904, p=0.001). As the protein consumption increased by one percent, the risk of developing gall stones decreased by 9.6%. Fat and energy consumption were both significant risk factors. As the fat consumption increased by 1%, the risk of

gall stones increased by 4.9%. As the energy consumption increased by 100 units the risk of gall stones increased by 2.6%.

The prevalence of gall stones was the lowest in the normal (18.5 – 24.9) BMI category which is (22.7%) and increased as BMI category changed to above normal (28.6%) and below normal (25%). Those with BMI above normal had the highest prevalence of gall stones. However, the differences in percentages was not statistically significant (p=0.482).

CONCLUSIONS

This study has found that there is a relatively high prevalence (26.74%) of gall stones amongst asymptomatic Black males and females and those with a history of upper abdominal pain in Ngwelezana hospital. Thus the 95% confidence intervals would not refer to the general population of this area, but to a more select subpopulation of individuals who may be at increased risk of developing gall stones. The profile of individuals in this population who are at the highest risk of developing gall stones are those with greater age, low plant protein consumption, and high fat and energy intake.

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DEFINITION OF TERMS

Gall bladder- The gall bladder is a small pear- shaped sac located beneath the liver on the right side of the abdomen, it stores and secretes bile into the intestine to aid in digestion.

Gallstones - are clumps of solid material that form in the bile stored in the gall bladder.

Body mass index (BMI)- is used to measure obesity in adults taking weight and height into consideration.

Diagnostic ultrasound - use of high frequency vibrations beyond the range of audible sound to produce images on a TV monitor for diagnostic purposes.

Biliary colic - severe cramp –like pain experienced when one or more stone is passed through the duct.

Computerized tomography - method of taking slices of parts of the body using radiation

Cholescintigraphy - use of radio active material injected into the blood stream to diagnose abnormal contraction of the gall bladder.

Endoscopic retrograde cholangiopancreatography (ERCP) - special radiologic examination where special dye is used to outline the pancreatic and common bile ducts and locate the position of the gallstones using an endoscope which is a long, flexible tube through which a doctor can directly view the digestive tract.

Hyperplasia - excessive growth due to increase cell division (Sanders,1998).

Cholesterosis - deposition of cholesterol crystals to the lining of the gall bladder.

Dysplasia - disordered growth of cells resulting in developmental abnormality

Carcinoma - cancer

Empyema - abscess formation

Acute cholecystitis - inflammation of the gall bladder usually caused by outlet obstruction.

Acute pancreatitis - inflammation of the pancreas

Cholecystectomy - surgical removal of the gall bladder

Lithotripsy:-non- surgical treatment of stones using high-energy ultrasound waves causing the stone to shatter into smaller particles

Helminthic(ascariasis) – an infestation with worms.

Peritonitis – inflammation of the peritoneal cavity

Septicaemia – the presence in the blood of large numbers of bacteria and their toxins.

Dyspepsia – indigestion

Canaliculi – small tube or channel

Metastases – transfer of a disease from one part of the body to another.

Radionuclide- a radioactive substance which is inherently unstable.

Vagotomy – surgical incision of the vagus nerve or any of its branches (Weller and Wells, 1992).

Scintigraphy- recording of the distribution of radioactivity in an organ following injection of a small dose of radioactive substance that is specifically taken up by that organ (Weller and Wells, 1992).

Billroth – removal of most of the lesser curvature and pyloric portion and joining of the duodenum to the refashioned stomach(Weller and Wells, 1992 and Sanders, 1998) .

LIST OF ABBREVIATIONS

NDDIC - National Digestive Disease Information Clearinghouse

KZN- KwaZulu Natal

BMI – Body Mass Index

CCK – Cholecystokinin

RUQ- Right upper quadrant

ALP – Alkaline phosphatase

AST- Aspartate aminotranfarase

ALT- Alanine aminotransaminase

HIDA- Hydroxyiminodiacetic

CBD- Common bile duct

ERCP- Endoscopic Retrograde Cholangiopancreatiography

MRCP- Magnetic Resonance Cholangiopancreatiography

CT- Computerized Tomography

US- Ultrasound

MRI- Magnetic Resonance Imaging

T2W – Time2 weighted

T1W – Time1 weighted

ESWL- Extracorporeal shockwave lithotripsy

HDL – High density lipoprotein

PA – Physical Activity

RR – Relative Risk

DIT – Durban Institute of Technology

SPSS –Statistical Package for the Social Sciences

SD – Standard deviation

OR – Odds ratio

D28 – District 28

SHIP –Study of Health in Pomerania

MRC – Medical Research Council

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND TO THE STUDY

Cholelithiasis is a major health problem worldwide, particularly in the adult population and its incidence has shown considerable geographical and regional variations (Mittal and Mittal, 2002).

Gallstones are described as crystalline structures, formed in the bile and stored in the gall bladder due to gradual accretion of components of bile (National Digestive Disease Information Clearinghouse, 2002). They can be divided into those composed of cholesterol, those of pigment and a mixture of cholesterol, calcium, salts and pigment. Cholesterol stones account for 80% of all gallstones in the western hemisphere and contain more than 70% cholesterol, often with bile pigment and calcium (Prasad, 2002). The list of risk factors for gall gallstone formation includes, age, obesity, dieting, race(high risk for native Americans), gender, cholesterol lowering drugs, diabetes, rapid weight loss, etc (wrong diagnosis,2003) .

The highest prevalence of gallbladder disease has been found among some North American Indians, Chileans and Mexican Americans followed by non-

Hispanics from North America, Europeans and Asians from India (Everhart et.al., 2002).

A study done at Santiago in 1998 involving 182 Mapuche Indians, 225 Maoris of Easter Island and 1584 Hispanics demonstrated an increased prevalence of gall bladder diseases in Mapuches (35%), followed by Hispanics (27%) and Maoris (21%) (Miquel et.al.,1998).

Increase in the prevalence of gallstones has been noted in the eastern countries as well, which is thought to be resulting from westernization of lifestyle suggesting that environmental factors are also important (Bateson, 1999).

According to Bateson (1999), in his international league table, White South Africans are grouped as having a high prevalence, meanwhile the Blacks are grouped as moderate. According to work written by Docrat et.al. (1999) in South Africa, a gradual increase in the prevalence of the gallstone was reported. This is noted when comparing a study they did in 1971 in Gauteng Province which showed a prevalence of 0.06 % , with a study done in 1983 which showed a prevalence of 2% for Blacks.

In all the studies that reported on the prevalence of gallstones, ultrasound was used as a diagnostic tool. It is the modality of choice used to diagnose gallstones, because of its simplicity and availability (Grainger and Allison, 1994).

A study done in 2002 proved that ultrasound was reliable as it yielded 99% sensitivity, 100% specificity and 99.3 % accuracy (Ahmad et.al., 2002).

This research project is important in District 28 because, although the area is said to be rural, the lifestyle of the people is now highly westernized. It is therefore hypothesized that there will be an increase in the prevalence of gallstones in the region.

1.2 MOTIVATION AND SIGNIFICANCE

Gallstones are a common cause of morbidity among the digestive tract diseases (Everhart et. al., 1999). About 80 % of the patients with gallstones may not be diagnosed in time because they are asymptomatic. Sometimes they present with abdominal symptoms, including abdominal pain, acute biliary complications and gall bladder cancer. The most specific symptom is actually, the biliary colic, which is most often located in the right upper abdomen just under the margin of the ribs but can also be felt in the back and right shoulder (Baig et.al., 2002).

It is therefore important to accurately diagnose gallstone- related pain so as to avoid the dreaded complications that may occur. This is important because pain in the right upper quadrant is not specific for gallstones but it may also come from the liver, part of the colon, and musculoskeletal injury (Moro, 2000). Identification of individuals likely to develop complications would be of benefit in the clinical practice as cholecystectomy could then be performed.

According to Indar and Beckingham (2002) acute inflammatory changes of the gall bladder wall may develop in 1-3% of patients with symptomatic gall stones. This is caused by Helminthic infection (ascariasis) which is a major cause of biliary disease in developing countries e.g. Asia, Southern Africa, and Latin America. If this inflammation persists it may cause perforation or gangrene of the gall bladder.

Furthermore, it is thought that gall bladder perforation, which is associated with a high mortality rate, may develop as early as two days after onset of symptoms (Sood et al., 2002). Therefore, early detection of gallbladder disease complications can reduce the associated mortality and morbidity rates (Everhart et. al., 2002).

Gallbladder perforation, being one of the most severe complications of acute cholecystitis occurs most often in men, Hispanics and older patients. It has been reported to occur in 2–15% of patients with acute cholecystitis and is associated with a mortality rate of up to 70%. Late surgical intervention has been suggested as the cause for the high morbidity and mortality of this complication and improved outcomes have been shown as a result of cholecystectomy within 72 hours (Stefanidis et. al., 2004). On the contrary, Stefanidis (2006) suggests that although an early cholecystectomy strategy may lead to improved outcomes, it may be difficult to implement and may not be cost-effective.

According to Muller (2004), past work on the prevalence of gallstones in Black South Africans, is sparse, and knowledge was largely based on impressions. New figures confirming the suspicion of a high incidence would be very helpful in clinical practice. It is hoped that the practice of ultrasonography will ease the detection of asymptomatic gallstones.

1.3 THE AIM OF THE STUDY

This study aims to determine the prevalence of gallstones in the Black population of District 28 in KwaZulu Natal (KZN) in relation to age, gender, diet and body mass index (BMI) in order to identify individuals likely to develop complications and therefore decrease the morbidity rate.

1.4 OBJECTIVES OF THE STUDY

1.4.1 First Objective

To determine the age specific prevalence rate of gallstones in the Black population over 18 years of age of District 28 in KZN in order to determine the age group at high risk for developing gallstones.

1.4.2 Second Objective

To determine the gender specific prevalence rate of gallstones in the Black population over 18 years of age of District 28 in KZN in order to determine the gender at high risk.

1.4.3 Third Objective

To determine the diet specific prevalence rate of gallstones in the Black population over 18 years of age of District 28 in KZN to ascertain what may contribute to the high incidence of gallstones.

1.4.4 Fourth Objective

To determine the BMI specific prevalence rate of gallstones in the Black population over the age of 18 years of District 28 in KZN in order to determine the factors contributing to the development of gallstones.

1.4.5 Fifth Objective

To determine the overall prevalence rate of gallstones in the Black population over 18 years of age of District 28 in KZN in order to determine the factors contributing to the development of gallstones.

1.5 DELIMITATIONS

Although risk factors for gallstone disease are numerous, this study will only cover the most common factors found in the literature i.e. age, gender, diet and obesity. Conclusion drawn from a study done in Pomerania in North- Eastern Germany where cholelithiasis is a frequent disorder was that female sex, age and being overweight are major risk factors for gallstone formation (Völzke et.al.,2005).

1.6 ASSUMPTIONS

It is assumed that the information given by the respondents during the interview was correct. It is also assumed that the ultrasound machines used to diagnose gallstones were reliable and equally sensitive in diagnosis of gallstones.

1.7 OUTLINE OF CHAPTERS

Chapter two gives an account of the literature review which contains the theoretical framework that informs about this study. This chapter reviews relevant research done nationally and internationally on the prevalence of gallstones and also in South Africa amongst the Black population.

The chapter also gives a short discussion on food analysis and how it is calculated. The chapter concludes with statements of the research aim and objectives. Chapter three outlines the research design and methodology that

was used. The type of data collected, the selection of research participants, data collection procedures, ethical considerations and the statistical methods employed are described.

Chapter four, which is the results section, describes the statistical analysis of the data. In chapter five, the discussion, the main trends and patterns emerging from the results are discussed. Chapter six describes the conclusion and recommendations made from the results of the study. This chapter is then followed by the list of references and appendices.

1.8 RESEARCH HYPOTHESIS

This study tested the hypothesis of the increased prevalence of gallstones in the Black population of District 28 relative to age, gender, diet and BMI. The hypothesis is stated as follows:

H.1 There would be an increase in prevalence of gallstones in the Black population of District 28 with an increase in age.

H.2 The prevalence of gallstones in females would be double that of males.

H.3. Increased carbohydrates, protein and fat consumption would increase the risk of developing gallstones.

H 4 The prevalence of gallstones would increase with an increase in BMI.

H.5 The overall prevalence of gallstones in the Black population of District 28 would be increased.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter provides a review of the literature related to gallstones, its prevalence globally and in South Africa among the different racial groups.

This chapter also describes how the gallstones are formed and highlights the common attributing factors and processes. Patterns of presentation are also discussed because 80% of gallstones are said to be asymptomatic (Kennedy et.al., 1994). A brief review of the anatomy and physiology of the biliary tree is presented to help in the understanding of the disorders of the biliary system. The normal and abnormal processes that lead to the development of stones are also discussed.

The chapter also highlights the common risk factors and the possible complications that can happen if the necessary management with regards to gallstone disease is not done. Common treatment given to the people affected by the gallstones is also highlighted. It also mentions some alternative treatments that can be given.

The chapter concludes with statements of the research aim and objectives.

2.2 ANATOMY AND PHYSIOLOGY OF THE BILIARY TREE

The gallbladder is a pear-shaped sac like structure on the inferior surface of the liver along the quadrate lobe in a shallow fossa (Miquel, 1998). It is about 8 cm long and 4 cm wide. There are three layers that form the wall of the gall bladder namely; an inner mucosa folded into rugae that allow the gallbladder to expand, a muscularis, which is a layer of smooth muscle that allows the gallbladder to contract and an outer covering called the serosa. It connects with the liver and intestine through small tubes called bile ducts (Seeley et.al., 1998).

For descriptive purposes, the gall bladder has a fundus or expanded end, a body and a neck which is continuous with the cystic duct. The fundus is its wide end which projects from the inferior border of the liver. (Argani,2004). The body is the main part which is directed superiorly, posteriorly, and to the left from the fundus. The neck is narrow and tapered, and is directed towards the porta-hepatis. It makes an S- shape bend and is twisted in such a way that its mucosa is thrown into a spiral fold (Misciagna, 1999).

The blood supply is through the cystic artery which is a branch of the hepatic artery and blood drainage is through the cystic vein which drains into the portal vein (Wilson and Waugh, 1996).

Bile is a yellow-green fluid containing minerals, cholesterol, neutral fats, phospholipids, bile pigments, and bile acids. The principal pigment is bilirubin, derived from the decomposition of haemoglobin (Sungal, 2000). Bacteria of the large intestine metabolize bilirubin to urobilinogen, which is responsible for the brown colour of faeces. In the absence of bile secretion the faeces are grayish white and are marked with streaks of undigested fat (Saladene, 2004).

Bile acids are steroids synthesized from cholesterol. Bile acids and lecithin, phospholipids, aid in fat digestion and absorption. All other components of bile are wastes destined for excretion in the faeces. When these waste products become excessively concentrated, they may form gallstones (Raoyle and Walsh, 1993).

The primary purpose of the gall bladder is to store and concentrate bile which is up to three cups a day. Bile is a fluid made up of mainly water, cholesterol, fat, bilirubin, which is the yellow-brown pigment, and bile salts (Tendler, 2005). It is first produced by the liver and then secreted through tiny channels within the liver into a duct. From here, bile passes through a larger tube called the common bile duct, which leads directly to the small intestine (Kennedy et.al., 1994).

Some of the bile drains to the gall bladder through a cystic duct. When eating fatty foods, a hormone called cholecystokinin (CCK) is secreted. It causes the gallbladder to contract and also causes relaxation of a small valve (the sphincter

of Oddi) at the end of the common bile duct (Walsh, 1999). This allows bile to flow into the duodenum and mix with food for digestion. After the hormone's effect wears off, the valve closes, the gallbladder relaxes, and the cycle is repeated (Pleatman, 2005).

2.3 PATHOGENESIS OF GALLSTONES

When the gall bladder emptying is impaired supersaturation occurs. This happens because of too much cholesterol being secreted into bile which therefore results in stagnation of the bile and thereafter gallstones develop (Kennedy et.al., 1994). The normal bile consists of 70% bile salts which are mainly cholic and chenodeoxycholic acids, 22% phospholipids (lecithin), 4% cholesterol, 3% proteins, and 0.3% bilirubin (Beckingham, 2001).

The most common type of gallstones are cholesterol or cholesterol predominant (mixed) stones which account for 80% of all gall stones in the United Kingdom. They are insoluble in water, but the presence of bile salts and lecithin keeps them in solution, in the bile (Rajan, 2002).

There are also black pigment stones which consist of 70% calcium bilirubinate and are more common in patients with hemolytic diseases (sickle cell anaemia, hereditary spherocytosis, thalassaemia) and cirrhosis(Beckingham,2001).

Furthermore, there are brown pigment stones which are not very common in Britain. They account for less than 5% of stones and are formed within the

intraheptic and extrahepatic bile ducts as well as the gall bladder. They form as a result of stasis and infection within the biliary system, usually in the presence of Escherichia coli and Klebsiella species, which produce β glucuronidase that converts soluble conjugated bilirubin back to the insoluble unconjugated state leading to the formation of soft, earthy, brown stones. Ascaris lumbricoides and Opisthorchis senensis have both been implicated in the formation of these stones, which are common in South East Asia (Walsh, 1999)

On the other hand, conditions such as obesity, high calorie diets, rapid weight loss and pregnancy also favour increase in biliary cholesterol which would also promote stone formation. These are associated with abnormal gall bladder motor function, which cause delayed emptying and stasis that promotes the formation of gallstones as well (Rajan,2002).

Biliary sludge, which is the thick mucous material that forms in the most dependent portion of the gall bladder, also promotes nucleation of stones. Most of these patients have no symptoms, but the sludge itself can cause acute cholecystitis (Indar and Beckingham, 2002).

Intestinal hypomotility has also been recently recognized as one of the factors in cholesterol lithogenesis. This is due to a prolong exposure of bile salts to intestinal micro-organisms (Tsai et. al., 2004).

2.4 PATTERNS OF PRESENTATION: SYMPTOMATIC AND ASYMPTOMATIC

The majority of the people with gallstones never experience any symptoms. These are called silent stones. Others remain asymptomatic for at least two years after the stone formation. They are usually detected during a routine medical check up or examination for another illness (Kennedy et. al., 1994).

On the other hand, symptomatic stones cause a variety of symptoms. Vomiting may sometimes accompany the symptoms. Dyspeptic symptom of indigestion, belching, bloating, abdominal discomfort, heartburn and specific food intolerance are also common in people with gallstones, but are probably unrelated to the stones themselves and frequently persist after surgery (Beckingham, 2001).

The upper abdominal pain is the most common symptom for gallstone disease. It is severe and is located in the epigastrium and/or the right upper quadrant(RUQ). The onset is relatively abrupt and often awakens the patient from sleep. The pain is steady in intensity, may radiate to the upper back, and is sometimes associated with nausea and lasts from 15 minutes to 24 hours(Health Link, 2003)

The nature of the pain described above is called biliary colic. This symptom is specific for gallstones but 80% of the patients referred with gallstones present with other abdominal symptoms such as upper abdominal pain, pain radiating to the back or shoulder, tenderness of the right upper quadrant of the abdomen, food and fat intolerance (Beauchamp, 2004)

A study was done by Berhane (2006) with an aim to characterize a pain pattern that is typical for gallstone disease and to describe the extent of associated dyspepsia. A total of 220 patients with symptomatic gallstone disease including complicated disease (acute cholecystitis and common bile duct stones) were interviewed using detailed questionnaires to disclose pain patterns and symptoms of indigestion.

All patients had pain in the right upper quadrant (RUQ) including the upper midline epigastrium. The pain was localized to the right sub-costal area in 20% and to the upper epigastrium in 14%, and in the rest (66%) it was more evenly distributed. An area of maximal pain could be defined in 90%. Maximal pain was located under the costal arch in 51% of patients and in the epigastrium in 41%, but in 3% behind the sternum and in 5% in the back. The pain was referred to the back in 63% of the patients. A pattern of incipient or low-grade warning pain with a subsequent relatively steady state until subsiding in the same fashion was present in 90% of the patients. An urge to walk around was experienced by 71%. Pain attacks usually occurred in the late evening or at night (77%), with 85% of the attacks lasting for more than one hour and almost never less than half an hour. Sixty-six percent of the patients were intolerant to at least one kind of food, but only 48% to fatty foods (Berhane, 2006).

People diagnosed with gallstones without the typical symptoms appear to have an annual incidence of biliary pain of 2–5 % during the initial years of follow-up, with perhaps a declining rate thereafter. Complications usually occur at a rate of

less than 1% annually (Festi et.al.,1999). On the other hand, people whose stones are symptomatic at discovery have a more severe course, with approximately 6–10% suffering recurrent symptoms each year and 2% biliary complications. The risk of acute cholecystitis as a complication appears to be greater in those with large solitary stones, and biliary pancreatitis is seen in people with multiple small stones, and gallbladder cancer in those with large stones of any number (Diehl, 1992).

Acute cholecystitis which is a complication of gallstone disease is diagnosed on the basis of symptoms and signs of inflammation in patients with peritonitis localized to the right upper quadrant. It is important that acute cholecystitis is differentiated from biliary colic by the constant pain in the right upper quadrant and Murphy's sign in which inspiration is inhibited by pain on palpation. Patients with acute cholecystitis may have a history of attacks of biliary colic or they may have been asymptomatic until the presenting episode (Indar and Beckingham, 2002).

