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Radiation doses for barium meals and barium enemas in the Western Cape South Africa

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RADIATION DOSES FOR BARIUM MEALS AND BARIUM ENEMAS IN THE WESTERN CAPE SOUTH AFRICA

by

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DECLARATION

I, Caroline Nabasenja, declare that the contents of this thesis represent my own unaided work, and that the thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

Signed **Date**

ABSTRACT

Since their discovery in 1895, the use of x-rays is continuously evolving in medicine making the diagnosis of injuries and diseases more practicable. It is therefore not surprising that x-rays contribute 90% of the radiation dose to the population from man-made sources (DWP, 1992). Moreover, these radiation doses are associated with both fatal and non-fatal cancer risk that is detrimental to adults between 20 to 60 years (Wall, 1996). Radiation dose to individuals therefore needs to be actively monitored in order to minimise such risk. Barium contrast examinations were characterised as one of the radiological examinations that contributed enormously to the collective dose to the patients in the radiology department (DWP, 1992). Determining the diagnostic reference levels of such examinations would reduce the over-exposure of individuals to ionising radiation. Currently in South Africa (SA), there are no diagnostic dose reference levels for barium meal (BaM) and barium enema (BaE) examinations. This study therefore investigated the radiation doses delivered to patients referred for BaM and BaE, obtained potential regional reference doses for these examinations, compared the radiation doses obtained with those from similar dosimetry studies and investigated sources of dose variation among the study sites.

A total of 25 BaM and 30 BaE patients in the age range 18 to 85 years, weighing 50 kg to 90 kg, at 3 hospitals in the Western Cape, SA were investigated. The radiation dose to the patients was measured using Dose Area Product (DAP) meters that were permanently fitted onto fixed fluoroscopy units at these 3 hospitals. The third quartile DAP values were 20.1 $Gycm^2$ and 36.5 $Gycm^2$ for BaM and BaE respectively. The median DAP values were 13.6 $Gycm^2$ and 27.8 $Gycm^2$ for BaM and BaE respectively. The median values were recommended as the potential Diagnostic Reference Levels for BaM and BaE as they are less affected by outlying values of under or over- weight

(Yakoumakis, Tsalafoutas, Sandilos, Koulentianos et al, 1999). The weights of the patients, fluoroscopy time, the number of images obtained, the use of digital or conventional fluoroscopy equipment and the level of training of the radiologists were the factors considered for dose variation among the 3 hospitals.

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If I have seen any further, it is by standing on the shoulders of giants (Isaac Newton)

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DEDICATION

I dedicate this to my entire family for if it was not for your prayers and support, this would have been a more challenging road to travel. And to kkojja Sam Kafeero who passed away when I was away pursuing my dreams, I know you would have been proud of me. Will always miss and love you.

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CHAPTER 1 INTRODUCTION

The exposure of individuals to ionising radiation in diagnostic radiology is based on a risk to benefit ratio; with the benefit of diagnosing the disease condition preceding clinical management. The radiation dose received by the patient needs to be monitored and quantified to avoid over-exposure of the patient to this ionising radiation. Such over-exposure results in the risk of the ionising radiation superseding the intended benefit (Trapp & Kron, 2008:12). Internationally, diagnostic reference levels (DRLs) have been developed to act as points of reference when exposing a patient to ionising radiation during diagnostic radiology examinations (Hart, Hillier & Wall, 2007).

Despite the contribution of barium contrast examinations to the collective dose to humans from radiological examinations (DWP[1], 1992), there are no DRLs for barium meal (BaM) and barium enema (BaE) examinations in South Africa (SA). This research project therefore investigated the radiation doses received by patients referred for BaM and BaE in the Western Cape, SA and recommended potential regional DRLs these examinations. When adopted, the DRLs would act as points of reference for these examinations in the radiology departments.

In this chapter, the background of the research project, the radiological examination options of the gastrointestinal tract and frequency of BaM and BaE are discussed. These are followed by a presentation of the research problem, the rationale and significance of the study. An overview of the methodology used and the delimitations of the study are highlighted and the chapter concludes with an introduction to the thesis.

1.1 Background

Since their discovery in 1895, the use of x-rays has continuously evolved in medicine making the diagnosis of injuries and diseases more practicable. It is therefore not surprising that x-rays contribute 90% of the radiation dose to the population from man-made sources (DWP, 1992). Moreover, these radiation doses are associated with both

[1] Dosimetry Working Party

fatal and non-fatal cancer risks that are detrimental to adults between 20 to 60 years (Wall, 1996) thereby necessitating radiation protection measures.

In attempts to maximise the benefits of x-rays, requirements to deliver the lowest possible radiation dose consistent with the clinical purpose of the examination are legally formalised internationally. In SA, there is legislation addressing this in the Health Act (South Africa Public Health Act, 1973). In the United Kingdom (UK), dose reference levels were adopted (RCR[2] & NRPB[3], 1990) to act as dose audits for quality control in radiology departments. In 1992, a Dosimetry Working Party devised national protocols that provided practical guidance for radiology departments in the use of these reference doses. In these protocols, it was emphasised that departments must focus on dose levels for examinations that are most frequently performed and that contribute enormously to the collective dose and therefore radiation risk (DWP, 1992).

1.2 Radiological examination of the gastrointestinal tract

Radiological examination of the gastrointestinal tract (GIT) utilising ionising radiation involves the exposure of sensitive organs of the body such as the thyroid, breasts and the reproductive organs to this radiation. Initially, barium contrast examinations were the basic routine radiological examinations of the GIT but the advancement of newer radiological imaging techniques and equipment such as Computed Tomography (CT), Virtual colonography, Magnetic Resonance Imaging (MRI), Endoscopy and Ultrasound have since decreased the frequency of BaM and BaE performance. Nonetheless, barium contrast examinations contribute enormously to the collective dose to the population from radiological examinations (Hart & Wall, 2004; Kaul, Bauer, Bernhardt, Nosske & Veit, 1997) thereby necessitating the investigation of radiation doses associated with them.