Furthermore, acute cholecystitis can be suspected in patients with a history of fever and right upper quadrant abdominal pain. Clinical examination often reveals fever, jaundice, and right upper quadrant tenderness. If pain with inspiratory arrest occurs when the inflamed gallbladder comes into contact with the examiner's hand, the patient has a positive Murphy's sign (Glasgow et.al. 2000).

In a review of 497 consecutive patients evaluated for suspected acute cholecystitis, Ralls and colleagues as cited in Musana and Yale (2005), found

that 98.8% of the patients in their series had a positive ultrasonographic Murphy's sign, making it a useful diagnostic test.

Some people develop superimposed bacterial infection after which septicaemia sets in. In the case of severe acute cholecystitis mild jaundice may develop, caused by inflammation and oedema around the biliary tract and direct pressure on the biliary tract from the distended gall bladder (Indar and Beckingham 2002).

Symptoms of functional indigestion (gastro-esophageal reflux, dyspepsia or irritable bowel symptoms) were seen in the vast majority in association with the attacks. It was concluded that gallstone-associated pain follows a certain pattern in the majority of patients. The pain is located in a defined area with a point of maximum intensity, is usually referred, and occurs mainly at night with duration of more than one hour. The majority of patients experience functional indigestion, mainly of the reflux type or dyspepsia (Berhane, 2006).

2.5 DETECTION AND DIAGNOSIS

The diagnostic challenge posed by gallstones is to be sure that abdominal pain is caused by stones and not by some other conditions. Simply finding stones does not necessarily explain a patient's pain, which may be caused by numerous other ailments. The following are the different diagnostic tools used in the diagnosis of gall bladder diseases.

`2.5.1 Liver function tests

Standard biochemical liver function tests are done routinely in all cases of suspected biliary disease. Most of these tests are non-specific and are more valuable in following the course of the disease in an individual patient than in providing diagnostic information (Grainger and Allison, 1994).

Liver function tests routinely combine markers of function (albumin and bilirubin) with markers of liver damage (alanine transaminase, alkaline phosphatase, and γ -glutamyl transferase). Any change in liver enzymes indicate a certain disease process i.e. a predominant rise in alanine transaminase activity (normally contained within the hepatocytes) suggests a hepatic process (Hayat et.al., 2005). Serum transaminase activity is not usually raised in patients with obstructive jaundice, although in patients with common duct stones and cholangitis a mixed picture of raised biliary and hepatic enzyme activity is often seen (Beckingham and Ryder, 2001).

Epithelial cells lining the bile canaliculi produce alkaline phosphatase, and its serum activity is raised in patients with intrahepatic cholestasis, cholangitis, or extrahepatic obstruction (Peng et.al.,2005). The increased activity of the alkaline phosphatase may also occur in patients with focal hepatic lesions in the absence of jaundice. In cholangitis with incomplete extrahepatic obstruction, patients may have normal or slightly raised serum alkaline phosphatase is also produced in bone, and bone disease may complicate the interpretation of abnormal alkaline

phosphatase activity (Rahman et.al.,2005). If increased activity is suspected to be from bone, serum concentrations of calcium and phosphorus should be measured together with 5'-nucleotidase or γ-glutamyl transferase activity. These two enzymes are also produced by bile ducts, and their activity is raised in cholestasis but remains unchanged in bone disease. (Beckingham and Ryder, 2001).

Elevated alkaline phosphatase (ALP) is usually noted in the presence of common duct stone. The bilirubin levels also increase after ALP levels rise. If the stone passes into the small intestine aspartate aminotranferase (AST) and alanine aminotransferase (ALT) may spike (Health and Age, 2002). It is concluded that liver enzymes changes alone, cannot give a conclusive assessment in terms of diagnosis of the presence of gallstone disease. Radiological examinations are also recommended for the diagnosis of gallbladder diseases.

2.5.2 Plain X-Rays

Plain radiography is a poor screening examination for gallstones. According to Bortoff et. al., 2000, only 15-20 % of gallstones contain enough calcium to be visible on plain radiographs. (Bortoff et. al.,2000).

Chest radiography may be used to show some other related abnormalities such as small amounts of subphrenic gas, abnormalities of diaphragmatic contour,

including metastases. Abdominal radiographs can be useful if a patient has calcified or gas containing lesions as these may be overlooked or misinterpreted on ultrasonography. Such lesions include calcified gall stones (10-15% of gall stones), chronic calcific pancreatitis, gas containing liver abscesses, portal venous gas, and emphysematous cholecystitis (Whitehouse and Worthington, 1996).

Plain x-rays can also be used in searching for gallstones in the right upper quadrant of the abdomen. The exact proportion of gallstones that are radiopaque is about 10-15 %. An x-ray will only detect the infrequently encountered pigment stones because only pigment stone have sufficient calcium to make them visible on a plain x-ray (Blanco, 2006)

2.5.3 Oral cholecystogram

Oral cholecystogram used to be the primary method of investigating the gall bladder although the problem was radiation dose to the patient and side effects of contrast agents. It showed an accuracy of 85- 90% (Grainger and Allison, 1994). Biloptin tablets are taken and absorbed by the intestine, and excreted by the following day. Gallstones are therefore seen as they are outlined by the dye. If the gall bladder is diseased or has a blocked outlet it will not absorb the contrast agent, therefore will not be visible in x-rays (Kennedy et.al., 1994).

It was first introduced in 1924 and remained the mainstay of radiographic diagnosis of gallbladder disease for decades. Although still used, oral

cholecystography has largely been replaced by ultrasonography for evaluation of cholelithiasis and its associated complications, such as acute cholecystitis (Whitehouse and Worthington 1996).

Sungal et.al., 2000, on the other hand describe oral cholecystography as an excellent method for gallstone detection, with sensitivities close to those of ultrasound. Furthermore, oral cholecystography allows better determination of the number and size of gallstones than ultrasound and can demonstrate cystic duct patency. Gallbladder contractility can be determined by administration of a fatty meal and re-imaging. According to Bortoff et.al. (2000) oral cholecystography has several disadvantages relative to ultrasound. These are:

(*a*) Adjacent organs cannot be evaluated,

(*b*) Non- visualization of the gallbladder is non-specific and can be attributable to multiple factors,

(*c*) Patients are exposed to ionizing radiation, and

(*d*) Bowel gas can obscure the gallbladder and yield false-positive or false-negative results.

The role of oral cholecystography has been limited due to the advantages of ultrasound in detecting gallstones and related disease. Oral cholecystography remains useful in certain circumstances, such as in patients being considered for orally administered bile acid therapy or contact dissolution. In these patients, oral

cholecystography can allow accurate determination of stone size, composition, and burden and provide information on gallbladder contractility (Razzaz and Sukumar, 2004).

2.5.4 Radio-isotope scanning

Cholescintigraphy (HIDA SCAN)

HIDA (hydroxyiminodiacetic) scan is a radionuclide examination using a minute dose of a radioactive substance(radiolabelled hydroxyiminodiacetic acid) which is injected into the vein. Once injected into the vein, it is captured by the liver and secreted into bile and if the cystic duct is open, it will enter into the gall bladder to visualize it using a gamma camera (Majeski, 2003). HIDA scan identifies obstructions of the cystic duct, evaluates the ability of the gall bladder to contract, and diagnose acute cholecystitis. If the radioactive substance bypasses the gallbladder and fills the liver and intestines, then the gallbladder is obstructed consistent with cholecystitis (Blanco, 2006).

On the other hand, ultrasound is the modality of choice for evaluating gallbladder diseases. When the diagnosis remains in doubt after ultrasound scanning, HIDA scan is regarded as the gold standard investigation. In patients with acute cholecystitis, the gallbladder lumen will not take up any radioactive isotope one to two hours after injection and therefore the gall bladder will not be visible on the scan. Occasionally, an acutely inflamed gall bladder may have delayed filling,

leading to a false positive result, but augmentation with morphine reduces this (Indar and Beckingham, 2002).

According to Zakko (2005), cholescintigraphy is known to be more sensitive in detecting acute cholecystitis with an advantage of being non-invasive. The problem is that it takes a long time to do which approximately one to two hours or longer. Its limitation is that it cannot identify individual gallstones nor can it detect chronic cholecystitis.

A study was done by Iqbal et.al., 2004 with an objective to evaluate the role of hepatobiliary nuclear scanning in diagnosing bile duct stones. Twenty-five patients with suspected common bile duct (CBD) stones underwent hepatobiliary scintigraphy. The results of scintigraphy were compared with cholangiograms obtained by endoscopic retrograde cholangiopancreatography (ERCP) in 11 patients and magnetic resonance cholangiopancreatography (MRCP) in 14 patients, considering MRCP/ERCP as the 'gold standard'. Results of scintigraphy showed features suggestive of CBD stones in 11 of the 25 patients. The results of ERCP/MRCP confirmed that eight of them had stones. Scintigraphy showed no features of CBD stones in the remaining 14 patients. ERCP/MRCP showed CBD stones in two of these 14 patients. Thus, scintigraphy had a sensitivity of 80% and a specificity of 80%. It was concluded that scintigraphy has good sensitivity and specificity in predicting CBD stones in patients with gallstone disease and a dilated CBD.(Iqbal et.al. 2004).

2.5.5 ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATIOGRAPHY

Endoscopic retrograde cholangiopancreatiography (ERCP) is used to locate and remove stones in the ducts without the need for surgery (NIDDC, 2002).
A flexible tube with a camera is inserted through the mouth and small intestine while the patient is under sedation. A smaller tube is advanced through the first tube into the bile duct through which contrast is injected and an x ray is taken to visualize the stones (Zakko, 2005)

ERCP is the best method for diagnosing bile duct stones but has the disadvantage of being invasive, and there is a risk of complications (Iqbal et. al., 2004). It is well suited for the evaluation and treatment of diseases of the bile ducts and pancreas, but it carries the risk of inducing MRCP and endoscopic ultrasonography have exceptional value in imaging the gallbladder, common hepatic duct, common bile duct, and pancreas. These imaging studies have replaced ERCP for diagnostic purposes in patients with a low pretest probability of finding lesions amenable to endoscopic therapy, such as bile duct stones (Dumot, 2006)

2.5.6 ULTRASOUND

It is a simple, rapid and non-invasive imaging technique that is also widely available even in small centres. It is a more sensitive technique when compared with all the above-mentioned radiological investigations and its accuracy is about 98 % when the classic finding of an echogenic lesion, acoustic shadowing and postural movement are present. It is used to diagnose gallstones in the gall bladder, bile ducts and other biliary lesions e.g. cancer. (Whitehouse and Worthington 1996).

According to Singh et.al., (2001), ultrasound is the method of choice for detection of gallstones. It has the following advantages:

(i) high sensitivity and accuracy (> 95%),

(ii) non-invasiveness,

(iii) the option of performing a bedside examination,

(iv) lack of ionizing radiation,

(v) relatively low cost,

(vi) and the ability to evaluate adjacent organs.

Ultrasound can also detect gallstones as small as two millimeters in diameter with accuracy of 90 t0 95 % (Surgeon's corner, 2000).

The characteristic findings of gallstones with ultrasound are:

(i) a highly reflective echo from the anterior surface of the gallstone,

(ii) mobility of the gallstone on repositioning the patient (typically in a decubitus position),

(iii) and marked posterior acoustic shadowing (Razzaz, 2004)

The latter finding is extremely important in regard to the specificity of the technique because non-shadowing structures are considerably less likely than shadowing structures to represent gallstones. When the gallbladder is filled with stones, the resulting appearance is termed the wall-echo-shadow sign. The anterior wall of the gallbladder is echogenic, below which is a thin, dark line of bile; finally, there is a highly echogenic line of superficial stones with associated posterior shadowing. The deeper stones and posterior gallbladder wall are not visible (Khan, 1999).

A study was done in Pakistan by surgeons in 2002 to check their accuracy in diagnosing gallstones using ultrasound. That study involved 142 patients with signs and symptoms suggestive of gallstone disease. It yielded, 99% sensitivity, 100% specificity and 99.3 % accuracy (Ahmad et. al., 2002).

Musana and Yale, 2005 re-affirmed the fact of ultrasonography being the diagnostic imaging study of choice in gallbladder disease. As had been documented in the Surgeon's corner (2000), they also mentioned that ultrasound can routinely detect gallstones as small as 2 mm in diameter; with the overall sensitivity of ultrasound scanning for gallstones larger than 2 mm in diameter greater than 95%. Ultrasonography can also diagnose acute cholecystitis in which pericholecystic fluid (in the absence of ascites) and thickening of the gallbladder wall beyond 4 mm (in the absence of hypoalbuminemia) are non-

specific findings suggestive of the disease. It has an adjusted sensitivity and specificity for the diagnosis of acute cholecystitis of 88% (95% CI: 0.74 to 1.00) and 80% (95% CI: 0.62 to 0.98), respectively (Majeski, 2003).

Focal tenderness over the gallbladder caused by the ultrasound transducer during imaging, also referred to as an ultrasonographic Murphy's sign, has a positive predictive value more than 90% for detecting acute cholecystitis if gallstones are present (Rahman,2005). This, however, requires an alert patient and a skilled operator. Moreover, a positive ultrasonographic Murphy's sign is present only when tenderness is maximal over the gall bladder and a positive Murphy's sign had a positive predictive value of 92.2% for acute cholecystitis, while the absence of gallstones together with a negative Murphy's sign had a 95% negative predictive value. Despite being a reliable predictor of acute cholecystitis in the appropriate clinical setting, a patient with a positive Murphy's sign needs to be further evaluated with an imaging study, preferably ultrasonography. (Musana and Yale 2005).

According to Singh et.al., 2001, ultrasound (U/S) provides better results than computerized tomography (CT) and similar results to those of perioral cholecystography in determining the number and diameter of the stones, but is not able to determine the calcium content which requires the use of CT. It also has a high sensitivity (97–100%), specificity (93.6–100%) and diagnostic accuracy (90.8–93%). The sensitivity of ultrasound in diagnosing gallbladder

stones is comparable to magnetic resonance cholangiography (97.7%), that is, however, superior for diagnosing biliary sludge or microlithiasis.

It is also generally accepted as the first imaging modality in gallstone complications, and in acute cholecystitis, including the emphysematous and hemorrhagic varieties. Sensitivity in gallstone complications appears to decrease when compared with their initial diagnosis. It ranges from 50 to 94%, specificity from 53 to 88% and accuracy from 68 to 77% (Sood et.al., 2002)

Although initial ultrasound has been shown to be superior to initial CT, recent research, however, has demonstrated the superior diagnostic accuracy of hepato-biliary scintigraphy in acute cholecystitis (92% for scintigraphy vs. 77% for ultrasound) (Chatziioannou et al., 2000) cited in Gandolfi et.al., 2003. Scintigraphy is, however, not so widely available, more expensive, uses radiation and its results are delayed due to the metabolism of the injected substance (Majeski,2003).

As far as the complications of acute cholecystitis are concerned, such as perforation, CT scan is advisable since it can detect the perforation site in a much higher percentage of cases than ultrasound (62.2 vs. 38.5%) (Kim et. al., 2002).

Ultrasound has also been used for the diagnosis of biliary complications after laparoscopic cholecystectomy. It is able to reveal the presence of an abnormal fluid collection and dilation of the main bile duct, due to stones in the common

bile duct, sometimes even showing the stone itself. The demonstration of a fluid collection in the gallbladder fossa is not, however, always a sign of bile leakage but could be blood or ascites. Correlation with the clinical picture and, if necessary, with other techniques (scintigraphy and above all ERCP) is thus still important. It should also be borne in mind that fluid collections after laparoscopic cholecystectomy close to the surgical site are not necessarily pathological. This phenomenon is observed in 53% of the patients examined with US on the first day after successful surgery, and do not, therefore, consider routine ultrasound the day after laparoscopic cholecystectomy to be justified (Gandolfi et. al., 2003).

Recently, Bingener et.al., 2004 have discovered the sensitivity for cholelithiasis to be 98%. Three patients (5.5%) were false positives and false negative was seen in 1 patient (1.8%).

Limitations for ultrasound are in diagnosing bile duct and cystic duct stones. It is not always reliable in cholecystitis in the absence of gallstones but laboratory tests with ultrasound will enhance the diagnosis. In this study the limitations are in a contracted gall bladder if the patient is not starved or in the case of chronic cholecystitis (Puspok et.al., 2005).

According to Schirmer et.al.(2005) there has been false negatives determined by the small size of the stones, their adherence to the gallbladder wall simulating a cholesterol polyp, or by their localization in the cystic duct.

2.5.7 MRI (magnetic resonance imaging), CHOLANGIOGRAPHY and CT(computerized tomography)

MRI cholangiography is very effective in detecting bile ducts stones but it is very expensive and it may not detect very small stones or chronic infections in the pancreas or bile duct. CT cholangiogram is an alternative but very costly as well (Health and Age, 2002). The CT scan is used to determine which gallstones are suitable for some of the non- surgical gallstone elimination modalities; however, it is a poor initial test for diagnosing stones. The problem with the above radiological investigations is radiation dose, and that they are only available at tertiary centers (Zakko, 2005).

MR imaging is able to predict the composition of gallstones. A study was done by Ukaji et.al.(2002) in Japan where cholecystectomy was performed on the fifty patients and all the gallstones were examined by MR imaging using a body phantom. After imaging, all gallstones were cut into two pieces, and the MR appearances were compared with their cross-sections. Chemical analysis was subsequently performed on 32 gallstones. On T2-weighted (T2W) images, 24 of 50 gallstones showed high signal intensities only in their center. These central high intensities seen on T2W images corresponded to the clefts filled with fluid within gallstones. In 45 of 50 gallstones there were high signal intensity areas in

central and/or peripheral regions on T1-weighted (T1W) images. On T1W images, not only the clefts within gallstones but also other regions were seen as high intensity, and these regions had a brown to black color, coarse structure, and contained much copper. The conclusion drawn was that MR imaging can visualize the structures and compositions of gallstones in detail. That can contribute to efficient indication of the non-surgical treatment of gallstones such as chemical dissolution and extracorporeal shock-wave lithotripsy (ESWL) (Ukaji et.al., 2002).

MRCP, which is a noninvasive, nonionic diagnostic procedure characterized by heavily T2 weighted images can be effectively used in the evaluation of biliary system of patients following pancreato-biliary and gastric surgery(Jendresen et. al., 2002). In a preliminary study, a capping appearance was found in the distal common bile duct in patients with previous vagotomy, antrectomy, and Billroth I or II procedures. That appearance could be attributed to Oddi sphincter dysfunction following vagotomy and gastrectomy, previous passage of stones, postoperative stricture, or oedema. Three of the patients had previous cholecystectomy. In the remaining six patients, two had gallstones. In one patient the gall bladder wall was thickened, accompanied with an irregular, unknown filling defect at the level of the fundus. Four of these patients had common bile duct stones and one patient had a stone in the common hepatic duct. Intrahepatic biliary ductal dilatation was seen in all the patients. That dilatation could be due to prior cholecystectomy in three of the patients opposed to the vagotomy and gastric surgery. Biliary system pathologies including thickening of

gallbladder wall and stones were well evaluated with MRCP, therefore it can be accepted as a valuable imaging method in the evaluation of biliary system pathologies in patients with previous history of biliary system and/or gastric surgery (Erden et.al., 2005).

Most patients with acute cholecystitis have gallstones. As opposed to ultrasound which is very sensitive for detection of gallstones, CT detects only approximately 75 % of gallstones. With CT gallstones have a varied appearance based on their composition and pattern of calcification. Stones with calcification tend to be well seen with CT, however stones with a high content of cholesterol may be difficult to detect because they may be hypo-attenuating compared with bile. (Sungal et.al., 1999).

Furthermore, both CT and ultrasonography have been used extensively for the diagnosis of acute cholecystitis, but diagnosis of perforation of the gallbladder is always difficult. Magnetic resonance, by its superior soft tissue resolution and multiplanar capability, is a better modality and is better than ultrasonography and CT. The advantage of MRI imaging is that it demonstrates the wall of the gall bladder and defects. In addition, MR cholangiopancreatography images demonstrate the biliary tree better than other modalities. It is suggested that in the case of acute cholecystitis, if perforation is suspected and CT and ultrasonography are not conclusive, MR should be the modality of choice. It can be used as a first line of investigation; however, it might not be cost-effective (Sood et.al., 2002).

2.6 RISK FACTORS

2.6.1 Age and Gender and Ethnic Groups

In South Africa, a study was done by Walker, et.al.(1989) among elderly Black women in Soweto which is a township with low and middle class people. This study also revealed that continued exposure to western lifestyle would be expected to increase the prevalence of gallstones. It is therefore important that population studies be carried out especially where lifestyle changes may have occurred.

Increasing age is an important risk factor for both sexes, and the only significant risk factor noted in men. Although very few men have asymptomatic gallstones before the age of 40, approximately 5% of women that are aged between 20 and 29 and 9% aged between 30 and 39 do have gallstones (Hopper et.al.,1991).

Another study was performed in Brazil among the Curitiba population by Coelho, (1999). The objective of the study was just to determine the prevalence of gallstones in relation to sex and age. A total of 1000 persons were randomly recruited among individuals who were visiting two shopping centers of the city in order to represent the Brazilian population in relation to age and sex. The selected people underwent ultrasonographic examination of the upper abdomen immediately after a medical interview. Of the 1000 persons evaluated, 93 (9.3%)

had gallstones (64 persons) or had been subjected to cholecystectomy due to cholelithiasis. The gallstone prevalence increased from 2.4% in persons of 20-29 years of age to 27.5% in persons of more than 70 years. The prevalence was 2.4 greater in females (12.9%) than in males (5.4%). The prevalence increased with the number of pregnancies from 4% in nulliparous women, to 34.6% in persons with a history of six or more pregnancies (Coelho et.al., 1999).

The prevalence of gall bladder disease differs in different racial and ethnic groups. According to the reviewed literature, American Indians have been recorded as the highest in prevalence in the whole world, with as many as 50% of men and 80 % of women affected. Dietary habits were also found to be responsible for the above. This conclusion however has been drawn from relatively small studies done decades ago without taking tribal diversity into account (Everhart et. al., 2002).

The majority of Native American men have gallstones by the age of 60. Among Pima Indians of Arizona, 70% of women have gallstones by the age of 30. Mexican American men and women of all ages also have high rates of gallstones (NDDIC, 2002).

In Europe as well, at least 10% of all adults, have gallstones with women having three times the prevalence of gallstones during their child bearing age. The overall prevalence in women is twice that of men. The prevalence is noted to rise

with age in the both male and female gender and at the age of 65 about 30% of women have gallstones, and by the age of 80, 60% of both men and women have developed gallstones (Johnson et.al., 2002).

Furthermore, a study was done by Beckingham (2001) in the United Kingdom among the White inhabitants to assess prevalence of gallstones according to age. Among the age group of 30 to 40 years approximately 2.5% of men had gallstones and 5.2 % of women had gallstones. This was similar to the findings of Johnson et.al., (2002) which recorded prevalence twice in women than in men. At the age of 50 years about 5.4% of men and 15% of women population had gallstones. At the age of 60, 12.5% of men and 22% of women had gallstones.

At the age of 70, 20% of men and 30 % of women population had gallstones. Although not similar, these findings are in line with the study of Johnson et.al. (2002).

Contrary to the study discussed above, Bateson, (2000) in Britain records no sex differences in respondents that were under 40 and over 90 years of age. He also records that gallstone disease is commoner in women than in men aged between 40 and 89 years.

A total of 534 adult men and women from a medium economic level population in Lima in July 2003 underwent ultrasonographic examination of the abdomen for detection of gallstone disease. The echographic evaluation was performed by 10 general surgeons trained in ultrasonography. The prevalence found was 15%.

Eighty-one of 534 participants had lithiasis. Compared to the age group under 30, the odds ratio for the 31 to 50 years and >50 years of age group was 0.9 and 1.1, respectively. The female-male ratio was 1.07 and the odds ratio 0.8 (Salinas et.al., 2004).

According to Volzke et. al. (2005) cholelithiasis is also a common problem in north-eastern Germany. Analyses of risk factors for gallstone formation in this population may have high explanatory power. Gender-specific risk factors for gallstone formation and their interactions were investigated by using data of the population-based Study of Health in Pomerania (SHIP). Data of 4,202 persons aged 20-79 years were available. Cholelithiasis was defined by either a prior history of cholecystectomy or the presence of gallstones on abdominal ultrasound. Multivariable analyses were performed to identify independent risk factors for gallstone formation.

In this study there were 468 persons (11.1%) with previous cholecystectomy and 423 persons (10.1%) with sonographic evidence of gallstones. Women had a two fold higher risk for cholelithiasis compared to men. Age, body mass index and low serum high density lipoprotein(HDL) cholesterol levels were independently associated with cholelithiasis in both men and women. In the male population, low alcohol and high coffee consumption and in the female population, low physical activity, were further independently related to gallstone formation. Conclusions drawn from this study are that female sex, age and being

overweight are major risk factors for gallstone formation in this region where cholelithiasis is a frequent disorder (Völzke et.al.,2005).

2.6.2 Diet

The most accepted hypothesis for the dietary cause of gallstones is the changing dietary habits. The incidence appears to be higher amongst populations where there has been a dramatic change in lifestyle in one generation. People moving from rural areas to urban areas far from their origin also seem to be more susceptible (Prasad, 2002).

Prevalence of gallstones in elderly black women in Soweto, Johannesburg, was assessed by ultrasound in a study done in 1989 by Walker et.al. In South Africa, cholelithiasis is reported to be increasing in urban blacks due to their recent dietary changes which include a rise in fat and a fall in dietary fiber intake. To assess the situation, ultrasonography studies were carried out on 100 urban black women, 55-85 year old, with no clinical evidence of gastrointestinal disease, especially with reference to the biliary system. Ten patients (10%) had gallstones. There was no association with parity. Their body mass index (27.8 +/- 6.9) was significantly higher (P less than 0.05) than those who were negative (25.7 +/- 6.1). From dietary intake assessments, there were no significant differences between those positive and negative with respect to mean intakes of energy, protein, fat, carbohydrate, dietary fiber or sugar (p greater than 0.05).

In the study done in Tygerberg, by Bourne et.al.(2002) in South Africa, data have shown that among urban Blacks fat intake has increased from 16.4 to 26.2 % of total energy (a relative increase of 59 %) while carbohydrate intake has decreased from 69.3 % to 61.7 % of total energy (a relative decrease of 10.9 % in the past 50 years). Shifts towards the Western diet are apparent among rural African dwellers as well.

Dietary habits of gallstone patients were studied in Northern India by Miquel, et.al. (1998). Two hundred patients with gallstones and 98 control subjects from a hospital in Northern India and were matched for age, sex, and social class. The intake of total calories and carbohydrates and the plasma triglyceride values were found to be higher in all patients with gallstones as compared to the controls. The dietary intake of refined carbohydrates was also higher than in controls, but only in the female patients with gallstones (35.6 +/- 32.9 g/day compared with 24.5 +/- 11.8 g/day; $p < 0.001$). By contrast, the male patients with gallstones had an increased intake of fat and had increased plasma cholesterol values. Such sex differences in the dietary intake and plasma cholesterol values may form a special feature of gallstone disease in Northern India and should be studied further (Miquel et.al., 1998).

Misciagna, (1999) evaluated the association between diet, physical activity, and incident cases of gallstones diagnosed by ultrasound in a population-based, case-control study. Energy and monounsaturated fat intakes were inversely related whereas intake of refined sugars was directly related to the risk of

gallstone formation in both models. Saturated fat intake appeared to increase the risk of gallstones whereas intake of dietary cholesterol had an apparent protective effect after adjustment for the intake of other nutrients. BMI and refined sugar and saturated fat intakes were associated with an increase in the risk of gallstones, whereas physical activity and monounsaturated fat intake were associated with a reduction in the risk of gallstone formation. There was a significant negative interaction between gender and saturated fat intake. Women appeared to have a greater risk of gallstone formation than men at all intakes of saturated fat, except for the highest quartile, for which men displayed a greater risk than women.

In the study done by Segal and Walker (1986) cited in Bourne et.al.(2002), in Johannesburg among urban Blacks they highlighted that diet among these people has been substantially westernized. Although they have managed to lower their fat intake, they decreased their fiber intake which will then increase the possibility of developing gallstones.

The South African Demographic and Health Survey conducted in 1998 revealed that 31.8 % of African women (of the age of 15 years) were obese (body mass index, BMI > or = 30 kg m (-2) and that a further 26.7 % were overweight (BMI > or = 25 to < 30kg m (-2). This is the reason for the noted increase in the prevalence of gallstones among the Black population. (Bourne et.al.,2002).

Older Black subjects in Cape Town have energy profiles in line with prudent dietary guidelines and more favorable than other elderly groups in the country, with regard to atherogenic risk. However, micronutrient and dietary fiber intake is inadequate largely due to low reported energy intakes, particularly in women (Park et.al.,2004). This is the obvious reason for this gradual increase in the prevalence of gallstones among the Black population.

2.6.2.1 Calculation of carbohydrates, proteins, fats and energy intakes (Food Analysis)

A large number of analytical techniques have been developed to measure the total concentration and type of carbohydrates present in foods. The carbohydrate content of a food can be determined by calculating the percent remaining after all the other components have been measured: %carbohydrates = 100 - % moisture - %protein - %lipid - %mineral. Nevertheless, this method can lead to erroneous results due to experimental errors in any of the other methods, and so it is usually better to directly measure the carbohydrate content for accurate measurements (Rampon, 2003)

Chemical methods are used to determine monosaccharides and oligosaccharides based on the fact that many of these substances are reducing agents that can react with other components to yield precipitates or colored complexes which can be quantified. The concentration of carbohydrate can be determined gravimetrically, spectrophotometrically or by titration. The disadvantages of this method are:

(i) the results depend on the precise reaction times, temperatures and reagent concentrations used and so these parameters must be carefully controlled;

(ii) it cannot distinguish between different types of reducing sugar, and

(iii) it cannot directly determine the concentration of non-reducing sugars,

(iv) it is susceptible to interference from other types of molecules that act as reducing agents.

There are also physical methods that have been used to determine the carbohydrate concentration in foods. These methods rely on a change in physicochemical characteristic of a food as its carbohydrate concentration varies. Commonly used methods include polarimetry, refractive index, Infrared radiation, and density (Avenell et.al.,2004).

2.6.2.1.1 Food Fundi soft ware

The Medical Research Council's (MRC) food composition tables have become the standard reference for dieticians and medical doctors. This programme is called Food Fundi and is able to calculate the amount of carbohydrates, proteins and fat exchanges. This product is easy to use, powerful and accurate in its search, display and advice facilities (Mittal and Mittal, 2002).

Food Fundi professional was written by a team including a registered research dietician, a medical scientist and a computer programme consultant. The programme was tested to eliminate any errors that might have crept into the

coding, so that it will give you smooth and faultless service. It is the only recommended programme because it is electronic. The calculations are done by the computer in order to reduce the margin of error. The number of carbohydrates, protein and fat exchanges is calculated by the computer in order to meet the guidelines i.e. not more than 30% of energy from fat, approximately 53 % of energy from carbohydrates; and approximately 17 % of energy from protein. The Food Fundi professional encourages eating of a wholesome and balanced diet, which will enhance the quality of life (Food Fundi professional, 1993).

2.6.3 Body Mass Index(BMI)

Body mass index (BMI) is used to measure obesity in adults and is calculated with weight and height of an individual. A BMI of 18.5 to 24.9 refers to a healthy weight, a BMI of 25 to 29.9 refers to overweight, and a BMI of 30 or higher refers to obesity. As the BMI increases, the risk for developing gallstones increases. The risk triples in women who have a BMI greater than 32 compared to those with a BMI of 24 to 25 (NIDDC, 2002).

A South African Demographic and Health survey conducted in 1998 revealed that 31% of African women were obese and further 26.7 % were overweight (Bourne et. al., 2002)

Obesity is also a strong risk factor for gallstones, especially among women (Torgerson et.al.,2003). People who are obese produce high levels of cholesterol, and have decreased motility of the gall bladder, causing stasis of bile in the gall bladder and thereafter developing gallstones. Bile also contains more cholesterol than it can dissolve, therefore gallstones can form. People who are obese may have larger gall bladders that don't empty normally or completely which therefore causes stasis of bile which will in turn cause stone formation as well (Tsai et.al.,2004).

Weight loss dieting also increases the risk of developing gallstones. People who lose a large amount of weight quickly are at greater risk than those who lose weight more slowly. It is believed that dieting may cause a shift in the balance of bile salts and cholesterol in the gall bladder. The cholesterol level is increased and amount of bile is decreased. Too much cholesterol will also promote gallstone formation. This is seen in individuals who engage in crash scheme whereby a large amount of weight is lost in a short time (Tsai et.al.,2004).

Lifang et.al., (2004) evaluated the association of gallstone disease with weight, weight change, and physical activity (PA) among Chinese women in Shanghai. The study included 8485 women with self-reported, physician-diagnosed, prevalent gallstone disease and 16,970 frequency-matched controls by birth year and age at gallstone diagnosis (4-year intervals). Information on height, weight history, PA, and other exposures was obtained by in-person interviews between

1997 and 2000.Odds ratios for gallstone increased significantly with usual body mass index (BMI) at age 50, but not BMI at age 20. After adjusting for usual BMI, weight gain between ages 20 and 50 further increased the risk. The effects of both overweight and weight gain were more prominent for postmenopausal women.

It was concluded that overweight and weight gain increase the risk of gallstone in women, and regular physical activity may reduce risk and the effects of overweight, weight gain, and physical activity on gallstone prevalence appear to be independent of each other (Lifang et.al., 2004).

2.6.4 OTHER RISK FACTORS

2.6.4.1 Diabetes

There are many more factors which are considered high risk for the development of gallstones. Diabetes is one of them. Early retrospective studies reported an alarmingly high incidence of gallstones in diabetics as compared with the general population. Because of the profound morbidity and mortality rates observed in the diabetics, prophylactic cholecystectomy was generally recommended only for symptomatic gallstones (Kim et.al., 2005).

2.6.4.2 Pregnancy

Pregnancy is associated with an increased frequency of gallstones. Studies performed in America demonstrate gallstones in 5–12% of pregnant women. Most pregnant women with cholelithiasis remain asymptomatic and the stones are spontaneously cleared after delivery. Only very few patients develop symptoms and, for these patients, the frequency of recurrent symptoms is high during pregnancy (Blum et.al., 2002).

A University of Southern California study observed 242 women recruited during the first trimester of pregnancy. Ultrasonography initially revealed gallbladder sludge in 15% and stones in 6%. New sludge or stones were found in 30% and 2% of the women, respectively, at the end of the pregnancy. Postpartum ultrasound scans revealed the disappearance of the sludge in 61% of those women who had previously demonstrated sludge, and disappearance of stones in 28% of those who had stones. Therefore, the study concluded that some patients who have symptomatic cholelithiasis during pregnancy may not have it after the delivery. The risk of gallstone formation is because of increased bile lithogenicity as a result of a decline in the bile salt pool and elevations in serum and biliary cholesterol levels. Increased bile stasis caused by impaired gallbladder emptying is also thought to be a contributing factor (Blum et.al., 2005).

Furthermore, acute cholecystitis is seen to be a common non obstetric emergency in pregnant women. The following conditions create a favorable environment for gallstone formation:

(i) elevated levels of estrogen during pregnancy increase the lithogenicity of bile.

(ii) progesterone impairs gastric and gallbladder emptying as well as decreases gut motility.

(iii) During the first and second trimesters, bile becomes saturated with cholesterol. Cholesterol secretion increases and the total bile acid pool grows.

(iv) Chenodeoxycholic acid levels decrease in relation to overall cholic acid levels.

Furthermore, stones can be passed into the ducts which become a serious complication of pregnancy. Cholangitis and pancreatitis usually follows as well. This scenario may potentially set up a life-threatening situation for mother and infant. Maternal and fetal mortality rates of 15% to 60%, respectively, are associated with gallstone pancreatitis (Simmons et.al., 2004).

2.7 COMPLICATIONS

Complications of gallstones have a detrimental effect on healthcare costs especially in the public sector and can also be life threatening. It is important that individuals likely to develop complications are identified so that elective cholecystectomy could then be performed and therefore benefit clinical practice (Halldestam et.al., 2004).

According to Baig et.al. (2002) gallstones can produce a number of histo-pathological changes in the gall bladder mucosa causing acute inflammation, chronic glandular hyperplasia, granulomatous inflammation, cholesterosis, dysplasia and carcinoma. The following are the most common life threatening complications identified with gallstone disease.

2.7.1 Acute cholecystitis

Acute cholecystitis is the inflammation of the gall bladder and is most often caused by gall stones. Acute cholecystitis develops in 1-3% of patients with symptomatic gall stones. Helminthic infection (ascariasis) is a major cause of biliary disease in developing countries in Asia, southern Africa, and Latin America. Acute cholecystitis starts because of obstruction of the cystic duct which causes an inflammatory process to start. If the inflammation persists it may cause further complications such as perforation or gangrene of the gall bladder (Indar and Beckingham, 2002).

In agreement is Johnson et. al. (2002) who state that inflammation of the gall bladder is recorded to be a more serious problem than biliary colic. It begins abruptly and it needs immediate surgical intervention. Empyema of the gall bladder occurs in 2-3 % in patients with acute cholecystitis and abdominal pain is severe (Johnson et al., 2002). Stones can block ducts and cause jaundice that also needs surgical intervention. Cancer is very rare but gallstone disease is a

predisposing factor. Gallstones are responsible for about 45 % of all cases of acute pancreatitis which can be life threatening (Surgeon's corner, 2000)

As stated above, over 90% of cases of acute cholecystitis result from obstruction of the cystic duct by gall stones or by biliary sludge that has become impacted at the neck of the gall bladder. Obstruction of the cystic duct causes the intraluminal pressure within the gall bladder to increase and, together with cholesterol supersaturated bile, triggers an acute inflammatory response. The trauma caused by the gall stones stimulates the synthesis of prostaglandins I_2 and E_2, which mediate the inflammatory response. Secondary bacterial infection with enteric organisms (most commonly Escherichia coli, Klebsiella, and Streptococcus faecalis) occurs in about 20% of cases (Indar and Beckingham, 2002).

2.7.2 Gall bladder perforation

Gall bladder perforation is a dreaded complication of acute cholecystitis that is associated with a high mortality rate. It may develop as early as two days after onset of symptoms of acute cholecystitis or as late as several weeks afterwards (Sood et.al., 2002). Early diagnosis and awareness can help to prevent these dreaded complications.

According to Stefanidis et.al., (2004) gallbladder perforation has been reported to occur in 2–15% of patients with acute cholecystitis and is associated with a

mortality of up to 70%. The diagnosis is easily made before operative exploration because of its clinical presentation being similar to that of acute cholecystitis. Sood et .al.(2002) Late surgical intervention has been suggested as the cause for the high morbidity and mortality of this complication and improved outcomes have been shown as a result of cholecystectomy within 72 hours. Factors associated with the development of this complication must be identified as early as possible because it could lead to earlier intervention and improved outcome.

2.7.3 Gall bladder cancer

Gallbladder cancer is rare, but can develop as a complication of gallstone disease. The highest gallbladder cancer incidence rates worldwide were reported for women in Delhi, India (21.5/100,000), South Karachi, Pakistan (13.8/100,000) and Quito, Ecuador (12.9/100,000). High incidence was found in Korea and Japan and some central and eastern European countries. Female-to-male incidence ratios were generally around 3, but ranged from 1 in Far East Asia to over 5 in Spain and Colombia. History of gallstones was the strongest risk factor for gallbladder cancer, with a pooled relative risk (RR) of 4.9 [95% confidence interval (CI): 3.3-7.4]. Consistent associations were also present with obesity, multiparity and chronic infections like Salmonella typhi and S. paratyphi [pooled RR 4.8 (95% CI: 1.4-17.3)] and Helicobacter bilis and H. pylori [pooled RR 4.3 (95% CI: 2.1-8.8)]. Diagnosis of gallstones and removal of gallbladder currently represent the keystone to gallbladder cancer prevention, but interventions able to

prevent obesity, cholecystitis and gallstone formation should be assessed (Randi et.al., 2006).

2.8 TREATMENT

Gall bladder related symptoms can be treated medically in the first instance but when gallbladder stones are proved to be the cause of severe symptoms, cholecystectomy is the best treatment for most patients (Bateson, 1999).

Cholecystectomy is described as the surgical removal of gallbladder, which guarantees that the patient will not suffer a recurrence of gallstones and prevents cancer (Surgeon's corner, 2000).

Asymptomatic stones usually don't need treatment, but it is important to find them early in order to prevent complications of the disease when the patient presents later with non-specific symptoms. Non-surgical approaches are used only for cholesterol stones. This includes oral dissolution therapy and shockwave lithotripsy that uses shockwaves to break up stones into tiny pieces that can pass through the ducts without causing blockages. These stones can always recur after treatment (Prasad, 2002).

Cholecystectomy is the optimal management because it removes both the gall stones and the gall bladder, preventing recurrent disease. The only common consequence of removing the gall bladder is an increase in stool frequency, which is clinically important in less than 5% of patients and responds well to standard anti-diarrhoeal drugs when necessary (Hobbs et.al.,2006).

Laparoscopic cholecystectomy has been used since it was introduced in1987, and 80-90% of cholecystectomies performed in the United Kingdom are now carried out in this way. The only specific contraindications to laparoscopic cholecystectomy are coagulopathy and the later stages of pregnancy. Acute cholecystitis and previous gastro- duodenal surgery are no longer contraindications but are associated with a higher rate of conversion to open cholecystectomy (Beckingham, 2001).

Laparoscopic cholecystectomy has a lower mortality than the standard open procedure because of a lower incidence of postoperative cardiac and respiratory complications. The main disadvantage of the laparoscopic technique has been a higher incidence of injury to the common hepatic or bile ducts usually associated with inexperienced surgeons(Hobbs et.al., 2006).

Alternative treatments used to treat gall stones include oral dissolution therapy (chenodeoxycholic and ursodeoxycholic acid), contact dissolution (direct instillation of methyltetrabutyl ether or mono-octanoin), and stone shattering with extracorporeal shockwave lithotripsy. Following is the criteria for non-surgical treatment of gallstones:

- Cholesterol stones <20 mm in diameter
- Fewer than 4 stones
- Functioning gall bladder
- Patent cystic duct (Fromm, 1986)

2.9 REVIEW OF PREVIOUS STUDIES ON PREVALENCE OF GALLSTONES

The general adult population afflicted by gallstone disease is 10 to 20 % in the developed countries including the United States and is more common in women, with a female to male ratio of approximately 2:1 (Rahman, 2005).