1.2.1 Barium meal examinations

The BaM is the basic routine radiological examination of the stomach and duodenum involving the ingestion of barium sulphate contrast medium that coats the stomach and aids and its radiological examination. The BaM is indicated in gastric and duodenal

[2] Royal College of Radiologists
[3] National Radiological Protection Board

displacements, structural abnormalities such as diverticulae, peptic ulceration and gastric cancers (Simpkins, 1993: 789-829). Gelfand (1988) found BaM to have a specificity of more than 90% and a sensitivity of 80-100% for ulcers more than 5mm in diameter.

1.2.2 Barium enema examinations

The barium enema is the routine radiological examination of the colon where barium sulphate contrast medium is administered through the rectum and aids in radiological examination of the colon. This examination is indicated in congenital lesions, inflammatory lesions such as colitis, ulcerative colitis, Crohn's disease and ischemic colitis, diverticular disease of the colon and tumours of the colon such as polypoid lesions (Thomas, 1993: 857-880).

1.2.3 Colonoscopy

Colonoscopy is an endoscopic examination of the large colon and distal part of the small bowel with a fibre optic camera attached to a flexible tube passed through the anal opening. Colonoscopy is indicated for polyps and in situations of uncertainty of the radiological finding such as a normal BaE in a patient with rectal bleeding of unknown origin (Thomas, 1993: 857-880). The high sensitivity of colonoscopy for detection of colon polyps has resulted in its being recommended as a first line investigation for the colon in some radiology departments. The use of colonoscopy is however limited by the difficulty of the endoscope reaching the right colon that is predominately affected by colon cancers (Rockey, Paulson, Niedzwiecki, Davis et al, 2005; Debatin & Patak, 1999). Thirteen percent of the patients referred for BaE in this study had incomplete colonoscopies.

1.2.4 Computed Tomography

Computed Tomography facilitates the viewing of cross-sectional images of the GIT. With such capabilities, CT diagnoses, differentiates and stages GIT tumours as well as gastric inflammatory conditions such as gastritis and peptic ulcer disease (Karen, Horton, Elliot & Fishman, 2003). However, BaE remain unsurpassed for mucosal definition (Bartam & Taylor, 2008: 680).

1.2.5 Virtual colonography

Virtual colonography uses a graphics-based software system to produce images similar to those obtained with a real endoscope. Contrary to the endoscope, a three dimensional (3D) image reconstructed from CT provides a virtual environment from which to obtain endoluminal views of the tubular structures such as the colon (Seeram, 2009: 363-375). Virtual colonoscopy is a non-invasive radiological examination well suited for patients contraindicated for invasive procedures. It is also sensitive in diagnosing abnormalities of the stomach and colon such as colon cancer (Caroline & Kendzierski, 2008: 648).

1.2.6 Magnetic Resonance Imaging

MRI uses non-ionising radiation. It provides good soft tissue contrast, and has short imaging time, results in less patient discomfort with absence of harmful side effects. MRI colonography coupled with MRI virtual colonoscopy are employed in the detection of polyps, examination of the GIT lumen and evaluation of patients with diverticular and inflammatory bowel disease (Debatin & Patak, 1999).

1.2.7 Positron Emission Tomography

PET is a functional imaging technique that is used to assess tissue activity. PET utilises Fluoro-2-deoxy-glucose as a marker to assess tumour activity such as gastric cancer (Caroline & Kendzierski, 2008: 649).

1.2.8 Abdominal Ultrasound

Ultrasound imaging uses high frequency sound waves to produce images of the GIT. Abdominal ultrasound allows the measurement of bowel wall thickness and Doppler flow assessment while endoscopic ultrasound evaluates the depth of gastric wall invasion by disease (Bartam & Taylor, 2008: 682).

1.3 Frequency of barium meal and barium enema examinations

The advancements in other imaging modalities such as CT, virtual colonography, MRI, colonoscopy and ultrasound with capabilities of tumour staging and high sensitivities for polyps and colon cancers are continually affecting the frequency of performance of BaM and BaE (Caroline & Kendzierski, 2008: 627-649; Bartam & Taylor, 2008: 679-705).

The decreased frequency of BaM and BaE in the Western Cape, SA was predominantly in the private sector where newer and more advanced imaging equipment such as Multi-detector CT and Colonoscopy are employed. Even in the public sector, patients were referred for BaE after failed or incomplete colonoscopy. This demonstrated that other imaging modalities are employed in the radiological examination of the GIT but BaM and BaE continue to have a role in imaging of this area. Despite their decreased frequency, BaE remain one of the largest contributors to the collective dose from radiological examinations (Hart & Wall, 2004) thereby necessitating dosimetry studies for barium contrast examinations.

1.4 Radiation doses in South Africa

In SA, protection of radiation workers and the public from unnecessary radiation exposure is continually emphasised (South Africa Public Health Act, 1973). Currently, it is a legal requirement for all fixed fluoroscopy equipment to have permanently fitted Dose Area Product (DAP) meters thereby allowing real time monitoring of patient's radiation dose during fluoroscopy examinations (DoH[4] SA, 2006). Engel-Hills (1997) investigated radiation doses to patients referred for BaE in the Western Cape, SA using a DAP meter and obtained dose levels more than twice as high as the UK values (Hart, Hillier, Wall, Shrimpton & Bungay, 1996). However, the tendency to record lower doses in subsequent dosimetry studies owing to improved radiation protection activities in radiology departments (DWP, 1992; Hart et al, 1996; Warren-Forward, Haddaway, Temperton & McCall, 1998) was observed in this study.