Cholesterol stones are more common among the European people, of advancing age, female sex with an element of obesity and a history of rapid weight loss. Pigmented stones, on the other hand, are far more often seen in Asian people, particularly with disorders of hemoglobin, resulting in an increase in hemolysis (Rajan, 2002).

In a review of gallbladder diseases by Bateson, (1999) an increase in prevalence among the Japanese is reported and thought to result from westernization of lifestyle, suggesting environmental factors also important for the noted increase. In an international table where he grouped countries in the world according to the prevalence of gallstones , White South Africans in South Africa are grouped as having a high prevalence, meanwhile the Blacks are grouped as moderate (Bateson, 1999). The current study is therefore important in district 28 because, although the area is said to be rural, the lifestyle of the people, as observed by the researcher is now highly westernized. One would therefore expect an increase in the prevalence of gallstones in the region.

Similarly, a study done in 1971 by Brebner among South African Whites and Blacks in Johannesburg as cited in Docrat, et. al., (1999), showed a prevalence of gallstones of 6 per 1000 and 0.67 per 1000, respectively. These were 9500 consecutive autopsies of people who died from gall bladder related pathology, from 1936 to 1950. There were equal number of Whites and Black Africans with twice as many males and females. Sixty four percent of Africans were under 40 years whereas 73% of Whites were over 40 years. The study revealed increased prevalence of gallstones amongst the White population of South Africa compared to the Black population.

Another study cited in Docrat et. al., (1999) involved 100 asymptomatic South African Black women at the Chris Hani Hospital in the Gauteng Province conducted by Segal et. al., in 1983(cited in Docrat et.al (1999). Ultrasound had been used to diagnose the gallstones. It recorded the prevalence of gallstones of 2 % which was relatively low. This incidence among the Black Africans was thought to be due to their diet which largely consisted of fiber (Docrat et.al., 1999). The current research is very necessary because of the expected increase in the prevalence of gallstones since the Africans are thought to have changed their dietary habits and even their lifestyle is now very westernized (Prasad, 2002).

Similarily, Walker et.al.,(1989) reported a recent change in diet among Black South Africans which included a rise in fat, which increases the risk for development of gallstones and a fall in dietary fiber intake.

The prevalence of 2% recorded in the study done in 1983 by Segal et.al., showed a marked increase when compared with the previous one done in 1971 by Brebner which was 0.067% as cited by Docrat et.al.,(1999).

Walker et.al., (1989) conducted a study testing prevalence of gallstones in elderly Black women in Soweto, at the Gauteng province, using ultrasound as a diagnostic tool. The 100 urban Black women were aged 55-85 yrs and had no clinical evidence of gastrointestinal disease with reference to the biliary system. Only 10% of these patients had gallstones. This showed evidence of increase in prevalence when compared with the study done in 1983 by Segal et.al., which was also done among the Black South African women, as cited by Walker et.al.(1989). The increase in prevalence could have been due to the age group of the respondents, although the age was not specified in the previous study. The body mass index (BMI) for the respondents who had gallstones in this study was higher (27.8 +/- 6.1)than those who were negative. From the dietary intake assessment, there was no significant differences between those positive and negative with respect to mean intake of energy, protein, fat, carbohydrates, dietary fiber or sugar.

American Indians are generally rated as the highest in the prevalence of gall bladder diseases in the world. In a strong heart study that began in 1989 by Everhart et.al.(1999) among the tribes in Arizona, Oklahoma, South and North Dakota, prevalence of gallstones was studied using ultrasound. Enrolled members were aged 47 years and older. Prevalence was determined amongst 3296 participants. A total of 64.1% of the women had gall bladder disease among which 17.8% had gallstones and 46.3 % had a history of cholecystectomy. Among men, 17.4% had gallstones, and 12.1% had evidence of a cholecystectomy, for a total of 29.5% with gall bladder disease. When figures were adjusted for age and Indian heritage, there was no significant difference in gall bladder disease prevalence across the three geographical areas (Everhart et. al., 2002).

On the other hand, Moro et.al.(2000) conducted a study among the Peruvian coastal natives and highland migrants between January 1997 and August 1997. This study was done to determine if high altitude (more than 1500 m) is a contributing factor for gallstone disease as previous studies had cited that gallstones were a common occurrence in the high altitude. Large proportions of adults from this community have migrated from rural areas in the Peruvian Andes to Lima and are casual workers. A total of 1000 households were examined for gallstones using ultrasound. The crude prevalence rate of gallstone disease was 14.3%. The results from this study showed that high altitude is not a positive risk factor for gallstone disease and confirmed that this disease was common in

Peruvians, which may be attributable to Peruvian- Indian ethnicity (Moro et. al., 2000).

Another study was done in 1998 by Miquel et.al. among the North American Indians, Chileans, and Mexican Americans followed by non-Mexican Hispanics from North America, Europeans, and Asians from India. The research tested the hypothesis that aborigine cholesterol lithogenic genes are widely spread among Chileans, a population with a high prevalence of gallstones. Abdominal ultrasound was performed for the diagnosis of gallstones in 182 Mapuche Indians, 225 Maoris of Easter Island, and 1584 Hispanics. Blood groups, DNA, lipids, and glucose were also analyzed. Prevalence was found to be higher in Mapuches (35%) than in Hispanics (27%) and Maoris (21%). Cholesterol lithogenic genes appeared widely spread among Chilean Indians and Hispanics. They could determine the early formation of gallstones and explain the high prevalence of gallbladder diseases among some South American populations (Miquel et.al., 1998).

A group of pregnant African women in Ibadan, Nigeria in 1999, were also involved in a study by Akute et.al. which an overall prevalence rate of gallstones of 2.1%. This confirmed the low prevalence of the disease in that environment even when compared with other Black population studies performed in South Africa. The study was done during September to December 1999, where 4124 Black patients were sonographically examined consecutively to exclude gallstone

disease. A gradual increase in the prevalence of gallstones was noted when compared with the previous study in the same country from January 1977 to December 1998 that had shown a prevalence of 1.79% (Akute et. al., 1999).
The prevalence of gallstones in the rural Caucasian population in Canada was 16%, compared to a study done in Micmac Indian women who are from an inland rural community which was 21% (Leitzmann et. al., 1999). District 28 is also predominantly rural although people have been westernized.

Similarly, in an urban teaching hospital in Nigeria, prevalence of gallstones and cholecystitis was tested in a study done from January 1997 to December 2001.
46 patients had cholecystectomy for cholelithiasis and cholecystitis in five years. In the first three years, 18 (39.1%) cases were seen, but in the next two years 28 (60.9%) patients had cholecystectomy. The male: female ratio was 1:4.8. Only four (8.7%) of these patients were obese. Thirty-two (69.6%) were multiparous. Only four (8.7%) of the patients had pigmented stones, the majority of which were mixed stones. Many of the patients had been on treatment for suspected peptic ulcer disease for a period ranging from four weeks to five years. This indicated an increase in prevalence of gallstones in the Black population (Rahman, 2005).

Chapman et.al.(2000), conducted a study to determine the frequency, risk factors and clinical significance of gallstones in a White New Zealand population. One thousand names were randomly selected from the Christ church electoral rolls to recruit controls for a study on the prevalence of gallstones in diabetics. Three

hundred and eighteen subjects (169 females, 149 males) were recruited. All subjects completed a questionnaire, provided a fasting blood sample and underwent an ultrasound examination of their gallbladder unless they had previously undergone a cholecystectomy. Overall gallstone disease, defined as previous cholecystectomy or a positive scan for gallstones was seen in 20.75% of the 318 subjects recruited. Gallstone disease was more frequent in females (23.1%) compared to males (18.1%) but this difference was not statistically significant. For both genders there was a significant increase in gallstones with age. On univariate analysis, risk factors for gallstone disease included age, increased body mass index, family history of gallstones and decreased alcohol intake in females. However, only age and family history were significant on multiple logistic regression.

Prevalence of gallstone disease and its association with various risk factors in the city of Chandigar in Northern India was studied in 2001. The respondents were above 15 years of age, with a history of gallstone disease and some were asymptomatic and were all asked to attend the outpatient department of the Postgraduate Medical Institute. Two hundred and fourty eight individuals underwent an ultrasound. There were 37 symptomatic and 211 asymptomatic individuals (male: female, 93:155). Gallstone disease was seen in 24 out of 37 (64.9%) in the symptomatic, and seven out of 211 (3.3%) in the asymptomatic group. Out of these, 27 females and four males had gallstone disease. Approximately 67% of patients were between 20 and 60 years of age. Gallstone disease was more frequently seen in those from high socioeconomic status as

compared to middle socioeconomic status. Body mass index, smoking, alcohol consumption, and a vegetarian/non-vegetarian diet did not influence the prevalence of gallstone disease (Singh et. al. 2001).

Reshetnikov et.al., (2002), conducted a study with aim of evaluating the prevalence of gallstones in a Western Siberian urban population and to compare the results of ultrasonographic screening of the living population with hospital autopsy data. A representative sample of 842 men and 870 women between the ages 25 and 64 years living in Novosibirsk, Western Siberia, was screened for the presence of gallstones using ultrasound as a diagnostic tool. Participants were considered to have gallstone disease if they had already had cholecystectomy or if gallstones were revealed during the survey. Hospital autopsy data (n = 1124) were reviewed retrospectively for the 8-year period in the same region. Results showed age-adjusted prevalence rates was 11.4% with a corresponding value in the autopsy series was 13.4 % (Reshetnikov et.al., 2002).

Diabetes is often considered as a condition characterized by an increased risk of gallstone disease. A study was therefore done in 2004 by Pagliarulo et.al. among the Italians to estimate the frequency of gallstone disease in a large cohort of consecutively enrolled type 1 and type 2 diabetics in Northern Italy.
Risk factors such as sex, age, body mass index (BMI) were identified as related to diabetes mellitus. Ultrasound was performed in 1337 patients (710 males and 627 females). The prevalence was significantly higher in diabetics than in the

general population, 24.8% in diabetes mellitus and 13.8% in general population (Dumot , 2006). Diabetes mellitus must then be considered as one of the major. The prevalence of gallstones is therefore higher compared to other studies because of diabetes as the risk factor.

2.10 CONCLUSION

Gall bladder stones are now becoming common in the developing world and their complications contribute substantially to healthcare costs and may be life threatening. The identification of individuals likely to develop complications would be of benefit in clinical practice as elective cholecystectomy could then be performed (Halldestam et.al., 2004).

On the other hand, in developed countries gallstones are still a major public health problem. There is a plea for a great epidemiology research in order to obtain reliable knowledge of the prevalence of the disease, in order to determine the best ways of applying present knowledge with existing and future resources (Rahman, 2005).

This chapter has discussed in detail how gallstones develop and also emphasized on the complications that develop, should the diagnosis not be made timeously.

The different diagnostic tools including plain x-rays, scintigraphy, cholecystogram, C.T scan, MRI were discussed with emphasis placed on

ultrasound which was found to be the modality of choice because it is readily available, accurate, cheap and non- invasive (Chapman et.al.,2000).

The common risk factors were discussed in this chapter and possible means of treatment also discussed. Cholecystectomy was found to be the most reliable treatment because gallstones are not likely to re-develop (Surgeon's corner, 2000).

A study of this nature is therefore urgently needed to determine the prevalence of gallstones among the Blacks of District 28, relative to the most common risk factors, i.e. age, gender, diet and body mass index (BMI).

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

This chapter describes the research design and methodology that was used to perform this study. It highlights the type of data collected, the selection of research participants, the data collection procedures, ethical considerations and the statistical methods employed.

3. 2 REQUESTING PERMISSION TO PERFORM THE STUDY

Permission was requested for the study to be performed at Ngwelezane Hospital. This is a regional hospital which receives patients from all the smaller hospitals in District 28 (The Uthungulu Health District). This district has a population of 898 913 and comprises six local authority areas which are Empangeni, Melmoth, Nkandla, Mbongolwane, eShowe and Amatigulu. A study for the population of this district can be done at this hospital because it is a referral hospital and therefore has a good representation of the population of the district at large (Dam, 2006).

Written permission was obtained from the Superintendent-General for Health, in KwaZulu-Natal, the hospital manager for Ngwelezane hospital, and the radiology manager (Appendix D).

3.3 INVITATION TO PARTICIPATE

Invitations (Appendix E) were printed in English and isiZulu and were displayed for the attention of all individuals who would comply with the inclusion criteria. The invitations were distributed in August 2004, December 2004 and February 2005. The invitations were placed on the notice boards at the reception area in the x-ray department, the out-patient department and the corridors in the hospital.

The invitation was extended to the Black community because of the assumed increase in the prevalence of the gallstone disease amongst the Blacks. Gall bladder diseases were previously not known to be common amongst the Blacks because of the high fibre diet they used to eat (Tseng, 1999).

3.4 PATIENT INFORMATION SHEET, INFORMED CONSENT.

Research participants that responded positively to the invitation were given information sheets that explained why the study was conducted and why they were selected (Appendix A).

They were required to sign an informed consent after reading the information sheet and understanding the information about the study, thereby agreeing to participate in the study (Appendix B).

3.5 STUDY DESIGN AND DATA COLLECTION

Primary data was obtained from research participants during the interview about their:

- health history,
- social history,
- diet history,

Results from the ultrasound examination also provided the primary data.

An interview was then conducted by the researcher. Information concerning health history and social history was recorded in the relevant data sheet (Appendix C).

Two diet questionnaires (Appendix G) had to be completed during the interview. The first was a 24 hr recall, where the research participants were asked about food eaten in the past 24 hrs before the ultrasound examination. The second was a general diet questionnaire on general food eaten by the research participants and also noting the frequency of other food types. These questionnaires were meant to determine the amount of fat intake by the respondents, since 80% of gallstones are said to be cholesterol stones (Prasad, 2002). The information from these diet questionnaires was captured on the computer using the food fundi software.

The research participants had to be changed into a hospital gown and weighed by the researcher in the ultrasound suite using a balance scale with a height attachment used to measure their height as well. Weight and height was then entered on the respondent's data sheet (Appendix C). Body Mass Index (BMI) was then calculated using a BMI calculator and then entered on the data sheet.

The researcher used the following technique to scan all the respondents that participated in this research.

- Equipment used was the Logic 400 PRO Series, Aloka SSD 4000 unit, Takashu Denshi portable ultrasound unit.
- Research participants were starved for 6 hours and more to make sure that the bowel was free of food substances which could obscure the gallbladder.
- Research participants were scanned in the supine position with right hand behind the head.
- The examination was performed at deep inspiration with the tranducer placed at the right upper quadrant just below the lower costal margin. Deep inspiration helps to flatten the diaphragm and therefore lowering the liver for better visualisation of the gallbladder.
- The gall bladder was examined in the longitudinal, sagittal and diagonal planes.
- The examination was repeated with the patient lying in the left lateral decubitas position, so that gallstones stuck at the neck region of the gall

bladder could be dislodged and moved to the fundal region of the gall bladder for good visualization.

- If gallstones were seen, the position of the patient was changed whilst observing to determine the mobility of the gallstones.
- The presence or absence of gallstones was recorded on the data sheet.

3.5.1 FOOD FUNDI SOFT WARE

The Medical Research Council's food composition tables have become the standard reference for dieticians and medical doctors. In this research these tables were incorporated into a microcomputer programme and used to analyse and plan diets. This programme is able to calculate the amount of carbohydrates, proteins and fat exchanges. This product is easy to use, powerful and accurate in its search, display and advice facilities (Sayed and Humphrey, 1991)

Food Fundi professional was written by a team including a registered research dietician, a medical scientist and a computer programme consultant. The programme was tested to eliminate any errors that might have crept into the coding, so that it will give a smooth and faultless service. The number of carbohydrates, protein and fat exchanges is calculated by the computer in order to meet the guidelines i.e. not more than 30% of energy from fat, approximately 53 % of energy from carbohydrates; and approximately 17 % of energy from protein. The Food Fundi professional encourages eating of a wholesome and

balanced diet, which will enhance the quality of life (Food Fundi professional, 1993).

3.6 SELECTION OF RESEARCH POPULATION

The research participants were all people who responded positively to the invitations that were placed on the notice boards at the reception area in the x-ray department, the out-patient department and the corridors in the hospital.
Any other qualifying individuals from the members of staff were also accepted.
The x-ray department receives an average of 1200 patients per month. The study group actually comprised 600 subjects. Unfortunately raw data for the 211 subjects was lost during a house burglary for the researcher. Data analysis was done on the remaining data of 389 subjects.
The study group comprised 389 subjects who responded positively to the advert (Appendix E). All respondents were selected according to the criteria below :

3.6.1 *Inclusion criteria*

- ✓ Black male and female patients above 18 years of age, because of ethical purposes younger subjects were not included.
- ✓ All patients with or without a history of abdominal pain.

3.6.2 Exclusion criteria

- ✓ Age restriction will be employed, excluding patients less than 18 years because of ethical purposes.
- ✓ Poor visualization of the gall bladder due to prior meal or other causes for example, overlying gases because the gall bladder contracts with meals and cannot be visualized. Gas in the abdomen can obscure the gall bladder (Grainger and Allison, 1994).
- ✓ Patients who have had cholecystectomies.
- ✓ Patients who have not starved because bowel gas from loaded colon may obscure the gallbladder.

3.7 ETHICAL CONSIDERATIONS

Appropriate ethical approval was obtained from the Faculty of Health Sciences Ethics Committee of the Durban Institute of Technology (DIT).

There are no known proven side effects noted from the use of ultrasound on humans (Razzaq and Sukumar,2004). Informed consent was obtained from all respondents, who agreed to participate in the study. The informed consent was signed after respondents had been given the information sheet in the language of their choice (isiZulu or English). The information sheet highlighted the importance of the study, confidentiality, and the risk and benefits of participating in the study.

The researcher collected all the data personally to maintain confidentiality at all times. All the data gathered were securely locked up in the office of the head of the department of radiology and only accessible to the researcher. The researcher ensured that the respondents' stay in the ultrasound department was minimal.

Patients' names and identity codes were used in the questionnaires, but patients were reassured about confidentiality. Names were used so as to ease the process of patient follow-up. This would help if a patient needed to be advised about potential risk if gallstones were discovered or if their dietary habits put them at high risk.

All respondents were told that they were free to withdraw from the study at any time if they wanted to and no coercion was used to get individuals to participate.

3.8 STATISTICAL ANALYSIS

The Statistical Package for the Social Sciences(SPSS) version 11.5 (SPSS Inc, Chicago, Ill) was used for data analysis. Help was obtained from the statistician, Tonya Esterhuizen from DIT in 2005 and 2006. Prevalence and 95% confidence intervals were calculated using the Epitable module of Epi Info version 6.04 (CDC, 2001). Pearson's Chi square tests were used to assess associations between categorical variables and gall stones. These are non – parametric tests,

therefore normality testing did not apply. Descriptive statistics (Demographic data) was also explained giving an account of the demographic layout of the study. Logistic regression analysis was applied to assess the independent effects of multiple risk factors on the development of gall stones. The backwards elimination method based on likelihood ratios was used with entry and exit probabilities set at 0.05 and 0.1 respectively.

3.8.1 STATISTICAL ANALYSIS TO MEET OBJECTIVES OF THE STUDY

3.8.1.1. Statistical Analysis of the first objective

This objective was addressed using Pearson's chi square test and reporting age specific prevalence in Table 4.3. Inferential statistics was use to compare the prevalence of gallstones in each age group.

3.8.1.2 Statistical Analysis of the second objective

This objective was addressed using Pearson's chi square test and reporting gender specific prevalence in Table 4.4. Inferential statistics was used to compare the prevalence of gallstones in each gender group.

3.8.1.3 Statistical Analysis of the third objective

This objective was addressed using Pearson's chi square test reporting diet specific prevalence in Tables 4.5 to 4.7. Inferential statistics was used to compare the prevalence of gallstones in each diet group.

3.8.1.4 Statistical Analysis of the fourth objective

This objective was addressed using Pearson's chi square test and reporting BMI specific prevalence in Table 4.8. Inferential statistics was used to compare the prevalence of gallstones in each BMI group

3.8.1.5 Statistical Analysis of the fifth objective

This objective was addressed by reporting that the overall prevalence of gallstones in the sample. Logistic regression was done to determine risk factors for gallstones in Table 4.9. Inferential statistics was used to compare the overall prevalence of gallstones in the sample group.

3.9 CHAPTER SUMMARY

This chapter highlighted the research methodology that was used in this study. Permission to perform the study had to be obtained from appropriate individuals.

Questionnaires used to get information related to diet were used and captured on the computer to determine the amount of energy, carbohydrates, proteins fat the respondents take.

Appendices A-C display the patient information sheet, informed consent and data collection sheet.

The chapter also highlighted how the research population was selected and stated clearly the inclusion and exclusion criteria used.