1.5 Rationale for the research project

Barium contrast examinations are categorised as one of the largest contributors to the collective dose from radiological examinations (Hart & Wall, 2004) yet DRLs[5] do not exist for these examinations in SA. Hence this study investigated the radiation doses received by patients referred for BaM and BaE and developed potential regional DRLs for these examinations in the Western Cape, SA. Despite the recommendations for

[4] Department of Health
[5] Diagnostic Reference Levels

subsequent dosimetry studies and country or region specific DRLs (ICRP[6], 1996; Wall, 2001), only one study (Engel-Hills, 1997) investigated radiation doses for barium contrast examinations in SA over a decade ago and this study focussed on BaE alone.

1.6 Statement of the problem

The absence of national DRLs for BaM and BaE in SA and the enormous contribution to collective dose to patients referred for these examinations; this study investigated the radiation doses received by patients referred for BaM and BaE by:

Sub-problem 1

Measuring the radiation dose for BaM and BaE using DAP meter that were permanently fixed to the fluoroscopy units

Sub-problem 2

Comparing the radiation doses obtained in this study with those from similar studies

Sub-problem 3

Determining the factors responsible for DAP variations among the study sites.

1.7 Significance of the study

The investigation of radiation doses received by patients referred for BaM and BaE in this study recommended regional DRLs for BaM and BaE and explained the factors responsible for the dose variations among the radiology departments and patients. When the DRLs recorded in this study are adopted by radiology departments as dose audits and measures of quality assurance, equipment and departments recording high radiation doses will be identified and corrective action undertaken.

1.8 Overview of the methodology

The radiation doses of patients referred for BaM and BaE to 3 hospitals in the Western Cape, SA were measured using DAP[7] meters that were permanently fitted onto the fluoroscopy equipment. Both male and female patients aged between 18 years and 85 years weighing 50 kg to 90 kg were included in the study. The patients' weights were measured using a digital bathroom scale. The age, gender, weight, indication for the

[6] International Commission on Radiological Protection
[7] Dose Area Product

study, exposure factors for the images acquired, number of images, fluoroscopy time and DAP value were recorded for each patient. These data were analysed and DRLs were obtained for BaM and BaE, these dose levels were compared with those from similar studies and causes of dose variation among the study sites were determined.

1.9 Delimitations of the study

The delimitations of the research project were that;

- Only public hospitals in the Western Cape, SA with DAP meters permanently fitted to their fluoroscopy equipment were included. These hospitals also performed a number of BaM and BaE that allowed sufficient data to be collected within the research time frame.
- The patient participants were aged between 18 years and 85 years weighing 50 kg to 90 kg. The age limit allowed for recruitment of adult patients. The weight restriction ensured that the mean weight of the sample lay 5 kg from 70 kg, the assumed average weight of an adult. As such the reference doses for an average adult were be obtained (DWP, 1992).

1.10 Introduction to the thesis structure

In order to understand the radiation doses delivered to patients referred for BaM and BaE in the Western Cape, SA; the next chapters of this work are going to discuss the concepts of ionising radiation as outlined below.

Chapter 2 Radiation protection

Under radiation protection, the biological effects of radiation, the radiation dose relationship that induces these effects and the techniques and equipment that reduce over exposure of individuals to ionising radiation; particularly for fluoroscopy equipment with emphasis on BaM and BaE are discussed.

Chapter 3 Radiation dosimetry

In this chapter, the dose quantities such as absorbed dose and dose equivalent, how the absorbed dose to tissue is measured, the equipment used in the measurement of absorbed dose with emphasis on the Dose Area Product meter are discussed.

Chapter 4 Dose limits

This chapter presents the principle of dose limits, the legislation surrounding these dose limits, recommended DRLs for BaM and BaE from other dosimetry studies and the causes of variation of these DRLs.

Chapter 5 Research methodology

The chapter systematically describes the data collection process and method followed when measuring radiation doses for BaM and BaE with the aim of identifying potential DRLs.

Chapter 6 Research findings

In this chapter, the Dose Area Product (DAP) values for BaM and BaE and the variations in these values are reported.

Chapter 7 Discussion

This chapter discusses the research findings giving reasons for DAP variations and compares the dose levels for this study with those from other dosimetry studies

Chapter 8 Conclusion

In the chapter, the conclusions are drawn and limitations and recommendations presented.

CHAPTER 2 RADIATION PROTECTION

When ionising radiation interacts with the body tissues, it excites the atoms in the tissues in a process known as ionisation. In order to minimise and avoid unnecessary over-exposure of patients and even radiology department personnel to ionising radiation, several techniques and devices are employed. In this chapter, the biological effects of ionising radiation and the techniques and devices for radiation protection are discussed.

2.1 Biological effects of radiation

The nature and severity of the symptoms of exposure to ionising radiation and the time at which they appear depend on the amount of radiation absorbed and the rate at which it is delivered to the tissue. These biological effects of radiation are classified as: deterministic, stochastic, somatic and hereditary (Trapp & Kron, 2008: 48-52).

2.1.1 Deterministic effects

Deterministic effects of ionising radiation occur above a certain threshold radiation dose value. Above this threshold value, the severity of the radiation injury increases with the dose and can occur within a few hours, or less if the individual is exposed to high doses of radiation. Examples of deterministic effects include direct tissue damage such as erythema, radiation sickness characterised by nausea and vomiting and gastrointestinal syndrome (Trapp & Kron, 2008: 48-50).

2.1.2 Stochastic effects

Contrary to deterministic effects, stochastic effects occur at all dose levels with no threshold dose. The probability of occurrence of stochastic effects increases with increasing dose to an individual. Additionally, the severity of stochastic effects is independent of the dose that induced the effect. An example of a stochastic effect is cancer that is equally harmful whether caused by a low or high dose value. Stochastic effects include all late-expressing health effects of radiation like hereditary effects but exclude late tissue reactions resulting from direct irradiation (Matthews & Brennan, 2008; Trapp & Kron, 2008: 50).

2.1.3 Somatic effects

Somatic effects appear in the irradiated individual after acute radiation exposure. Somatic effects include nausea and vomiting, organ death, erythema, cancer, cataract and decreased life expectancy (Trapp & Kron, 2008: 48-52).

2.1.4 Hereditary effects

Hereditary effects appear in the descendants of the irradiated individual. The International Commission on Radiological Protection (ICRP) estimated the risk of serious hereditary ill health within the first two generations to be 10 per million per milli Sievert with the risk being twice this value in subsequent generations (Martin & Harbison 1996: 35-41; Trapp & Kron, 2008: 51).

2.2 Techniques and devices for radiation protection

In view of the need for radiation protection in radiological examinations, the following techniques and devices have been adopted to minimise exposure of individuals to ionising radiation. These include; image intensification fluoroscopy, intermittent and pulsed fluoroscopy, beam limiting devices, adjusted exposure factors, filtration, source to tabletop distance, cumulative timing device, fluoroscopic unit exposure rate limitation, film screen combinations, radiographic processing, effective communication, immobilisation and gonadal shielding. However, for BaM and BaE where fluoroscopy and spot films are acquired, the complexity of the examination and uniqueness of each patient influence the radiation dose received by the patient (Statkiewicz-Sherer, Visconti & Ritenour, 1993: 159-193; Trapp & Kron, 2008: 110-113).

2.2.1 Fluoroscopic unit dose rate limitation

With the high doses associated with fluoroscopy, regulating the rate at which an individual receives radiation (dose rate) results in dose reduction. The United States Food and Drug Agency (2006) has recommended that the maximum radiation skin dose rate must not exceed 100 mGy/ minute under normal imaging conditions without backscattered radiation. The dose rate can be minimised by restricting the maximum kilovoltage peak (kVp) and tube current of the x-ray generator and providing additional

filtration in the x-ray tube housing so that more highly penetrative x-rays are produced for image acquisition (Trapp & Kron, 2008: 113).

2.2.2 Image intensification fluoroscopy

The image intensification capability of fluoroscopy amplifies the fluoroscopy image to 7000 times the brightness of the image allowing the viewing of the image under regular white light. Additionally, less tube current is required in obtaining a diagnostic image resulting in low patient doses (Statkiewicz-Sherer et al, 1993:159-193).

2.2.3 Intermittent fluoroscopy

Intermittent fluoroscopy is a technique adopted by radiologists using conventional fluoroscopy units where the radiologist activates the fluoroscopic tube for a few seconds at a time so as to view an area of interest. The technique is most effective when combined with the last image hold feature of the fluoroscopy equipment resulting in short fluoroscopy times and low radiation dose to the patient. Intermittent fluoroscopy further prolongs the life of the fluoroscopy tube (Mahesh, 2001).

2.2.4 Pulsed fluoroscopy

Pulsed fluoroscopy involves emission of the x-ray beam in a series of pulses rather than continuously. Some modern digital fluoroscopy equipment are equipped with this dose saving feature where images are acquired at varying frame rates per second such as 3, 7.5, 15 and 30 frames per second depending on the phase of imaging. Imaging at lower frame rates results in higher dose saving than imaging at higher frame rates (Trapp & Kron, 2008: 110-113). However, imaging fast moving objects such as barium contrast passing through the oesophagus at very low frame rates results in increased image noise. In order to compensate this increased image noise, manufacturers increase the milliampere setting on the fluoroscopy unit to allow acquisition of a good diagnostic image. This in turn affects the dose saving possible with a certain decrease in frame rate. For example, a frame rate reduction from 30 to 15 frames per second may result in 25% dose saving rather than the expected 50% dose reduction (Mahesh, 2001). Mean frame rate of 7.5 frames per second was used at sites 2 and 3 in this study. The difference

between intermittent and pulsed fluoroscopy is that the former is operator dependant whereas the latter is a feature of the equipment.

2.2.5 Last image hold and electronic collimation

The last image hold feature of fluoroscopy equipment allows the radiologist to view the last acquired image on the television monitor. This facilitates the planning of the next sequence of images without additional exposure of the patient to ionising radiation. For fluoroscopy equipment with electronic collimation superimposed on the collimator blade of the last image hold, the radiologist adjusts the field dimensions of the image without additional radiation exposure to the patient (Mahesh, 2001; Trapp & Kron, 2008: 110-113).

2.2.6 Beam limiting devices

Beam limiting devices work in such a way that they restrict the primary beam to the area of interest for the radiological procedure. Consequently, the amount of scattered and absorbed dose to the surrounding anatomical area is reduced. Beam limiting devices used during barium contrast examinations include; aperture diaphragms and collimators (Statkiewicz-Sherer et al, 1993: 159-193).

2.2.7 Exposure factors

When appropriate exposure factors are selected, radiographs that are diagnostic with minimal dose to the patient are obtained. This is achieved by using high kilovoltages (kV) and low milliamperes (mA) over time in seconds. Increasing the kV and lowering the mAs (product of milliampere and time) results in radiographic images with decreased contrast but lower patient dose. These factors must therefore be adjusted in such a way that patient dose is minimised while adequate image contrast is maintained (Statkiewicz-Sherer et al, 1993: 159-193). The kVp and mAs ranged from 88 kV to120 kV and 5 mAs to 25 mAs respectively.