Ethical considerations were highlighted and patients' confidentiality was highly stressed. SPSS version 11.5 (SPSS Inc, Chicago, Ill) was used for data analysis.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter presents the results of this research. Tables, graphs and charts were used where necessary to display results. Descriptive statistics for the independent variables, namely, age, gender, diet and BMI (body mass index) was used in the presentation of results based on the results from frequency distribution and cross tabulations. Where indicated, inferential statistics was used to indicate the strength and direction of the relationship between variables and the level of significance. Pearson's Chi square tests were used to assess association between the categorical variables and gallstones. Logistic regression analysis was applied to assess the independent effects of multiple risk factors on the development of gallstones. Backwards elimination method based on likelihood ratios was used with entry and exit probabilities set at 0.05 and 0.1 respectively.

The study demonstrated sufficient power to detect a statistical significant difference between two groups where the difference in prevalence was greater or equal to 15%. The difference in prevalence can also be considered as clinically significant however in tests where the difference in prevalence was less than 15%, no statistical significance was achieved. Anything less than 15 % was not

considered as clinically significant therefore no type 2 error occurred therefore the study was sufficiently powered to detect clinically important differences as statistically significant.

The main aim of this research was to determine the prevalence of gallstones in the Black population of District 28 in KwaZulu- Natal. Research questions sought answers to the following:

1. The age specific prevalence of gall stones in the Black population of District 28.
2. The gender specific prevalence of gallstones in the Black population of District 28.
3. The diet specific prevalence of gallstones in the Black population of District 28 with reference to carbohydrates, proteins and fat consumption.
4. The BMI (body mass index) specific prevalence of gallstones in the Black population of District 28.

4.2 DESCRIPTIVE STATISTICS (DEMOGRAPHIC DATA)

Data on gallstones was available for the 389 participants. Their demographics are presented in Table 4.1 below. The sample was predominantly female (75.8%), and the mean age of the entire sample was 39.4 years (standard deviation (SD) 16.15 years). Ages ranged from 18 to 89 years. Average weight

was 73.7 Kg and the average height was 1.61m. BMI was on average 28.5 kg/m^2 (Table 4.2).

Table 4.1: Gender of study participants (n=389)

	Frequency	Percent
Female	295	75.8%
Male	94	24.2%
Total	389	100%

Table 4.2: Statistics for age, weight, height and BMI of study participants (n=389)

		AGE (Years)	WEIGHT (Kg)	HEIGHT (m)	BMI (kg/m^2)
Mean		39.44	73.727	1.6126	28.504
Median		36.00	72.000	1.6300	28.000
Std. Deviation		16.145	16.5631	.07805	6.2544
Minimum		18	40.0	1.14	15.0
Maximum		89	125.7	1.88	53.5
Percentiles	25th	26.00	61.750	1.5700	24.000
	50th	36.00	72.000	1.6300	28.000
	75th	49.00	85.000	1.6600	33.000

4.2.1 DESCRIPTIVE STATISTICS – AGE

The descriptive statistics for age is presented in Table 4.2. The mean age for the participants in this study was 39.4 years with a standard deviation of 16.15. The minimum age was 18 and the maximum age was 89 years.

4.2.2 DESCRIPTIVE STATISTICS – GENDER

As demonstrated in Table 4.1, of the 389 participants, 295 were female which constitutes 75.8 % of the group and 94 men, which constitutes 24.2 % of the group.

4.2.3 DESCRIPTIVE STATISTICS – BMI

The mean BMI for all the respondents was 28.5 kg/m2 with a standard deviation of 6.25. The minimum BMI was 15 and the maximum BMI was 53.5. The 25^{th} percentile was 24 and the 75^{th} percentile was 33.

4.3 INFERENTIAL STATISTICS

4.3.1 Gall stones

The overall prevalence of gall stones in the sample was 26.74% (95% CI 22.51 to 31.30). The prevalence of sludge was 10.54% (95% CI 7.77 to 13.89).

4.3.2 Age-specific prevalence

The cross-tabulation of gall stones by age group in 10 year intervals is shown in Table 4.3 and figure 4.1. The prevalence of gall stones was the lowest in the youngest age (< 20yrs) group (13.3%). The age-specific prevalence increased until the 41-50 age group (33.3%), but thereafter there was a slight decrease to 24.4% in the 51-60 group. The over 60 year group had a high prevalence of 33.3%. There was no significant association between the age group and gallstones (p=0.192), although a slight trend was demonstrated.

Table 4.3: Gallstone prevalence by Age-group

			GALL STONES		Total
AGE GROUP			NO	YES	
	<=20	Count	26	4	30
		% within AGE GROUP	86.7%	13.3%	100%
	21-30	Count	84	23	107
		% within AGE GROUP	78.5%	21.5%	100%
	31-40	Count	66	28	94
		% within AGE GROUP	70.2%	29.8%	100%
	41-50	Count	48	24	72
		% within AGE GROUP	66.7%	33.3%	100%
	51-60	Count	31	10	41
		% within AGE GROUP	75.6%	24.4%	100%
	>60	Count	30	15	45
		% within AGE GROUP	66.7%	33.3%	100%
Total		Count	285	104	389
		% within AGE GROUP	73.3%	26.7%	100%

Pearson's chi square = 7.413, p=0.192

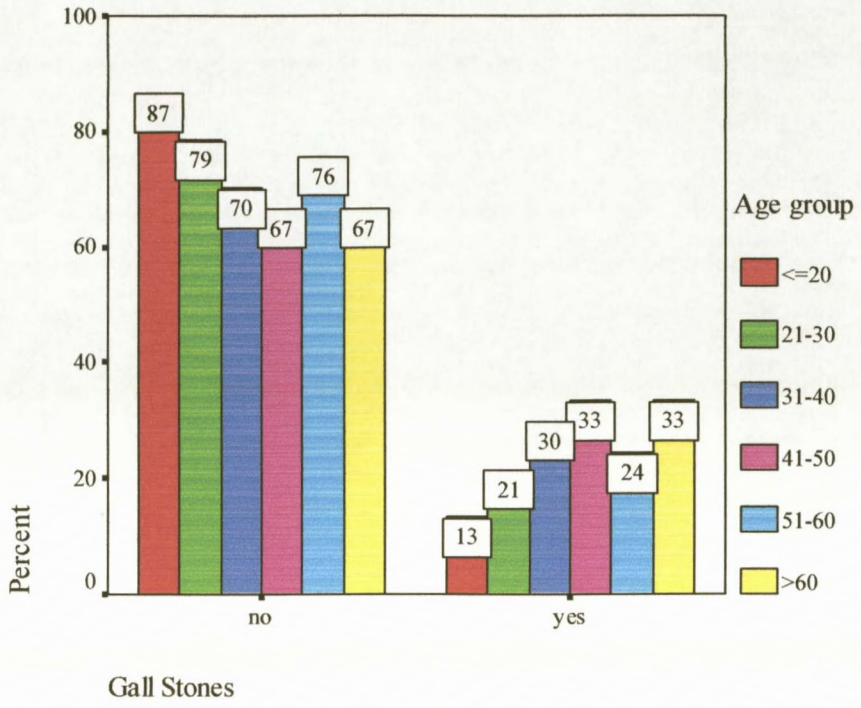

Figure 4.1: Age group specific prevalence of gall stones (n=389)

4.3.3 Gender specific prevalence

There was a slightly higher prevalence of gall stones in the females (28.1%) than in the males (22.3%), although the difference was not statistically significant (p=0.269). This is shown in Table 4.4 and Figure 4.2.

Table 4.4: Gallstone prevalence by gender

			GALL STONES		Total
			NO	YES	
GENDER	FEMALE	Count	212	83	295
		% within GENDER	71.9%	28.1%	100%
	MALE	Count	73	21	94
		% within GENDER	77.7%	22.3%	100%
Total		Count	285	104	389
		% within GENDER	73.3%	26.7%	100%

Pearson's chi square = 1.22, p=0.269

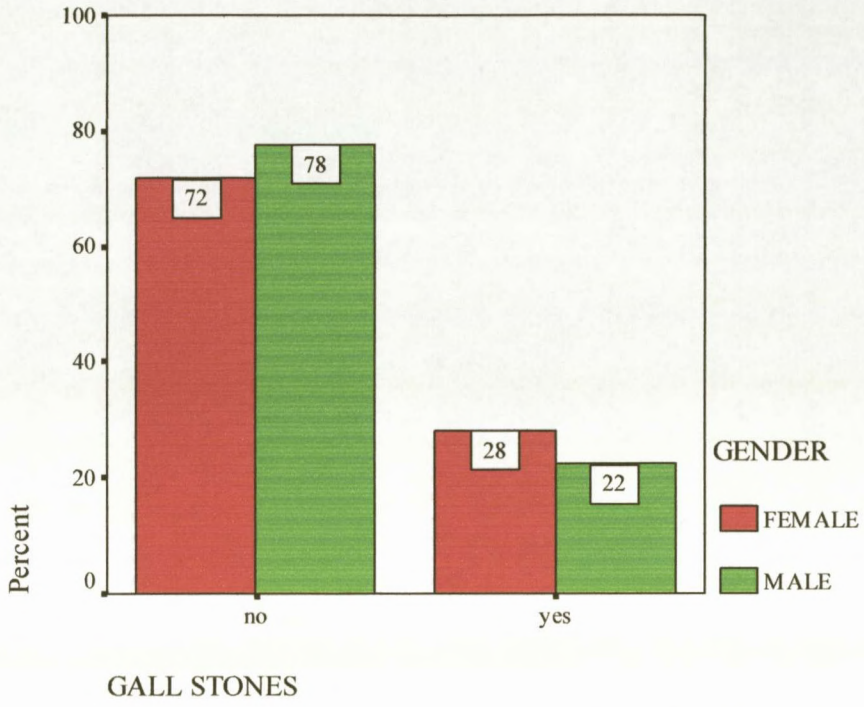

Figure 4.2: Gender specific prevalence of gall stones (n=389)

4.3.4 Diet specific prevalence

4.3.4.1 Carbohydrates

A slightly higher proportion of those who consumed a diet of >53% carbohydrates had gallstones than those who consumed under 53%, but this was not statistically significant (p=0.541) (See Table 4.5 and Figure 4.3).

Table 4.5: Carbohydrate consumption in the presence of gallstones

Carbohydrates			Gall Stones		Total
			no	yes	
	<=53%	Count	147	50	197
		Row %	74.6%	25.4%	100%
	> 53%	Count	138	54	192
		Row %	71.9%	28.1%	100%
Total		Count	285	104	389
		Row %	73.3%	26.7%	100%

Pearson's chi square=0.374, p=0.541

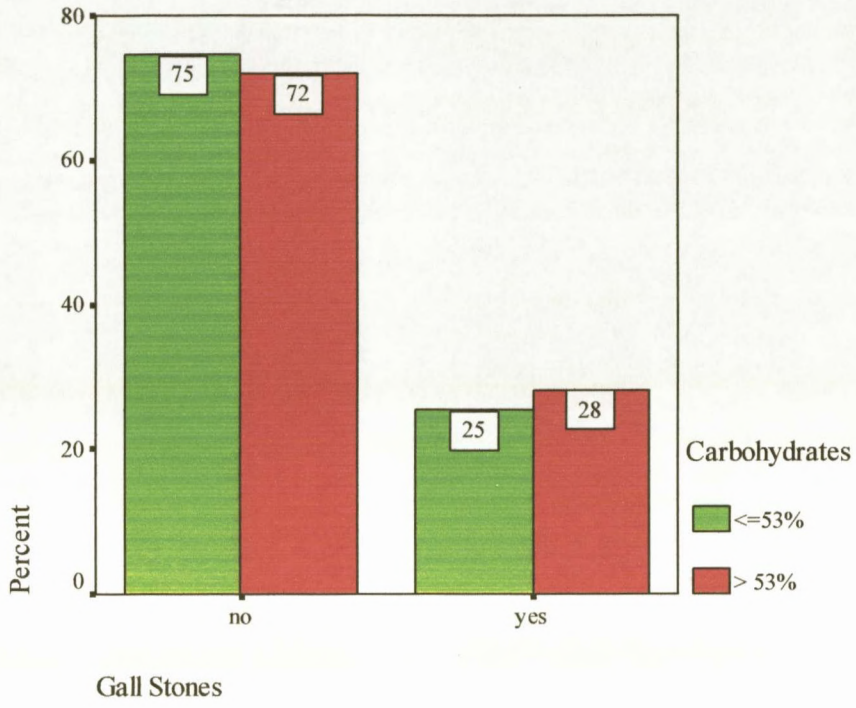

Figure 4.3: Carbohydrate specific prevalence of gall stones (n=389)

4.3.4.2 Fat

Table 4.6 shows that there was a significantly greater proportion of participants with high fat consumption who had gall stones than those who had low fat consumption (p=0.001). This is shown graphically in Figure 4.4.

Table 4.6: Fat consumption in the presence of gall stones

			Gall Stones		Total
Fat			no	yes	
	<=30%	Count	186	49	235
		% within Fat	79.1%	20.9%	100%
	>30%	Count	99	55	153
		% within Fat	64.1%	35.9%	100%
Total		Count	285	104	389
		% within Fat	73.2%	26.8%	100%

Pearson's chi square 10.765, p=0.001

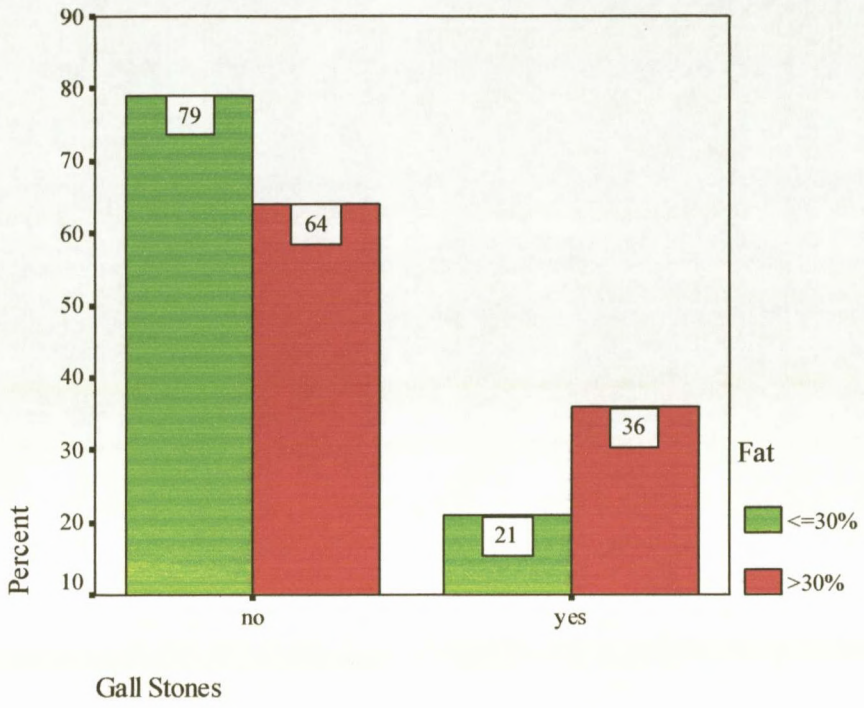

Figure 4.4: Fat specific prevalence of gall stones (n=389)

4.3.4.3 Protein

High protein consumption was associated with low prevalence of gallstones ($p<0.001$). A lower percentage of those who consumed high protein diets had gallstones than those who consumed low protein diets. This is shown in Table 4.7 and Figure 4.5.

Table 4.7: Protein consumption in the presence of gall stones

			Gall Stones		Total
Protein			no	yes	
	<=17%	Count	117	64	181
		% within Protein	64.6%	35.4%	100%
	>17%	Count	168	40	208
		% within Protein	80.8%	19.2%	100%
Total		Count	285	104	389
		% within Protein	73.3%	26.7%	100%

Pearson's chi square=12.853, p<0.001

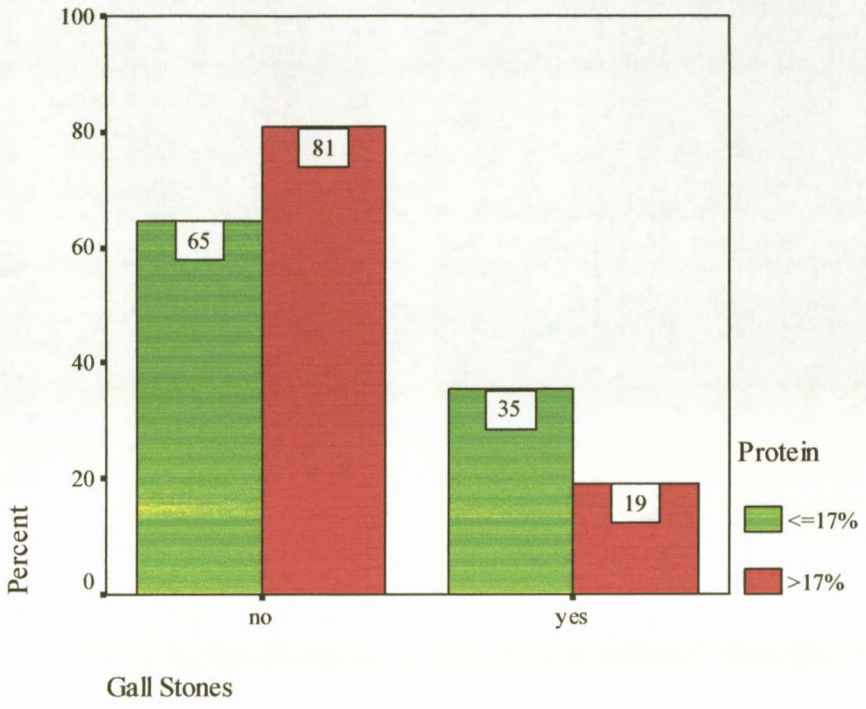

Figure 4.5: Protein specific prevalence of gall stones (n=389)

4.3.5 BMI specific prevalence

The prevalence of gall stones was the lowest in the normal category (22.7%) and increased as BMI category changed to above normal (28.6%) and below normal (25%). Those with BMI above normal had the highest prevalence of gall stones. However, the differences in percentages was not statistically significant (p=0.482). This is shown in Table 4.8 and Figure 4.6.

Table 4.8: BMI category in the presence of gall stones

BMI category		Gall Stones		Total
		no	Yes	
<18 (below normal)	Count	3	1	4
	% within BMI category	75.0%	25.0%	100%
18-24.5 (normal range)	Count	92	27	119
	% within BMI category	77.3%	22.7%	100%
>24.5 (above normal)	Count	190	76	266
	% within BMI category	71.4%	28.6%	100%
Total	Count	285	104	389
	% within BMI category	73.3%	26.7%	100%

Pearson's chi square 1.459, p=0.482

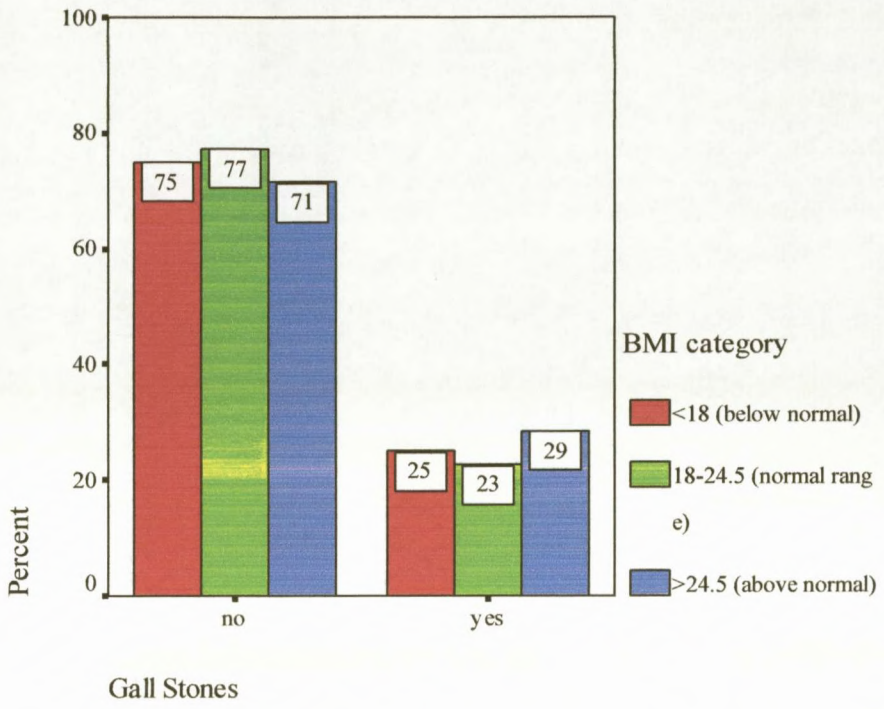

Figure 4.6: BMI category specific prevalence of gall stones (n=389)

4.3.6 Factors contributing to the development of gallstones

The logistic regression model was completed in 5 steps. The final results are shown in Table 4.9. Age in years was a significant predictor for gall stones (odds ratio (OR) = 1.015, p=0.047). As age increased by one year, the risk of developing gallstones increased by 1.5%. Consuming protein was protective for developing gall stones (OR = 0.904, p=0.001). As the protein consumption increased by one percent, the risk of developing gall stones decreased by 9.6%. Fat and energy consumption were both significant risk factors. As the fat consumption increased by 1%, the risk of gall stones increased by 4.9%. As the

energy consumption increased by 100 units the risk of gall stones increased by 2.6%. BMI, gender and carbohydrates did not significantly influence the risk of gall stones whilst controlling for the other predictors in this study.