2.2.8 Beam quality

The quality of the x-ray beam is influenced by the applied kilovoltage peak and the amount of filtration. Selection of a high kilovoltage produces a high energy x-ray beam

that is more penetrating. Such a high energy beam reduces the absorbed dose to the irradiated individual. In order to increase the number of highly penetrating x-ray photons, an Aluminium (Al) or Copper (Cu) filter is added to absorb the low energy x-ray photons. This process is referred to as filtration and results in x-ray beam hardening. In this way, the radiation dose to the individual is reduced by allowing only high energy x-ray photons to reach the image receptor (Statkiewicz-Sherer et al, 1993: 159-193; Mahesh, 2001).

2.2.9 Source to image receptor distance

When the source to image receptor distance (SID) is short, the patient receives an increased entrance skin dose as compared to using a longer SID. A minimum distance of 38 centimetres is recommended to reduce the entrance skin dose to the patient. All study sites investigated used a source to image distance of 100 centimetres (Statkiewicz-Sherer et al, 1993: 159-193).

2.2.10 Cumulative timing device

Fluoroscopy units must be equipped with cumulative timers with an audible alarm that sounds after 5 minutes of fluoroscope activation. This timer makes the radiology personnel aware of the duration of exposure of the patient and enables them to work cautiously to avoid exposure of patients for long periods to ionising radiation (Statkiewicz-Sherer et al, 1993: 159-193).

2.2.11 Film screen combination and radiographic processing

Film screen combination and radiographic processing conditions affect the absorbed dose to the patient when repeat radiographs are acquired due to poor images being produced as a result of the film screen combination used and radiographic image processing conditions. Since conventional and digital fluoroscopy systems use different films and image processing conditions, they are discussed individually.

Conventional fluoroscopy

Currently, radiographic films are manufactured with various speeds that influence their response to the radiographic exposure. In combination with intensifying screens, the

conversion of x-rays to visible light is accelerated. High speed film-screen combinations are more sensitive to x-rays as compared to low speed film screen combinations. As a result, less x-ray exposure is required to produce a diagnostic image with a high speed film screen combination as compared to a low film screen combination. Consequently, there is reduced dose to the patient (Statkiewicz-Sherer et al, 1993: 159-193). At the study site with conventional fluoroscopy equipment, a 200 speed film screen combination was used.

Additionally, the temperature and the age of the radiographic film processing chemicals affect the final image on the radiograph in such a way that, if the temperature is not properly regulated or exhausted chemicals are used without varying the radiographic factors, a poor radiograph is produced. This will necessitate repeat radiographs resulting in additional exposure of the patient to ionising radiation that would have been avoided if the processing conditions were checked. It is therefore essential that a quality assurance program exists in the department to check the temperature and working conditions of the processor and processing chemicals. Good quality control minimises the need for repeat radiographs resulting from using a faulty processor or exhausted processing chemicals and therefore reduces unnecessary additional radiation dose to the patients (Sprawls & Kitts, 1996; Grey, 1997).

Digital fluoroscopy

Contrary to conventional fluoroscopy, digital fluoroscopy employs laser imagers to produce hard copies of images. Radiology departments have advanced from employing wet film laser imagers to using dry film laser imagers. The two study sites in this research project that employed digital fluoroscopy units used dry film laser imagers.

The dry film laser imager uses photothermographic blue base films made of silver behenate crystals. During image reproduction onto the film, the film is exposed on both sides using a laser beam in a z pattern to obtain the high level of exposure required for this film. The film is then exposed to controlled heat of the order of 140 degrees Celsius for a few seconds to transform the latent image into a permanent image (Gahleitner,

Kreuzer, Schick, Nowotny et al, 1999). There are no processing chemicals required for dry film laser imagers as is the case with the wet film laser imager, yet the image quality of the former is comparable to that of the latter. Another advantage of dry film laser imagers is the absence of latent image degradation resulting from the use of exhausted processing chemicals that would result into repeat radiographs and unnecessary additional radiation exposure to patients (Schueller, Kaindl, Langenberger, Stadler et al, 2007; Zähringer, Wassmer, Krug, Winnekendonk et al, 2001). Currently, the increased use of the picture archiving and communication system (PACS) is eliminating the need for radiographic films and film processing. This is because the information is stored and transferred electronically to the departments throughout the hospital (Samei, Seibert, Andriole, Badano et al, 2004).

2.2.12 Effective communication

This is an important part of radiological imaging where the radiographer or radiologist must explain the procedure thoroughly and truthfully to the patient. BaM and BaE require GIT preparation for successful imaging of the stomach and colon respectively. The instructions must therefore be effectively communicated to the patient to ensure adequate GIT preparation. On the day of the examination, the procedure must be clearly and continuously communicated to the patient before and during the examination to reduce anxiety and increase cooperation of the patient thereby minimising the chances of repeat images that result in additional radiation exposure to the patient (Statkiewicz-Sherer et al, 1993:159-193).

2.2.13 Immobilisation

Immobilisation of the patient prevents blurring of the radiographic image. When the image is blurred, repeat images are undertaken that result in additional radiation exposure to the patient. Immobilisation is only possible for voluntary movements of the patient for example limb movement. For involuntary movements such as of the digestive system, short exposure times are employed to minimise blurring of the resultant image. During the BaE examination, Hyoscine-N-butylbromide is administered intravenously or intramuscularly to regulate the bowel movements (Statkiewicz-Sherer et al, 1993: 159-193).

2.2.14 Gonad shielding

Gonad shielding devices protect the reproductive organs of the patient from being irradiated when in close proximity to the area of interest such as imaging of the pelvis. The use of gonad shields during barium contrast examinations is however not feasible as they will obscure the gastrointestinal structures. This results in unavoidable high radiation exposure to the reproductive organs of females as compared to males given the anatomical location of the former. Other techniques of radiation protection must therefore be sought, for example, the ten day rule must be applied in females of reproductive age referred for barium contrast examinations to prevent exposure to the unborn foetus (Statkiewicz-Sherer et al, 1993: 159-193).

The effects associated with exposure of individuals to ionising radiation and uncertainty surrounding the threshold dose levels at which these effects occur substantiate for knowledge of radiation protection techniques. During barium contrast examinations, the adoption of intermittent fluoroscopy, use of equipment with pulsed fluoroscopy and last image hold features, collimating the x-ray beam to area of interest, using long SID[8] and high kV[9] with low mAs[10] to improve the beam quality reduce the radiation dose to the patient. Additionally, effective communication of the procedure to the patient improves patient cooperation and reduces the incidence of repeat radiographs due to movement blur.

When radiation protection techniques are adopted, the radiation dose to the patients is minimised. It is however essential to quantify this radiation dose. Quantification of the radiation dose provides knowledge on the amount of radiation dose received by individuals. Knowledge of the amount of radiation dose delivered during radiological examinations and how it is measured can be used to assess of the effectiveness of the radiation protection procedures. The next chapter is therefore going to discuss how radiation dose is measured, in what units and the dosemeters employed in its measurement.

[8] Source to Image receptor Distance
[9] Kilovoltage
[10] milliampere seconds

CHAPTER 3 RADIATION DOSIMETRY

X-rays are electromagnetic waves with high energy, short wave length and high frequency with the ability to produce positive and negative charged particles on interacting with matter. When x-rays interact with body tissue, they deposit energy into the tissue resulting in excitation of electrons from the atoms in the tissue and formation of ion pairs (Bushong, 2004: 5). In this chapter, the units used to quantify ionising radiation, how these quantities of ionising radiation are measured and the equipment employed to obtain these measurements are discussed.

3.1 Dose quantities

3.1.1 Absorbed dose

The energy deposited into the tissue by ionising radiation is referred to as the absorbed dose. The international system (SI) unit of absorbed dose is the Gray (Gy) where; Gray is the deposition of 1 Joule of energy in a kilogram of any medium. The value of absorbed dose depends on both the photon energy of the ionising radiation and type of the absorbing medium; whereby a high energy beam produces less absorbed dose than a low energy beam of the same intensity. This is because more of the high energy beam photons are transmitted without absorption in comparison to the low energy beam (Ball, Moore & Turner, 2008: 295).

3.1.2 Equivalent dose

Different types and energies of ionising radiation do not cause the same degree of biological damage even with the deposition of the same amount of absorbed dose in the tissue. Hence, if only the absorbed dose to tissue is considered, it does not give an accurate indication of the tissue damage caused by any particular ionising radiation. To overcome this, equivalent dose that accounts for the type and energy of the ionisation radiation deposited in the tissue was introduced. Equivalent dose is therefore used as a measure of the biological effect of ionising radiation and to establish the probability of stochastic effects to an individual. The SI unit of equivalent dose is the Sievert (Sv). The equivalent dose is calculated from the product of the absorbed dose and the radiation weighting factor.

Dose equivalent (Sv) = Absorbed dose (Gy) x Radiation weighting factor (W_R)

The value of the W_R is dependent on the density of ionisation caused by the type of radiation deposited in the absorbing medium. The weighting factor for x- and gamma rays is 1 (Martin & Harbison, 1996: 23-31; Trapp & Kron, 2008: 32-33).

3.2 Dose measurements

The quantity of energy absorbed by a medium can be measured both directly and indirectly. The direct measurement of this energy is not feasible in diagnostic radiology. Indirect methods are therefore sought to measure the absorbed dose from the easily measurable effects of radiation that include; ionisation in air, thermoluminescence and fogging of a photographic emulsion (Ball et al, 2008: 296-307).

3.2.1 Fogging of a photographic emulsion

A photographic film emulsion contains microscopic particles of silver bromide. When the film is exposed to x-rays, the silver bromide molecules are converted into metallic silver. On developing the film, the areas of the film emulsion that were irradiated appear grey or black due to the metallic silver. The degree of blackening is used to estimate the exposure and dose by measuring the photographic density of the emulsion. Dosemeters that use this principle have been adopted for personnel monitoring (Ball et al, 2008: 304-305).

3.2.2 Thermoluminescence

Estimation of absorbed dose using thermoluminescence in crystals such as lithium fluoride is used in some dosemeters. When these crystals are exposed to x-rays, their electrons absorb the energy of the ionising radiation and are transmitted to higher energy levels. These electrons only release this energy when heat is applied to them thereby releasing the energy in the form of light photons. The quantity of light emitted is related to the absorbed dose. The dosemeters that use this principle are called thermoluminescent dosemeters (TLDs). They are ideal for personnel monitoring and measurement of entrance surface dose involving single or multiple radiographs in the

same area of interest for example the chest or pelvis. Being thin discs with an atomic number similar to tissue, TLDs are not visible on the resultant radiograph when placed on the skin of the patient or in a body cavity (Engel-Hills, 2002).