Table 4.9: Logistic regression analysis of factors contributing to the development of gallstones

	B	S.E.	Wald	df	P value	OR	95.0% C.I. for OR	
							Lower	Upper
AGE (Years)	.015	.007	3.946	1	0.047	1.015	1.000	1.030
PROTEIN (%)	-.100	.031	10.540	1	0.001	.904	.851	.961
FAT (%)	.048	.019	5.993	1	0.014	1.049	1.010	1.090
ENERGY (per 100 units)	.026	.008	9.800	1	0.002	1.026	1.010	1.043
Constant	2.343	1.007	5.419	1	0.020	.096		

4.4. SUMMARY

This chapter presented the results of this research. Tables and graphs were used to simplify the understanding of the results where necessary. The demographic data was presented to highlight the sample characteristics.

Inferential statistics was also presented to indicate the strength and direction of the relationship between variables and the level of significance. Finally the logistic regression analysis of factors that contribute to the development of gallstones is presented.

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 INTRODUCTION

The data collected in the form of figures, tables and text was presented in chapter four. The principal trends and patterns in the data are discussed below with reference to the main aim and research questions as defined in chapter four.

5.2 REDEFINITION OF THE RESEARCH AIM

This study aimed to determine and evaluate the prevalence of gallstones in the Black population of District 28 in relation to age, gender, diet and body mass index (BMI) in order to ascertain people at high risk so that they could be advised, then complications and morbidity rate could be decreased.

5.3 DISCUSSION OF RESULTS

5.3.1 Gallstones

Results showed an overall prevalence of gallstones of 26.74%. The sample group comprised of people who were in the hospital for many different illnesses, some even not related to gall bladder diseases. Amongst the respondents, were

also staff members who had no complaints and some had symptoms related to gallbladder diseases. The prevalence of gallstones in this study appeared higher when compared with studies done previously in South Africa. The highest reported prevalence is that from North American Indians, Chileans and Mexican Americans followed by non-Hispanics from North America, Europeans and Asians from India. The prevalence of gallstones in a study in 1998 was 35% for Mapuches, followed by Hispanics (27%) and Maoris (21%) (Miquel et. al., 1998).

The prevalence of gallstones in the rural Caucasian population in Canada was 16%, compared to a study done in Micmac Indian women who are from an inland rural community which was 21 % (Lietzmann et.al.,1999). District 28 is also predominantly rural although people have been westernized. The prevalence of gallstones in the current study is higher when compared with those studies done elsewhere in a rural environment discussed above. Further research is recommended which will cover a larger geographic area.

5.3.2 Age

The prevalence of gall stones was found to be lowest (13.3 %) in the youngest age group, less than 20 years old. The age-specific prevalence increased until the 41-50 age group (33.3%), but thereafter there was a slight decrease to 24.4% in the 51-60 age group. The over 60 year group had a high prevalence of 33.3%. This is shown in table 4.3 in chapter four. Statistical analysis shows no significant

association between the age group and gallstones although a slight trend was demonstrated.

According to Leitzmann et.al.,(1999), the prevalence of gallstones peaks between the ages of 30 and 39 years and the risk factors were found to be obesity, a narrow range of energy intake, a low daily calcium intake and limited activity.

A study was done by Walcher et.al. (2005) to investigate the prevalence and risk factors, in an urban population in Germany. The highest prevalence was found in the group of females aged 51-65 years .The overall prevalence of gallbladder stones increased with advancing age from 1.5% among subjects aged 18-30 years to 15.2% in the 51-65 years age group.

5.3.3 Gender

Of the 389 respondents 295 (75.8%) were female and 94 (24.2%) were male.
The results in chapter 4 (Table 4. 4 and Figure 4.2) showed that there was slightly higher prevalence of gallstones in the females (28.1%) than in the males (22.3%), although the difference was not statistically significant.

This study is in agreement with Bateson (2000) in the study done in Britain which reported that gallstone disease is commoner in women than in men with no sex

differences detected for respondents less than 40 years and over 90 years of age. According to Johnson et.al., (2002), 10% of all adults have gallstones with women having three times the prevalence of men during fertile period. The current study did not look at factors relating to fertility as risk for gall bladder disease.

5.3.4 Diet

Diet was analyzed in terms of energy (KJ), carbohydrate (%), protein (%), and fat (%). Energy levels for all the respondents were within normal limits for the different age groups.

In the results (Table 4.5 and figure 4.3), those that had gallstones were a slightly higher proportion of those who consumed a diet of more than 53% carbohydrates than those who consumed under 53%. This was not statistically significant. According to literature, increased intake of carbohydrates in the form of simple sugars in drinks and sweets was associated with gallstone formation (Indiadiets Diets: 1999).

As demonstrated in table 4.7 and figure 4.5 of the results, high protein consumption was associated with low prevalence of gallstones. A lower percentage of those who consumed high protein diets had gallstones than those who consumed low protein diets. Most of these respondents came from Manguzi

and Ngwavuma areas where they eat a lot of peanuts which is known to have plant protein. This is in agreement with the study done by Beauchamp (2004) who reported that women who ate the most plant-derived protein had a significantly lower risk of gall bladder removal than those who ate the least amount. Contrary to the above higher animal protein increases biliary cholesterol concentration which increases the risk of stone formation (indiadiets Diets: 1999. Results show that there was a significantly greater proportion of participants with high fat consumption who had gallstones than those who had low fat consumption (Table 4.6 and figure 4.4). High fat intake seems to be the most important food constituent that has contributed to the increased prevalence of gallstones among Blacks. One of the reasons is that rural African dwellers have shifted towards the Western diet and the fat intake among urban South African Blacks has increased from 16.4 to 26 % of total energy (Bourne et.al., 2002)

5.3.5. Body Mass Index (BMI)

In this research, results have shown the lowest prevalence of gallstones in respondents who had a normal BMI, between 18 and 24.5. The prevalence of gallstones increased as BMI increased above the normal range which is above 24.5. Those with a BMI above the normal range had the highest prevalence of gall stones. However, the differences in percentages were not statistically significant. This is shown in Table 4.8 and Figure 4.6.

This is in agreement with NIDDC (2002) which stated that obesity is a strong risk factor for gallstones. As the BMI, which is a measure of obesity increases, the risk for developing also rises.

Furthermore, Acalovschi, (2001) in his study in Romania discovered that women with a BMI greater than 45 had a sevenfold excess risk when compared with those with a BMI less than 24 . He further discovered that obesity in men as expressed by BMI, was not related to an increased gallstone formation.

Lifang, (2004) in the study in Italy also discovered a high prevalence of gallstone disease(30%) in the females with a body mass index greater than 30 compared to 24% in patients with a BMI less than 30.

5.4 SUMMARY

This chapter discussed the findings of this research project using the available literature as a source of discussion. Results showed an overall increase in the prevalence of gallstones (26.74%) among the Black population of District 28. It highlighted the most common factors contributing to the increased prevalence of gallstones.

The chapter highlighted the following factors:

- ✓ The age specific prevalence increased most at 41- 50 age group and above 60 years.
- ✓ There was slightly higher prevalence of gallstones in females than in male.

- ✓ Respondents who consumed a diet of more than 53% carbohydrates had more gallstones than the ones that consumed less than 53%.
- ✓ Respondents with high fat consumption had gallstones more than those with low consumption.
- ✓ High protein consumption was associated with low prevalence of gallstones.
- ✓ Those that had a BMI above normal range had the highest prevalence of gallstones.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

The data presented in this thesis represent the first study to determine and evaluate the prevalence of gallstones in the Black population in District 28 in KwaZulu -Natal in terms of age, gender, diet and body mass index (BMI) in order to identify the risk factors. The study was conducted on 389 respondents from the Black population of District 28.

This chapter presents the conclusions based on the results discussed in chapter four and the discussion presented in chapter five. It will also highlight the limitations of this research as well as recommendations for both future research and what can be done to reduce the risk of developing gallstones.

6.2 CONCLUSIONS AND SIGNIFICANCE

In this study the main aim was to determine and evaluate the prevalence of gallstones in the Black population of District 28. A remarkable increase in the prevalence of gallstones was demonstrated for a sample population of 389 respondents. The age of the subjects ranged from 18 to 89 years, and the mean

age was 39.4 years (SD16.15 years). The sample comprised 295 females and 94 males. The overall prevalence of gallstones in the sample was 26.74% (95% CI 22.51 to 31.30).

The prevalence of gallstones in this study has markedly increased when compared with previous studies done in a similar population but in a different place. A similar study was done during 1983 in South Africa (Gauteng Province) at the Chris Hani Hospital which recorded a prevalence of 2% (Docrat et.al., 1999). A change in dietary habits is thought to have a major contribution to the increase in the prevalence of gallstones among the Black population.

This can be best compared with a more recent study done in the rural Caucasian population in Canada which recorded a prevalence of 16%, and also a study done in Micmac Indian women who are from an inland rural community which was 21% (Leitzmann et.al.,1999). District 28 is also predominantly rural although people are now being westernized. The prevalence of gallstones in the current study is higher when compared with those studies done elsewhere in a rural environment.

The significance of this is that Black population from District 28 in KZN has a relatively high prevalence of gallstones, irrespective of whether they showed symptoms of gallbladder disease or not. Patients that will present with symptoms

related to gallstones will have to be investigated with ultrasound and if gallstones are confirmed, the necessary management must be implemented to prevent the potential complications. Hypothesis 5, which stated that the prevalence of gallstones in the Black population of District 28 is increasing, is accepted.

This study also had to determine the age specific prevalence rate of gallstones in the Black population over 18 years of age of District 28 in order to determine the age group at high risk for developing gallstones.

Results showed that age specific prevalence was highest in the 41 to 50 years age- group and also above 60 years. Analysis further shows that there was no significant association between age group and gallstones, although a slight trend was demonstrated. The prevalence of gall stones was the lowest in the youngest age group less than 20 years of age (13.3%). The age-specific prevalence increased until the 41-50 age group (33.3%), but thereafter there was a slight decrease to 24.4% in the 51-60 group. The over 60 year group had a high prevalence of 33.3%. The significance of this is that Black people from any age group above 18 years in the District 28 have a high risk for developing gallstones. Hypothesis 1, which stated that there will be an increase in prevalence of gallstones in the Black population of District 28 with increase in age, is accepted.

This study has shown that the difference in the prevalence of gallstones between males and females is not statistically significant. There was only a slightly higher prevalence in females than in males. The significance of this is that prevalence of gallstones is increasing irrespective of gender differences. Therefore, hypothesis 2 which stated that the prevalence of gallstones in females is double that of males, is rejected.

This research project had to determine the diet specific prevalence of gallstones in the Black population over 18 years of age of District 28 in order to determine what food substances may contribute to the high prevalence of gallstones. The study reported that although a slightly higher proportion of those who consumed a diet of more than 53 % carbohydrates had gallstones than those who consumed less, it was not statistically significant. The study also showed that there was a significantly higher proportion of participants who had high consumption of fat that had gallstones. The study also showed that high protein consumption was associated with low prevalence of gallstones. The significance of this is that consumption of carbohydrates yields a risk of developing gallstones even if the consumption is less than the cut off point of 53%. It also means that high protein consumption can be protective from developing gallstones. The type of protein that is protective is from plants. Rich sources of plant- derived protein include legume (such as soya beans, peanuts, black beans and peas), buckwheat, nuts and seeds (Beauchamp, 2004). The significance also means that high fat consumption increases the risk of developing gallstones.

Hypothesis 3 which stated that increased carbohydrates and protein consumption will increase the risk of developing gallstones is rejected but it will be accepted that increase in fat consumption will increase the risk of developing gallstones.

The research project also had to determine the body-mass index (BMI) specific prevalence of gallstones in the Black population of District 28 over the age of 18 in KwaZulu -Natal. The study reports that those with a BMI above the normal range (24.5) had the highest prevalence of gallstones. The differences in percentages of the normal range (18-24.5), below the normal range (below 18) and above the normal range (above 24.5) were however, not statistically significant. The significance of this is that prevalence of gallstones can increase irrespective of BMI. Therefore, hypothesis 4, which stated that the prevalence of gallstones will increase with increase in BMI, is rejected.

6.3 SUMMARY OF RESULTS

The results in chapter 4 showed an increase in overall prevalence (26.74%) of gallstones in the Black population of District 28 in KwaZulu- Natal.

A significant finding discovered from this research project is that participants with high fat consumption (more than 30%, which is a cut off point for fat) had high prevalence (35.9%) of gallstones than those who consumed less than 30% fat (20.9%). This is shown in figure 4.

The results showed that high protein consumption was associated with low prevalence of gallstones.

The study has shown that there is no significant association between age group and gallstones.

This study has shown that the difference in the prevalence of gallstones between males and females is not statistically significant.

The study reported that although a slightly higher proportion of those who consumed a diet of more than 53 % carbohydrates had gallstones than those who consumed less, it was not statistically significant.

The differences in percentages of the BMI (18-24.5), below normal BMI (below18) and above normal BMI (above 24.5) was not statistically significant.

6.4 LIMITATIONS

An important limitation of the study was the low rate of participation among males. Females participated more. This bias may contribute to an increase in the crude prevalence of gallstone disease in the total population. However, this was minimized by stratifying the data by sex.

There is a feeling that some of the respondents had pre- knowledge of having gallstone disease but they did not disclose it during the interview. This bias therefore contributed to an increased prevalence of gallstone in the sample population, because the number of those with gallstones will increase the number of the respondents with stones. It is also thought that some of the respondents especially staff members at the hospital knew that they were at high risk for developing gallstones. This must have also contributed to the increased prevalence of gallstones among the sample population.

There are many factors found in the pool of knowledge that contribute to gallstone disease but the study only looked at the most common factors i.e. age, gender, diet and BMI.

6.5 FUTURE RESEARCH

Future studies should be done to verify these results using a cohort design where the sample is selected randomly from the community at large, not only those who have come to the hospital.

Research should be done to look for factors that can contribute to a lower prevalence of gallstone in the Black population.

Research must be done to compare prevalence of gallstones amongst the different race groups in South Africa in order to determine which race group is at high risk for developing gallstones.

6.6 RECOMMENDATIONS

Future studies should be done to verify these results using a cohort design where healthy participants are selected randomly from the community and followed up for the development of gallstones. In this way it can be verified that the exposure was pre-existing before the event of gallstones.

Although symptomatic and complicated stones represent less than 20% of all gallstones according to Kennedy et.al. (1994), they lead to important morbidity and complications, and to high costs of medical care. Gallstone formation and prevention of complications are therefore highly important.

A healthy lifestyle is recommended to the whole population, but could be most productively focused on subjects at increased risk, that is obese and ageing women. The strategy for preventing cholesterol gallstone formation should be targeted to the main pathogenetic mechanisms such as, supersaturation of bile in cholesterol, accelerated nucleation, impaired gallbladder emptying and intestinal hypomotility (Rajan, 2002).

Gallbladder stasis should be approached by a regular eating pattern, avoiding long periods between meals, by a bedtime snack to reduce overnight fasting or

by small fatty meals during rapid weight loss. Stimulation of intestinal motility would decrease bacterial bile acid metabolisation. People (particularly women) should limit their energy intake and especially readily absorbed carbohydrates and animal fats so as to maintain the ideal body weight. They should also eat enough dietary fibre to avoid constipation and respect a regular eating pattern avoiding long overnight fasting (Tseng, 1999).

6.7 SUMMARY

This study has found that there is a relatively high prevalence (26.74%) of gall stones amongst asymptomatic Black males and females and those with a history of upper abdominal pain in Ngwelezana hospital. The sample may have been biased due to the selection of volunteers who may have been more at risk than the general population. Thus the 95% confidence intervals would not refer to the general population of this area, but to a more select subpopulation of individuals who may be at increased risk of developing gall stones. The profile of individuals in this population who are at the highest risk of developing gall stones are those with greater age, low plant protein consumption, and high fat and energy intake. However, due to the cross-sectional design, it cannot be verified that the exposures pre-existed before the development of gallstones.

This chapter presented the study design limitations. It also presented the research conclusions based on the major highlights of the results. The conclusions were presented in line with the objectives of this research. The

chapter also presented the recommendations drawn up from the conclusions of this research project.

LIST OF REFERENCES

Acalovschi M. 2001. Cholesterol gallstones: from epidemiology to prevention. *Postgraduate Medical Journal*. April ;77: 221-229

Akute O.O., Marino A.O., Kalejaiye A.O., Sogo K. 1999. Prevalence of gallstones in a group of antenatal women in Ibadan, Nigeria. *African Journal of Medical and Medical Science*(on line). 28(3-4): 159-61(Accessed on 19 April 2005)

Ahmad S., Zafar A. Ahmad M., Ghafoor A., Malik E., Ali A. 2002. Accuracy of surgeon- peformed abdominal ultrasound for gallstones. *Dept. of Surgery, Ayub Medical College*

Avenell A., Brown T.J., McGee M.A., Campbell M.K., Grant A.M., Broom J. 2004. What interventions should we add to weight reducing diets in adults with obesity? Journal of Human Nutrition and Diet.; 17(4):293-316

Baig S.J., Biswas S., Das S., Basu K., Chattophay G. 2002. Tropics in Gastroenterology. Histopathological changes in gall bladder mucosa in cholelithiasis: correlation with chemical composition of gallstone (on line). (Accessed 26 November 2002)

Bateson M.C. 1999. Gall bladder disease. *British Medical Journal.* (26 June); 318:1745-1748. (Accessed 13 September 2005).

Bateson M.C. 2000. Gallstones and cholecystectomy in modern Britain. *Postgraduate Medical Journal.*(November); 76:700-703 (on line). (Accessed 08 November 2005).

Beauchamp K. 2004. Health conditions and Concerns. (on line) Newswire. September 2. (Accessed 29 December 2005).

Beckingham I.J. 2001. ABC of diseases of liver, pancreas, and biliary system Gallstone disease. *British Medical Journal.* January 13; 322(7278): 91–94.

Beckingham I.J., Ryder S.D. 2001. ABC of diseases of liver, pancreas, and biliary system ; Investigation of liver and biliary disease . Clinical review. *British Medical Journal; 322:33-36 (6 January)*

Berhane T, Vetrhus M, Hausken T, Olafsson S, Sondenaa K. 2006. Pain attacks in non-complicated and complicated gallstone disease have a characteristic pattern and are accompanied by dyspepsia in most patients: The results of a prospective study. *Scandinavian Journal of Gastroenterology.* Jan;41(1):93-101.

Blanco N.M. 2006. General health information. University Medical Centre of Southern Nevada. (on line) available at www.umc-cares.org/index.asp.(Accessed On 23 March 06)

Blum A., Tatour I., Monir M., Khazim K., Simsolo C. 2005. Gallstones in pregnancy and their complications: Postpartum acute pancreatitis and acute peritonitis. *European Journal of Internal Medicine.* Volume 16, Issue 7, November, Pages 473-476

Bortoff G.A., Chen M.Y.M., Ott D.J., Wolfman N.T., Routh W.D. 2000. Gallbladder Stones: Imaging and Intervention *Radiographics.* 2000;20:751-766.

Bourne L.T., Lambert E.V., Steyn K. 2002. Where does the Black population of South Africa stand on the nutrition transition? *Public Health Nutrition.* February 5(1A):157-162)

Chapman B.A., Frampton C.M., Wilson I.R., Chisholm R.J., Allan R.B., Burt M.J. 2000. Gallstone prevalence in Christchurch: risk factors and clinical significance. *New Zealand Journal of Medicine*: 113(1104): 46-8 February 25

Coelho JC; Bonilha R; Pitaki SA; Cordeiro RM; Salvalaggio PR; Bonin EA. 1999. Prevalence of gallstones in a Brazilian population. *Internal Surgey*; 84(1): 25-8 Jan – March.

Dam Wayne. 2006. Municipal dermacation board: available at http://en.wikipaedia.org/wiki/uthungulu_district_municipality. (Accessed on 25 July).

Diehl A.K. 1992. Diagnosis and Management of Biliary Stones Symptoms of gallstone disease. *Baillière's Clinical Gastroenterology* Volume 6, Issue 4 , November, Pages 635-657.

Docrat H.Y., Thomson SR., Haffejee A.A., Singh B., Moodley J. 1999. Cholecystecytomy in a predominantly African Population before and after the advent of the laparoscopic technique. *Department of Surgery, University of KwaZulu Natal.*

Dumot J.A.,2006.ERCP: current uses and less- invasive options. Cleveland Clinical Journal of Medicine.May: 73(5):418,421, 424-5.

Erden G.A., Kendi A.T., Erden I. 2005. MRCP evaluation of biliary system following vagotomy and gastric surgery. *Clinical Imaging*. Jan-Feb;29(1):42-5.

Everhart J.E., Khare M., Hill M., Maurer K.R. 1999. Prevalence and ethnic differences in gallbladder disease in the United States. *Gastroenterology.* Volume 117, Issue 3 , September, Pages 632-639

Everhart J.E.,Yeh F., Lee E.T., Hill M.C., Fabsitz R., Howard B.V. 2002. Prevalence of gallbladder disease in American Indian Population. *Hepatology.* 35:1507-1512

Food Fundi professional. 1993.Penta Medical Systems: Medical Research Council.