3.2.3 Ionisation in air

Air in its normal state is a good electrical insulator. When air is however exposed to x-rays, its atoms are excited resulting in the release of electrons and formation of ion pairs thereby enabling it to conduct an electric current. In order to measure the strength of the x-ray beam, knowledge of the quantity of charge on the ion pairs and the mass of air ionised is required and is known as the radiation exposure. The SI unit of radiation exposure is coulombs per kilogram. The exposure measurement is converted into absorbed dose by multiplying it with a conversion factor.

Absorbed dose (Grays) = exposure (coulombs per kg) x conversion factor

The value of the conversion factor is different for different materials and may also vary for the same material at different beam energies. Free air ionisation chambers, thimble ionisation chambers and DAP meters are some of the dosemeters that employ the air ionisation effect. While thimble ionisation chambers are widely adopted for radiotherapy, the DAP meters are employed in diagnostic radiography (Ball et al, 2008: 297-303). The DAP meter is therefore going to be discussed in detail.

Dose Area Product meter

The DAP meter is used to measure Dose Area Product of an ionising radiation beam. A transmission ionisation chamber attached to the diaphragm of the x-ray tube is used to measure the Dose Area Product (Wall, 1996). A DAP meter consists of a flat large parallel plate ionisation chamber measuring approximately $15cm^2$ that is transparent to allow the light beam diaphragm device to still be used. The chamber is designed to be mounted on the light beam diaphragm (figure 3.1). The use of cones, field delineators and external beam filters require some amendment to the positioning. The chamber is connected to an electrometer and display unit by a cable such that the display unit can be

placed in an accessible position (figure 3.2) thereby allowing the operator to have easy access to read and reset the DAP meter to zero (DWP, 1992).

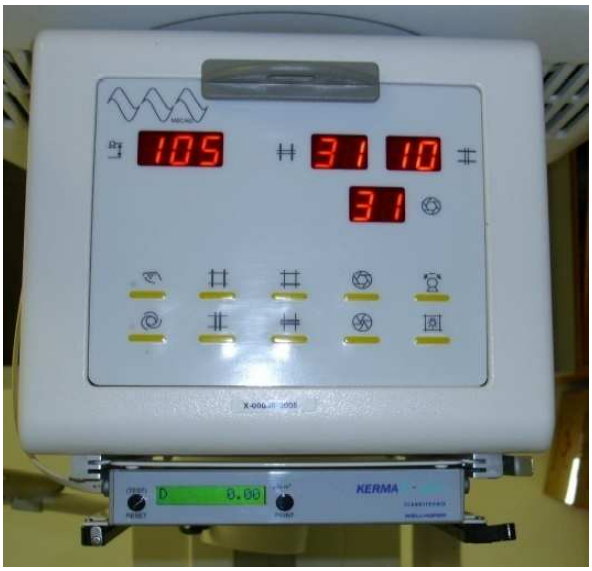

Figure 3. 1 DAP meter mounted onto light beam diaphragm of x-ray tube at one of the study sites. This DAP meter is read-out and reset in the x-ray room.

Figure 3. 2 DAP meter electrometer and display connected by a cable and operated remote from the x-ray tube at one of the study sites.

According to the charge collected by the chamber, the reading of the DAP meter is the product of the area of the chamber that is exposed to the primary x-ray beam and the

average dose in that area. It is essentially an integration of the absorbed dose over the whole beam area for the total exposure to the patient. This means that the DAP meter can provide a single measurement of the total amount of radiation in even the most complex examinations involving both radiography and fluoroscopy (DWP, 1992).

The chamber should be set perpendicular to and at the centre of the x-ray beam axis such that the beam area will never exceed the area of the chamber. These criteria are easily achieved when the chamber is attached to the diaphragm housing of the x-ray tube. In this position, the chamber does not interfere with the examination and is unlikely to receive significant back scattered radiation from the patient. The fact that the reading of the DAP meter is proportional to the product of the beam area and the dose, which is the same for all planes normal to the beam axis, means that the DAP meter can be mounted well away from the patient and close to the tube focus where the area of the x-ray beam is relatively small and dose rates are highest.

The intensity of the x-ray beam decreases with increasing distance from the source. The relationship between the intensity and the distance from the source is an inverse square law, provided that the reduction in intensity is due only to the geometrical divergence and not to any absorption or scattering of the radiation. The area of the radiation beam however increases with the square of the distance (Wade, 1994), as shown in figure 3.3. This means that although the measurement is being made at the level of the light beam diaphragm assembly, it will equal that at the surface of the patient.