Fromm H. 1986. Gallstone dissolution therapy. Current status and future prospects. *Gastroenterology.* Dec;91(6):1560-7

Gandolfi L., Torresan F., Solmi L., Puccetti A. 2003. The role of ultrasound in biliary and pancreatic diseases. *European Journal of Ultrasound* Volume 16, Issue 3 , February, Pages 141-159

Glasglow R.E., Cho M., Hutter M.M.,Mulvihill S.J. 2000.The spectrum and cost of complicated gallstone disease in California. Archives of Surgey. 135(9):1021-5.

Grainger R.G. and Allison D.J. 1994. *Diagnostic Radiology*, Vol 2, 2nd Edition. Churchill Livingstone: London, ISBN 0443041121, 1600p.

Halldestam I.,Enell E.L., Kullman E., Borch K., 2004. Development of symptoms and complications in individuals with asymptomatic gallstones. *British Journal of Surgery(*On line*)*. June; 91(6): 734-8. (Accessed 22 July 2004).

Hayat J.O., Loew C.J., Asrress K.N., McIntyre A.S., Gorard D.A. 2005. Contrasting liver function test patterns in obstructive due to biliary strictures and stones. *QJM*. 2005 Jan;98(1):35-40.

Health and Age. 2002. Gallstones and gall bladder disease (on line). September 30. Available from:http//www.healthandage.com

Health Link Medical College of Wisconsin Physicians. 2006 On line. Available at http://healthlink.mcn.edu/article/950732863.html (Accessed on 16/07/06.

Hobbs MS, Mai Q, Knuiman MW, Fletcher DR, Ridout SC. 2006. Surgeon experience and trends in intraoperative complications in laparoscopic cholecystectomy. *British Journal of Surgery*. May 2

Hopper K,D., Landis J.R., Meilstrup J.W., Mc Causlin M.A., Sechtin A.G. 1991. The prevalence of asymptomatic gallstones in the general population. *Investigative Radiology.* Nov; 26(11):939-45.

Indar A.A. and Beckingham I.J. 2002. Acute cholecystitis. Clinical review. *British Medical Journal* ;325:639-643 (Accessed on 21 September 2005)

Indiadiets Diets, 1999. Gallstone disease (on line). Available from: *Indiadiets.com.* (Accessed 29 December 2005)

Iqbal M; Aggarwal S; Kumar R; Garg PK; Bandhu S; Kumar A. 2004. The role of 99mTc mebrofenin hepatobiliary scanning in predicting con bile duct stones in patients with gallstone disease. *Nuclear Medicine Communal.* 25(3):285-9

Jendresen M.B., Thorboll J.E., Adamsen S.,Nielsen H., Gronvall S., Hart-Hansen O. 2002. Preoperative routine magnetic resonance cholangiopancreatography before laparoscopic cholecystectomy. *European Journal of Surgery*;168(12): 690-4

Johnson A.G., Fried M., Tytgat G.N.J., Krabhuis J.H. 2002. Asymptomatic Gallstone Disease(online). Available form :http://www.omge.org/. (Accessed 12 January 2002).

Kennedy J.S., Park A.D., Cornwell M.J., Fern D.R., Champney M.S. 1994. Gallstones and Gallbladder (online). Available from: http://www.dekalbsurgical.com/meet_the_doctors.htm (Accessed 17 October 2005)

Khan A.Z. 1999. Gall bladder disease and Laparoscopic Cholecystectomy. British Medical Journal. 8 July (on line) . available at: bjm.com (Accessed on 13 September 2005)

Kim A.Y., Choi B.I., Lee J.Y., Kim K.W., Han J.K. 2002. Functional analysis of gall bladder using three dimensional ultrasound. *Ultrasound in Medicine and Biology*. May; 28(5): 581-8

Kumar P. J. and Clark M.L. 1989. *Clinical Medicine* . Bailliere Tindall : Tokyo. ISBN 07020-1137-1 1011p

Leitzmann M.F., Rimm E.B., Willet W.C, Spiegelman D., Grodstein F. Stampfer M.J. 1999. Recreational Physical Activity and the risk of Cholecystectomy in Women. *New English Journal in Medicine* (on line). September 9; 341(11):777-784 . (Accessed 04 January 2006).

Lifang H., Xiao-Ou S., Bu-Tian J., Gong Y., Aaron B., Zheng W. 2004. BMI, physical activity and risk of gallstone disease in Chinese women. Annals of

Epidemiology, Volume 14, Issue 8, September 2004, Pages 604-605

Majeski J. 2003. Gall bladder ejection fraction: accurate evaluation of symptomatic acalculous gall bladder disease. Internal Surgery. April – June; 88(2): 95 – 99

Miquel J.F., Covarrubias C., Villaroel L., Mingrone., Greco A.V., Puglielli L. 1998. Genetic Epidemiology of Cholesterol Cholelithiasis among Chilean Hispanics, Amerindians and Maoris. *Gastroenterology* : 115:937-946

Misciagna G.,Centonze S., Leoci C., Guerra V., Cisternino A.M., Ceo R. 1999. Diet, physical activity, and gallstones—a population-based, case-control study in southern Italy· *American Journal of Clinical Nutrition*, Vol. 69, No. 1, 120-126

Mittal B. and Mittal R.D. 2002. Genetics of gallstone disease. *Journal of postgraduate Medicine*(on line). 48(2): 149-152. Available from: http://www.jpgmonline.com/. (Accessed 04 January 2006).

Moro P.L., Checkley W., Gilman R.H., Cabrera L., Lescano A.G., Bonilla J.J. 2000(on line). Gallstone disease in Peruvian coastal natives and highland migrants. *GUT* (on line). April; 46:569-573. (Accessed 08 November 2005).

Muller S.P. 2004. Principal Specialist Surgeon, Ngwelezana Hospital, Empangeni(personal communication).

Musana KA, Yale SH.2005. *Murphy's Sign.* Clinical Medicine Research. Aug;3(3):132.

National Digestive Disease Information Clearinghouse. 2002. *Gallstones (*online). Available from:http: //www.niddk.nih.gov/tools/mail_nddic.htm. (Accessed 25 November 2002).

National Digestive Disease Information Clearinghouse. February 2002. *Dieting and Gallstones(online).* Available from : www.niddk.nih.gov/health/nutrit/nutrit.htm (Accessed 12 September 2003).

Pagliarulo M., Fornari F., Fraquelli M., Zoli M., Giangregorio F., Grigolon A. 2004. Gallstone disease and related risk factors in a large cohort of diabetic patients. *Digestive Liver diseases.* Feb 36(2):130-4

Park Y.H.; Park S.J.; Jang J.Y.; Ahn Y.J.; Park Y.C.; Yoon Y.B. 2004. Gallstones. *World Journal of Surgery.* 2004; 28(2):206-10

Peng W.K., Sheikh Z., Paterson B. 2005. Role of liver function tests in predicting common bile duct stones in acute calculous cholecystitis. *British Journal of Surgery.* Oct; 92(10):1241-7.

Pleatman M.A. 2005. Advanced laparoscopic surgery. (on line). Available at www.pleatman.laparoscpy.com (Accessed 26 September 2006).

Prasad A. 2002. Gall bladder disease- Is surgery always needed? *Laparoscopic Surgery.* (on line). Available from: *WebHealth Centre.com-Surgeon's Corner.* (Accessed 12 August 2005).

Puspok A, Lomoschitz F, Dejaco C, Hejna M, Sautner T, Gangl A. 2005 Endoscopic ultrasound guided therapy of benign and malignant biliary obstruction: a case series. American Journal of Gastroenterology. Aug;100(8):1743-7.

Rahman GA. 2005. Cholelithiasis and cholecystitis: changing prevalence in an African community. *Journal of National Medicine Association.* Nov;97(11):1534-8.

Rajan T.V. 2002. Cholelithiasis. (online). Available from: http://radiology.uchc.edu/eAtlas/GI/954.htm. (Accessed 20 November2002).

Rampon V., Genot C., Riaublanc A., Anton M., Axelos M. A. V., McClements D. 2003. Front-Face Fluorescence Spectroscopy Study of Globular Proteins in Emulsions: Displacement of BSA by a Nonionic Surfactant, *Journal of Agriculture and Food Chemistry*; 51: 2482-2489

Randi G, Franceschi S, La Vecchia C. 2006. Gallbladder cancer worldwide: Geographical distribution and risk factors. *Internal Journal of Cancer.* Apr 1;118 (7):1591-602

Raoyle J.A., Walsh M. 1993. 4th Edition. *Watson's Medical- Surgical Nursing and related Physiology.* Bailliere Tindall: London ISBN 0-7020-1515-6. 1037p

Razzaz R. and Sukumar S.A. 2004. Imaging of the jaundiced adult. *Imaging.* September 1; 16(4):287-300.

Reshetnikov OV; Ryabikov AN; Shakhmatov SG; Malyutina SK. 2002. Prevalence and risk factors for gallstone disease. *Journal of Gastroenterology and Hepatology*; 17(6):702-7

Saladene K.S., 2004. *Anatomy and Physiology.*,3rd Edition.,Mc Graw Hill:New York., ISBN 0-07-242903-8, 1120p.

Salinas G; Velásquez C; Saavedra L; Ramírez E; Angulo H; Tamayo JC. 2004. Epidemiology of gallstone disease in Chandigarh: a community-based study. *Surgical Laparoscopic Endoscopic Percutaneous Technology*. 2004; 14(5):250-3

Sayed N. and Humphrey J. 1991. Evolution of the South African Food Composition Database Management Systems. Diatetics and Human Nutrition. University of Natal, MRC

Schirmer B.D., Winters K.L., Edlich R.F. 2005. Cholelithiasis and cholecystitis. *Journal of Long Term Efficiency in Medical Implants*. 2005;15(3):329-38.

Seeley R.R., Stephens T.D.,Tate P., 1998, *Anatomy and Physiology*. 4th edition. Mc Graw hill:New York,ISBN 0-697-41107-9, 1098p.

Simmons D.C., Tarnasky P.R., Rivera-Alsina M.E., Lopez D.J.F., Edman C.D. 2004. Endoscopic retrograde cholangiopancreatography (ERCP) in pregnancy without the use of radiation . *American Journal of Obstetrics and Gynecology* . Volume 190, Issue 5 , May 2004, Pages 1467-1469.

Singh V; Trikha B; Nain C; Singh K; Bose S. 2001. Changing patterns of gallstone disease in Korea. *Journal of Gastroenterology and Hepatology.* 2001; 16(5):560-3

Sood B; Jain M; Khandelwal N; Singh P; Suri S. 2002. MRI of perforated gall. bladder. *Australas Radiology.* 46(4):438-40

Stefanidis D., Sirinek K.R., Bingener J. 2004. Gallbladder Perforation: Risk Factors and Outcome . Journal of Surgical Research Presented at the 38th Annual Meeting, The Association for Academic Surgery, Houston, TX, Nov 11–13, 2004.

Stefanidis D, Sirinek KR, Bingener J. 2006. Gallbladder Perforation: Risk Factors and Outcome. *Journal of Surgery Research.* Jan 10

Sungal S., Coakley E.H., Willett W.C.1999. Long –term weight patterns and risk factors for cholecystectomy in women. *Annal in Internal Medicine*; 130:471-477.

Surgeon's Corner. 2000. *Gallstones* (online). Available from: www.webhealthcentre com . (Accessed 25 November 2002).

Tendler D.A. 2005. Gallstone disease. Healthology- Duke University centre (on line). Available at: www.healthology-gallstones.org.htm. (assesd on 15 May 2006)

Tsai C.J., Lietzmann M.F., Willet W.C., and Giovannucci E. 2004. Dietary protein and the risk of Cholecystectomy in a cohort of US women. *American Journal of Epidemiology.* 160:11-18.

Tseng M. 1999. Dietary intake and gallbladder disease: a review. *Public Health Nutrition* ;**2**:161-172

Torgerson J.S., Lindroos A.K., Naslund I., Peltonen M. 2003.Gallstones, gallbladder disease, and pancreatitis: cross-section and 2- year data from Swedish Obese Subjects(SOS) and SOS reference studies. *American Journal of Gastroenterology.* May; 98(5): 1032-41

Ukaji M; Ebara M; Tsuchiya Y; Kato H; Fukuda H; Sugiura N; Saisho H. 2002. Diagnosis of gallstone composition in magnetic resonance imaging: in vitro analysis. *European Journal of Radiology*; 41(1):49-56

Völzke H; Baumeister SE; Alte D; Hoffmann W; Schwahn C; Simon P. 2005. Independent risk factors for gallstone formation in a region with high cholelithiasis prevalence. *Digestion*; 71(2):97-105

Walker A.R., Segal I., Posner R., Shein H., Tsotetsi N.G., Walker A.J. 1989. Prevalence of gallstones in elderly Black women in Soweto, Johannesburg, as assessed by ultrasound. *American Journal of Gastroenterology*. November; 84(11):1383-5

Walcher T., Haenle M.M., Kron M., Hay B., Mason R.A.2005. Pregnancy is not a risk factor for gallstone disease: Results of a randomly selected population sample. World J Gastroenterol 2005 November 21;11(43):6800-6806

Walsh M. 1999. *Watson's Clinical Nursing and related Sciences*. 5th Edition. Bailliere Tindall: London. ISBN 0-7020-2025-7. 998p.

Weller B.F. and Wells R.J. 1992. Bailliere's Nurses' Dictionary. 21st edition. Bailiere Tindall Ltd : London. ISBN 0-7020-1456-7 508p

Whitehouse G.H. and Worthington B.S. 1996. *Techniques in Diagnostic Imaging*. 3rd Edition.Blackwell Science: Austria . ISBN 0-86542-617-1,526p

Wilson J.J.W and Waugh A. 1996., *Anatomy and Physiology in Health and Illness*. 8th Edition. Churchill livingstone: Tokyo ISBN 0443051569 463p.

Wrong diagnosis. 2003. Risk factors for Gallstones.(On line). Available from: *Wrong diagnosis.com.*

Zakko S.F. 2005. Up to Date. *Patient information: Overview of gallstones.* April 2005. Available from:http://www.update.com (Accessed 12 October 2005).

APPENDIX A: -

(*ENGLISH VERSION*)

DURBAN INSTITUTE *of* TECHNOLOGY

PARTICIPANT INFORMATION LETTER

TOPIC FOR RESEARCH: INCIDENCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER, DIET AND BODY MASS INDEX(BMI)

Dear Participant

You are invited to participate in the research project aimed at evaluating the prevalence of gallstones in the Black population using ultrasound as a diagnostic tool. Ultrasound is an imaging tool that uses sound waves to produce images.

It is noted that diseases of the gall bladder which were previously very rare among Blacks, are increasing. this study will look at the common causes inorder to inform people at risk to avoid possible complications that might be life threatening.

The project aims to include a total of 600 subjects from patients referred to the x-ray department for different examinations.

PROCEDURE:
The researcher will verify the clinical history for the interested subjects and will be recorded in the data sheet.
The researcher will perform an ultrasound examination of the tummy paying attention to the gall bladder(liver) using the ultrasound machine in the Ultrasound Unit at Ngwelezane Hospital. The findings obtained will be recorded on record/data sheets and confidentiality will be assured.
The procedure will take approximately fifteen minutes. The results of the ultrasound examination will be made available to you.

RISK/ DISCOMFORT
Participation in the study carries no risk. The technique used does not cause any discomfort.

BENEFITS
The results of the study will benefit people at high risk for gallbladder disease because of their age, the type of food they eat and their gender.

CONFIDENTIALITY
All information obtained from you will be treated confidentially and will be used for research purposes only. Names will be excluded from data analysis and data presentation. Please be aware that you are free to withdraw at any stage of the project.

COST
The study will be done free of charge.

PERSON TO CONTACT FOR PROBLEMS OR QUESTIONS:
Rev. Bheki G. Mhlongo (Master's student at Durban Institute of Technology)
Contact details: Tel no.: 035-9017115/6 (bus.) 035- 7921530 (telefax.) home
Cell no. : 0837540232
E-mail: makhedama@webmail.co.za

Supervisor:
Mrs Loganee Moodley
M-Tech.Radiography(cum laude)
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Appendix A

DURBAN INSTITUTE of TECHNOLOGY

(ZULU TRANSLATION)

INCWADI ECHAZA NGOCWANINGO KOBAMBE IQHAZA

ISIHLOKO SOCWANINGO:

UCWANINGO NGOKWANDA KWAMATSHE ATHOLAKALA ESIGUJINI SENYONGO KU BANTU ABANSUNDU ABAHLALA KU DISTRICT 28 ESIFUNDAZWENI SAKWAZULU-NATALI. KUBHEKWA MAQONDANA NOBUDALA, UBULILI , NOKUDLA OKUDLIWAYO NESISINDO SOMZIMBA.

Ngiyakubingelela wena obambe iqhaza,

Uyenxuswa ngentando yakho ukuthi ubambe iqhaza ocwaningweni lokuthola izinga lokwanda kwesifo samatshe atholakala esigujinii senyongo yomuntu ngokuhlolwa ngamafutha (ultrasound) .
Loluhlobo lokuhlola luveza izibilini zakho ngohlobo lomsindo ohamba ngesivinini esikhulu kangangoba izindlebe zethu azikwazi ukuthi ziwucoshe ebese lukhipha izithombe..
Kuye kwabonakala ukuthi izifo zesigubhu senyongo, nakuba bezingavamile kubantu abaMnyama ngaphambilini, seziya zanda manje. Lolucwaningo luzobheka kakhulu izinto ezijwayelekile ekubeni yimbangela yalezizifo ukuze kuqwashiswe abantu abasengozini yokuba bazithole, ngaleyondlela baphephe ekutheni zidlondlobale ngendlela yokuthi zilimaze impilo.

Ucwaningo lolu luhlose ukuba nesibalo sabantu abangamakhulu ayisithupha kwabeze esithombeni.

INGQUBO
Umcwaningi uyoxoxa nobambe iqhaza ukuthola isiqinisekiso ngomlando wokugula kwakhe ebese ebhala phansi. Umcwaningi uyohlola isisu ngamafutha ikakhulukazi enhla naso esibindini lapho kukhona isigaxa inyongo esebenzisa umshini wokuhlola ngaloluhlobo eNgwelezane esibhedlela. Imiphumela nolwazi oluzotholakala lapha luyobhalwa phansi emabhukwini ocwaningo agcinwe ngokuyimfihlo..
Ukuhlola kuyothatha imizuzu ebalelwa eshumini nanhlanu. Imiphumela yokuhlolwa iyonikezwa wena kanye nodokotela wakho.

UBUNGOZI NOKUHLUKUMEZEKA
Ukubamba iqhaza kulolucwaningo akunangozi. Umcwaningi uyoqiniseka ukuthi ekuhloleni kwakhe ungahlukumezeki nakancane.

APPENDIX A

USIZO
Kuyakholeka ukuthi imiphumela yalolucwaningo iyosiza iziguli ezisengcupheni yokuhlaselwa yilokhukufa kwenyongo ngenxa yeminyaka yabo, uhlobo lokudla abakudlayo kanye nobulili babo.

IMFIHLO
Yonke imininingwane nolwazi olofunyanwa kuwena luzosetshenziselwa ucwaningo kuphela futhi luzogcinwa ngemfihlo enkulu. Amagama ngeke avezwe wkuhlaziyweni kwemiphumela nalapho sekushicilelwa. Uhlale wazi ukuthi ungayeka noma nini uma uthanda.

IZINDLEKO
Ngeke ukhokhiswe mali ngalokhukuxilongwa.

UMUNTU ONGAXHUMANA NAYE MAYELANA NEZINKINGA KANYE NEMIBUZO

REV. BHEKI.G.MHLONGO (Umfundi weziqu ze Master's e Durban Institute of Technology)

IMININGWANA YOKUXHUMANA
Inombolo yocingo: 035-9017115/6 (emsebenzini kusuka ku 0630 kuya ku 11h15)
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Tel: 031-2042922

e-mail : Nalenen@dit.ac.za

APPENDIX B

DURBAN INSTITUTE *of* TECHNOLOGY

INFORMED CONSENT FORM

I ,.....hereby voluntarily
Print name
Give consent to participate in the research entitled:

INCIDENCE OF GALLSTONES IN THE BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER , DIET AND BODY MASS INDEX(BMI).

Conducted by:

Name of Researcher : Rev. Bheki G. Mhlongo (DIT: Radiography)
Name of Supervisor : Mrs Nalene Naidoo (DIT: Radiography)
Name of co- supervisor: Dr W. Lake(Lake, Bortz and Partners, Durban)

PLEASE CIRCLE THE APPROPRIATE ANSWER:

1. Have you read and understood the research information sheet ?	YES/NO
2. Have you had an opportunity to discuss the study?	YES/NO
3. Have you had an opportunity to ask questions regarding this study ?	YES/NO
4. Have you received satisfactory answers to your questions ?	YES/NO
5. Have you received enough information about the study?	YES/NO
6. Do you understand that you are free to withdraw from this study	
(a) at any time and;	
(b) without having to give reason for withdrawing?	YES/NO
7. Do you agree to voluntarily participate in this study?	YES/NO

if you have answered NO to any of the above questions, please obtain the appropriate information before signing

Please print clearly in block letters:

Subject Name:----------signature

Witness Name----------signature Date:----------

APPENDIX B

(Zulu translation)

DURBAN INSTITUTE of TECHNOLOGY

IMVUME YOKUBAMBA IQHAZA OCWANINGENI

Mina.....ngiyavuma
Ngentando yami ukubamba iqhaza ocwaningeni olusihloko esithi:

UCWANINGO NGOKWANDA KWAMATSHE ATHOLAKALA ESIGAXENI SENYONGO KUBANTU ABANSUNDU ABAHLALA KU DISTRICT 28, KUBHEKWA MAQONDANA NOBUDALA, UBULILI , UHLOBO LOKUDLA UMUNTU AKUDLAYO, KANYE NESISINDO SOMUNTU
Oluhlolwa ngu:

Igama lomcwaningi: Rev Bheki G. Mhlongo(DIT: Radiography)
Igama lombheki wocwaningo: Mrs Nalene Naidoo (DIT: Radiography)
Igama lomsekeli wombheki wocwaningo : Dr W, Lake(Lake, Bortz and Partners

UYANXUSWA UKUBA WENZE INDILINGA EMPENDULWENI EFANELEYO

1.Ulifundile waliqonda yini iphepha elinikeza l imiininingwane ngalolucwaningo? YEBO/CHA
2. Ulitholile yini ithuba lokuxoxa nomcwaningi ngocwaningo na ? YEBO/CHA
3.Ingabe ulitholile yini ihtuba lokubuza imibuzo mayelana nalolucwaningo na? YEBO/CHA
4.Wanelisekile yini ngezimpendulo oziholile emibuzweni obunayo mayelana nalolucwaningo? YEBO/CHA
5.Uthole imininingwane eyanele yini ngalolucwaningo? YEBO/CHA
6.Uyaqonda yini ukuthi ukhululekile ukuyeka ukubamba iqhaza kulolucwaningo:
a. noma nini YEBO/CHA
ngaphandle kokunikeza ngentando yakho ukubamba iqhaza kulolucwaningo na? YEBO/CHA

Uma uphendule wathi CHA kunoma yimuphi umbuzo kulemibuzo engenhla uyanxuswa ukuthi uthole imininingwane efaneleyo NGAPHAMBI kokuba usayine.
Bhala ngokucacile ngamagama amakhulu-

Igama lobambe iqhaza ocwaningeni.....
Igama likafakazi.....
Usuku:.....

APPENDIX C

DURBAN INSTITUTE *of* TECHNOLOGY

DATA SHEET

NAME OF PARTICIPANT: .....
DATE:.....
AGE: .....

GENDER: MALE / FEMALE
WEIGHT:.....**HEIGHT**.....**BMI:**.....

1. **HISTORY**

	YES	NO	UNCERTAIN	COMMENT
EPIGASTRIC PAIN				
RIGHT UPPER QUADRANT PAIN				
PAIN ELSEWHERE IN ABDOMEN				
NO PAIN				
LOCALISED PAIN				
PAIN RADIATES TO THE BACK				
PAIN RADIATES TO THE SHOULDER				
BILIARY COLIC				
FOOD INTOLERANCE				
FAT INTOLERANCE				
INDIGESTION AND BLOATING				
HISTORY OF FEVER				

Appendix C

2. DIET

	YES	NO	UNCERTAIN	COMMENT
ARE YOU A VEGETARIAN ?				
DO YOU EAT MEAT ?				
DO YOU EAT FOOD RICH IN SUGARS				

3. MEDICAL AND SOCIAL HISTORY

	YES	NO	UNCERTAIN	COMMENT
HAVE YOU BEEN DIAGNOSED AS HAVING GALL STONES BEFORE ?				
IS THERE ANYBODY IN THE FAMILY WITH HISTORY OF GALLSTONES				

4. ULTRASOUND FINDINGS

	YES	NO
ONE OR MORE ECHOGENIC STRUCTURES IN THE GALL BLADDER LUMEN WITH DISTAL SHADOW		
STRONGLY ECHOGENIC STRUCTURE IN THE REGION OF GALL BLADDER WITH DISTAL SHADOWING (GALL BLADDER NOT VISUALIZED)		
ONE OR MORE ECHOGENIC STRUCTURES WITH OR WITHOUT DISTAL SHADOW IN THE BILIARY TREE		
PRESENCE OF SLUDGE WITHIN GALL BLADDER LUMEN		
NO VISUALIZED GALL BLADDER LUMEN IN PATIENT WITH OPERATIVE SCAR IN RIGHT UPPER QUADRANT(RUQ)		

APPENDIX D(i)

DURBAN INSTITUTE *of* TECHNOLOGY

BOX 10331
EMPANGENI
3880
19/02/04

Secretary General of Health
Professor R.W. Green Thompson
Department of Health
Natalia

Dear Professor Green Thompson

RE: Request to perform research in the Radiology Department

I am currently a Master's student at the Durban Institute of Technology. I am keen to conduct a research project towards an
M-Tech in Radiography.
The proposed title of my dissertation is : **INCIDENCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER ,DIET AND BODY MASS INDEX (BMI).**
The aim of this study is to investigate the prevalence of gall stones using diagnostic ultrasound in a Black population of District 28 in terms of gender, age, diet and BMI in order to identify high risk factors.
The study is limited to the Black population of District 28 In KZN, because although literature reports very low incidence among Blacks, a gradual increase has been observed in this district.
I hereby seek permission to undertake this research using the mid- range ALOKA5000 an LOGIC 400 PRO series(ultrasound equipment) located at Ngwelezane Hospital. The study will be done during working hours, which will then increase the daily load in ultrasound. The researcher will ensure a reasonable stay (time) in the ultrasound suite. Clinical information and surgery findings will be obtained from patient's file and confidentiality will be ensured.
The subjects for study will be 600 patients who will respond positively to the advert which will placed in the reception area and walls at the x-ray department

My proposal has been reviewed by the Department of Radiography and approved by the Research Committee of the Faculty of Health Sciences at the Durban Institute of Technology. Appropriate ethical approval has been obtained. Experts in the field will supervise the project internally and externally.

The results of this study help the department of surgery in determining the incidence of gallstones in the Black population and determine the high risk factors and help prevent complications from occurring.

Your support and permission (in writing) to perform this study at Ngwelezane Hospital will be greatly appreciated

Yours sincerely
B.G. Mhlongo (Rev.)

Student number: 8522758
Nat.Dip. Rad (D), B-Tech: Rad.(u/s)
Box 10331 ,Empangeni , 3880
Tel.: 035-9017115 (w) 035-7921530 (h)
Cell.: 0837540232 e-mail: makhedama@webmail.co.za

Mrs Loganee Moodley(Supervisor)
M-Tech. Radiography(cum laude)
Tel 031-3039567 (h)
e-mail: loganeem@dit.ac.za

Mrs Nalene Naidoo(co- supervisor)
B. Tech. Radiography
Tel: (031) 2042922
e-mail: Nalenen@dit.ac.za

Appendix D(1)

PROVINCE OF KWAZULU-NATAL
HEALTH SERVICES

ISIFUNDAZWE SAKWAZULU-NATALI
EZEMPILO

PROVINSIE KWAZULU-NATAL
GESONDHEIDSDIENSTE

PRIVATE BAG X 9051
PIETERMARITZBURG
3200

TELEPHONE (033) 395-2785

330 LONGMARKET STREET
PIETERMARITZBURG
3201

ENQUIRIES: Mr G.J. Tromp
EXTENSION: 2761
REFERENCE: 9/2/3/R

Rev. B.G. Mhlongo
Department of Radiography
PO. BOX 10331
EMPANGENI
3880

Dear Reverend

REQUEST TO CONDUCT RESEARCH ON PREVELANCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER, DIET AND BODY MASS INDEX, AT NGWELEZANE HOSPITAL.

Your letter dated 19 February 2004 refers.

Please be advised that authority is granted for you to conduct a research regarding prevelance of gallstones in black population of district 28, provided that:

(a) Prior approval is obtained from the Heads of the relevant institutions;

(b) Confidentiality is maintained

(c) The Department is acknowledged;

(d) The Department receives a copy of the report on completion; and

(e) The staff of the hospital are not disturbed and/or inconvenienced in their work and that patient care is not compromised.

Yours sincerely

SUPERINTENDENT-GENERAL
HEAD: DEPARTMENT OF HEALTH
NPB/rev mhlongo research

APPENDIX D (ii)

DURBAN
INSTITUTE *of*
TECHNOLOGY

BOX 10331
EMPANGENI
3880
19/02/04

The Hospital Manager
Dr P. Haselau
Ngwelezane Hospital
P/Bag X20021
Empangeni

Dear Dr. Haselau

RE: Request to perform research in the Radiology Department

I am currently a Master's student at the Durban Institute of Technology. I am keen to conduct a research project towards an
M-Tech in Radiography.
The proposed title of my dissertation is : **INCIDENCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER ,DIET AND BODY MASS INDEX (BMI).**
The aim of this study is to investigate the prevalence of gall stones using diagnostic ultrasound in a Black population of District 28 in terms of gender, age, diet and BMI in order to identify high risk factors.
The study is limited to the Black population of District 28, because although literature reports very low incidence among Blacks, a gradual increase has been observed in this district.
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The results of this study help the department of surgery in determining the incidence of gallstones in the Black population and determine the high risk factors and help prevent complications from occurring.

Your support and permission (in writing) to perform this study at Ngwelezane Hospital will be greatly appreciated

Yours sincerely
B.G. Mhlongo (Rev.)

Student number: 8522758
Nat.Dip. Rad (D), B-Tech: Rad.(u/s)
Box 10331 ,Empangeni , 3880
Tel.: 035-9017115 (w) 035-7921530 (h)
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Mrs Loganee Moodley(Supervisor)
M-Tech. Radiography(cum laude)
Tel 031-3039567 (h)
e-mail: loganeem@dit.ac.za

Mrs Nalene Naidoo(co- supervisor)
B.Tech. Radiography
Tel: (031) 2042922
e-mail: Nalenen@dit.ac.za

APPENDIX D(i)

NGWELEZANA HOSPITAL

RECOMMENDATION AND APPROVAL TO CARRY OUT RESEARCH

1. Persona s of Researcher

Name: . ..... Persal No.: 60482087

ID. NO.:

Address:

Employer: DEPT. OF HEALTH: NGWELEZANA HOSPITAL

2. Recommendation by Study Leader / Research Committee Leader

I undertake to ensure that a copy of research project will be supplied to Head of Institution.

COMMENTS: .....

See attached

.....

Signed: ..... **Date:** ..... **Name:** .....

3. Recommendation by Nursing Management (Institutional)

COMMENTS: Supported / Not Supported

Signed: ..... **Date:** ..... **Name:** .....

4. **PROJECT APPROVED / ~~NOT APPROVED~~**

SIGNED: ..... DATE: 14/11/03

SENIOR MEDICAL SUPERINTENDENT

APPENDIX D (iii)

DURBAN INSTITUTE of TECHNOLOGY

BOX 10331
EMPANGENI
3880
19/02/04

Diagnostic Imaging Services : Manager
Mr A.D. Zulu
Ngwelezane Hospital
P/bag X20021
Empangeni

Dear Mr Zulu

RE: Request to perform research in the Radiology Department

I am currently a Master's student at the Durban Institute of Technology. I am keen to conduct a research project towards an M-Tech in Radiography.
The proposed title of my dissertation is : **INCIDENCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER ,DIET AND BODY MASS INDEX (BMI).**
The aim of this study is to investigate the prevalence of gall stones using diagnostic ultrasound in a Black population of District 28 in terms of gender, age, diet and BMI in order to identify high risk factors.
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Clinical information and surgery findings will be obtained from patient's file and confidentiality will be ensured.

The subjects for study will be 600 patients who will respond positively to the advert which will placed in the reception area and walls at the x-ray department

The results of this study help the department of surgery in determining the incidence of gallstones in the Black population and determine the high risk factors and also help prevent complications from occurring.

Your support and permission (in writing) to perform this study at Ngwelezane Hospital will be greatly appreciated

Yours sincerely
B.G. Mhlongo (Rev.)

Student number: 8522758
Nat.Dip. Rad (D), B-Tech: Rad.(u/s)
Box 10331 ,Empangeni , 3880
Tel.: 035-9017115 (w) 035-7921530 (h)
Cell.: 0837540232 e-mail: makhedama@webmail.co.za

Mrs Loganee Moodley(Supervisor)
M-Tech. Radiography(cum laude)
Tel 031-3039567 (h)
e-mail: loganeem@dit.ac.za

Mrs Nalene Naidoo(co- supervisor)
B.Tech. Radiography
Tel: (031) 2042922
e-mail: Nalenen@dit.ac.za

APPENDIX D(iii) FOR QUESTIONNAIRE MEMBER 03/06/04

PROVINCE OF KWAZULU-NATAL
HEALTH SERVICES

ISIFUNDAZWE SAKWAZULU- NATALI
EZEMPILO

PROVINSIE KWAZULU NATAL
GESONDHEIDSDIENSTE

DIAGNOSTIC IMAGING SERVICES
NGWELEZANA HOSPITAL
P/BAG X20021
EMPANGENI 3880

TELEPHONE: 035 9017115
FACSIMILE: 035 7941684
E-MAIL: ZULUAD@DOHNGW.KZNTL.GOV.ZA
A.D.ZULU

COMMITMENT TO CARING

DATE: 31st May 2004

Mr. B.G. Mhlongo
Chief Ultrasonographer
Ngwelezana Hospital

Dear Sir,

RE: REQUEST TO PERFORM RESEARCH WORK

1. Your letter, hand-delivered to me on 31/05/2004, dated 19/05/2004 refers.

2. As head of the unit, I have no qualms with this venture taking place in this division. I would like to assure you that we will give you all the cooperation you need for it to succeed, because in the end our people, who are our Patients, will benefit.

3. I also wish you luck, Bheki.

.....
A.D.ZULU
ASSISTANT MANAGER
DIAGNOSTIC IMAGING SERVICES

APPENDIX E
Advert(English translation)

DURBAN
INSTITUTE *of*
TECHNOLOGY

TO: THE COMMUNITY OF DISTRICT 28 IN KWAZULU NATAL
i.e. EMPANGENI., RICHARDS BAY,MTUBATUBA AND
THE SURROUNDING ARES

IF YOU ARE:

1. BLACK
2. 18 YEARS AND ABOVE AND
   - HAVE NOT EATEN FOR AT LEAST 6 HOURS

YOU ARE INVITED TO PARTAKE IN THE RESEARCH PROJECT TITLED:
"PREVALENCE OF GALLSTONES IN THE BLACK POPULATION USING ULTRASOUND AS DIAGNOSTIC TOOL"

COME TO THE ULTRASOUND ROOM FOR A

FREE EXAMINATION

OF YOUR GALL BLADDER(LIVER)

For enquiries please contact:
Rev. Bheki G. Mhlongo
Ultrasound suite, Ngwelezane Hospital
Phone : ext.7115/6 or 9017115/6 or 0837540232

E.

Zulu translation

DURBAN INSTITUTE of TECHNOLOGY

KININA: ENINGUMPHAKATHI WAKU DISTRICT 28 LAPHA KWAZULU NATALI i.e. EMPANGENI, RICHARDSBAY, MTUBATUBA NAMAPHETHELO

UMA

1. UNGUMUNTU ONSUNDU
2. UNEMINYAKA ENGU 18 KUYA PHEZULU FUTHI UNGAKAZE UDLE OKUNGENANI AMAHORA AYISITHUPHA

UYAMENYWA UKUBA UBAMBE IQHAZA OCWANINGWENI OLUNALESIHLOKWANA:
"UKWANDA KOKUFA KWAMATSHE ATHOLAKALA ESIGUJINI SENYONGO KUBANTU ABANSUNDU KUHLOLWA NGAMAFUTHA"

WOZA EMAFUTHENI UZOHLOLWA ISIGUBHU SENYONGO YAKHO

MAHHALA ! ! !

Uma unemibuzo thintana no:
Rev. Bheki G. Mhlongo
Emafutheni, Ngwelezane Hospital
Phone : ext.7115/6 or 9017115/6 or 0837540232APPENDIX F

APPENDIX F.

DURBAN INSTITUTE of TECHNOLOGY

Faculty of Health Sciences
Tel: 204 2701
Fax: 204 2407

RESEARCH ETHICS COMMITTEE

Student: **Rev B G Mhlongo**
Student No.: **8522758**

Research Title: **PREVALENCE OF GALLSTONES IN BLACK POPULATION OF DISTRICT 28 IN RELATION TO AGE, GENDER, DIET AND BODY MASS INDEX.**

A. The proposal meets the professional code of ethics of the Researcher

☑ Yes ☐ No

B. The proposal also meets the following ethical requirements

	YES	NO
❖ Provision has been made to obtain informed consent of the participants	✓	
❖ Potential psychological and physical risks have been considered and minimised	✓	
❖ Provision has been made to avoid undue intrusion with regard to participants and community	✓	
❖ Rights of participants will be safe-guarded in relation to:	✓	
- Measures for the protection of anonymity and the maintenance of Confidentiality.	✓	
- Access to research information and findings.	✓	
- Termination of involvement without compromise	✓	
- Misleading promises regarding benefits of the research	✓	

Signature of Student ---------- Date 28/05/04

Signature of Supervisor ---------- Date 28/05/04

Signature of Head of Department ---------- Date 28/05/04

Signature of Chairperson of the Faculty
Of Health Sciences Research Committee -- Date 28/05/2004

APPENDIX G

DIET HISTORY – 24 HR RECALL

NAME:..............................

AGE:......... SEX:.............

WEIGHT(kg) in light clothing:........... HEIGHT(m) without shoes:..........

BUILD(small, medium, large):.......... WEIGHT REDUCING DIET(Y/N):......

ACTIVITY AT WORK(sedentary/active/ very active)....................

MATERNAL STATE(pregnant or not/ pregnant stage).................

FOOD ITEM	QUANTITY
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APPENDIX G

DIET HISTORY CHECK LIST

MILK EXCHANGES
(UBISI)

How much per day_____
(Kangakanini)

As such ((Lu) Lodwa) _____

Skim milk, low fat _____
(Ubisi oluyizaqheqhe/olunamafutha)

Coffee creamer _____
(Cremora/Ellis Brown)

Yoghurt/Maas, how much
(Iyogathi/amasi, kangakanani)

type/uhlobo _____

red/brown, (Bomvu/insundu)

Custard (Ukhasitede "Ucustard")_____

Tea/Coffee, how much _____
(Itiye/ikhofi)

Milo/cocoa, (Milo/Ukhokho)_____

FAT EXCHANGES (AMAFUTHA)

Oil_____

Butter/Margarine _____
(Ibotheli/imajalini)

Ghee _____

Salad dressing _____
(Okukunogisa isaladi)

Hoisum_____

Nuts, peanuts (Inati, amakinati) _____

Fried foods (Ukuthosa ukudla) _____

Cream (Ulazi) _____

Gravy (Igravi) _____

FRUIT EXCHANGE
(IZITHELO)

Fruit, how many _____
Iziothelo, kangakanani)

Fruit juice, type (Amajuice) _____

Dried fruit (Isithelo ezonyisiwe) _____

Tinned fruit _____
(Izithelo esemathinini)

VEGETABLE EXCHANGES
(IMIFINO)

Vegetables (IMIFINO) _____

Salads (Isaladi) _____

Tomato and onion sauce_____

STARCH EXCHANGES
(ISITASHI)

Breakfast cereal-_____All
bran, Rice Krispies, Weet Bix

Porridge (Iphalisi) _____

Putu (Phutu) _____

Bread, White/brown/wholewheat_____
(Insinkwa, mholphe/nsundu)

Toast (Itosti)_____

Sandwiches (Isendiwishi)_____

Potatoes (Izambane) _____

Crisps_____

Rice (Irayisi) _____

Mealie rice _____
(Isi helerayisi)

Samp (Isitambu)_____

Pasta (Umakaroni, Isipagethi)_____

Crackers _____Provitas,
Cream Crackers

Rusks (Umqathane)_____

Soup, type (Isobho) _____

MEAT EXCHANGES
(INYAMA)

Meat, biltong _____
(Inyama, Umqwayiba)

Fish, pilchards (Ufishi) _____

Poultry (Inkukhu)_____

Bacon (Ubhekheni) _____

Eggs, how often / wk _____
(Amaqanda, kangakanani/sonto)

Preparation

MEAT EXCHANGES (cont .....)

Cheese, how often (ushizi kangakanani)

Type (Uhlobo) _____

Cottage cheese _____(Mhlophe
shizi)

Dried legumes, baked beans_____
(Ubontshisi owomile ne osemathini)

Soya (Isoya)_____

Peanut butter_____
(Ibhotela lamakinati)

SWEET THINGS
(NOSHUKELA)

Sugar (Ushukela) _____

Syrup (Isiraphu) _____

Jam, Marmalade (Ujamu) _____

Honey (Izinyosi) _____

Sweets, chocolates_____
(Uswidi, ushokoledi)

Dessert, type_____
(Uphuthini, ujelo)

Cake (Ikhekhe)_____

Biscuits (Ibhisikidi) _____

Synthetic sweeteners, type _____
(Ushukela owensiwe, nge sweetex)

DRINKS
(IZIPHUZO)

Cold Drink (Unemenayidi)_____

Alcohol, type (Ugologo)_____

MISCELLANEOUS

Diabetic products _____
Fast foods _____

Vinegar (Uvinika) _____

Supplements _____
Spreads (Bovril, Fish paste,)_____

Bran _____

CONDIMENTS
Salt & Pepper (Usawoti & Upelepele)_____
Spices & Herbs (Isipayisi, isithombo)____

GENERAL

Over week-ends _____