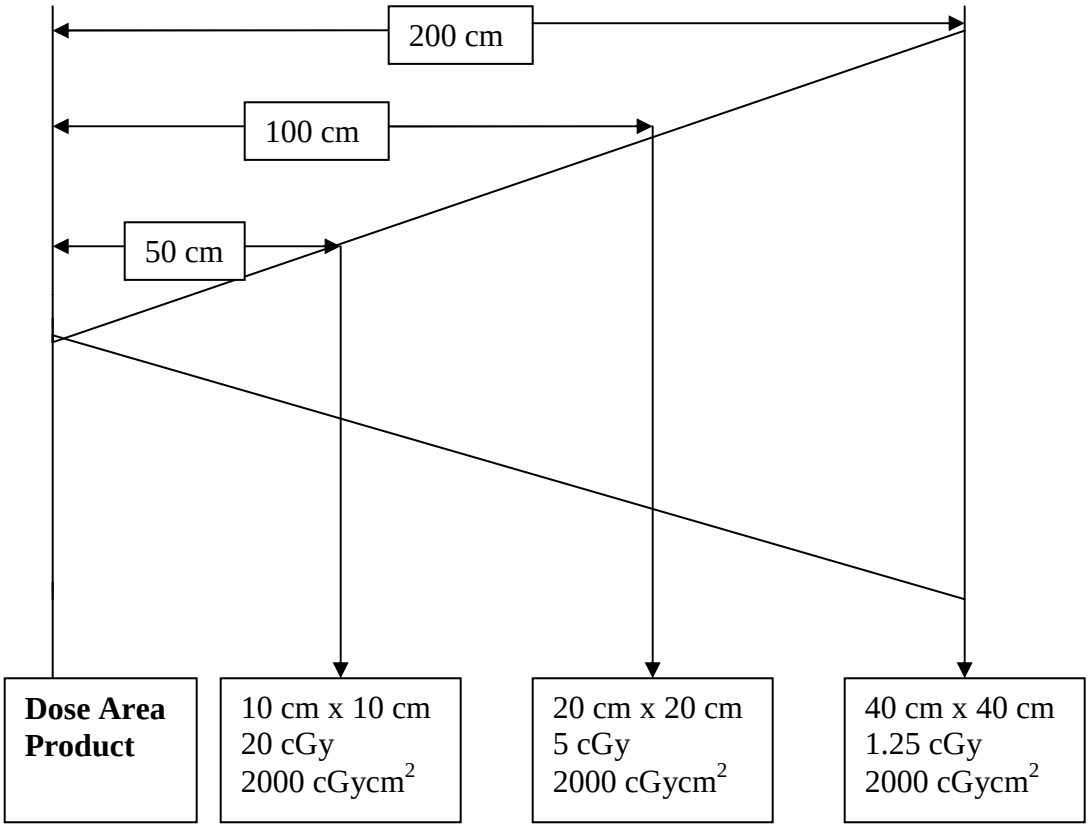

Figure 3.3 Diagrammatic sketch of the relationship between distance and area for DAP meters (adapted from Wade, 1994)

The quantity measured by the DAP meter is the absorbed dose in air multiplied by the area of the x-ray beam. The SI unit for DAP measurements is $Gycm^2$. Dose Area Product was defined as the absorbed to air (or air kerma) averaged over the area of the x-ray beam in a plane perpendicular to the beam axis (Hart, Jones & Wall, 1994). In this quantity, radiation backscattered from the patient is excluded. DAP can therefore be measured at any level between the diaphragm housing of the x-ray tube and the patient provided the place of measurement is not close enough to the patient to receive significant backscattered radiation (DWP, 1992). The SID[11] was 100 cm at all the study sites in this research project.

[11] Source to Image receptor Distance

The DAP meter must be calibrated for a range of measured field sizes, kilovoltages, doses and dose rates. The calibration must cover both fluoroscopy and radiography modes for diagnostic energies, and be made against a dosemeter calibrated in a manner traceable to the national primary standard of air kerma with an uncertainty not exceeding 5% at a 95% confidence level for the x-ray qualities and dose rates used in the calibration (DWP, 1992). The calibration must be done when the dosemeter is first received and annually thereafter. As the calibration is accurate for the specific equipment in use, it is preferable to calibrate the DAP meter in situ. If the dosemeter is moved to another x-ray unit then the calibration should be checked again at installation. In a situation where the chamber is used for an under-couch x-ray tube, the calibration should be adjusted for the couch attenuation so that the readings taken need no further corrections when data is being processed. Alternatively, a correction factor can be measured for the couch attenuation and this can be applied to the readings in order to obtain the correct dose. For DAP meters that are fitted with timers, these timers need to be checked for accuracy. The DAP meter uses an ionisation chamber necessitating temperature and pressure corrections (DWP, 1992).

During barium meal and barium enema examinations, radiography and fluoroscopy techniques are employed with the effective x-ray beam moving over a large area of the patient to demonstrate the necessary anatomy. If thermoluminescent dosemeters were used, a large number would be required to give the same amount of information as the DAP meter. The total DAP summed over all the views and fluoroscopy is therefore better measures of patient dose than entrance surface dose. Since the DAP meter integrates the total exposure throughout the study despite the continuous alterations in beam position and beam area (Hart et al, 1994), it is highly suitable for BaM and BaE.

The interaction of ionising radiation with the body tissue results in deposition of energy referred to as absorbed dose. Since it is not feasible to measure this dose directly in diagnostic radiology, the effects of this ionising radiation on matter are used to estimate the absorbed dose. The degree of fogging of a photographic emulsion, the amount of light photons emitted from a thermoluminescent crystal and amount of ionisation of air

provide estimates of absorbed by a medium. A DAP meter operates under the principle of ionisation of air and provides a single measurement for absorbed dose in examinations involving both fluoroscopy and radiography and therefore a suitable dosemeter for barium contrast examination.

With knowledge of an appropriate dosemeter to measure the radiation dose associated with barium contrast examinations and the sole goal of delivering the lowest possible radiation dose coupled with acceptable image quality, the concept of dose limits was adopted internationally to allow low radiation dose delivery to man. The next chapter is therefore going to discuss the principle of dose limits and how they are achieved.

CHAPTER 4 DOSE LIMITS

4.1 The principle of dose limits

The substantial biological and epidemiological evidence of radiation induced effects in man motivated the concept of dose limits and control of radiation risks (ICRP[12], 1998). The ICRP and NRPB[13] published dose limits to eradicate the possibility of deterministic effects and minimise the possibility of stochastic effects. Since medical exposure is based on benefit versus risk criteria, the "As Low as Reasonably Achievable" (ALARA) principle was adopted to optimise limiting the exposure of patients to radiation. This chapter is going to discuss; the legislation of DRLs[14], the need for these DRLs, the DRLs for BaM and BaE from dosimetry studies both internationally and in SA, and the factors causing variation in these DRLs.

4.2 Diagnostic reference levels

4.2.1 Legislation on diagnostic reference levels

In 1990, the RCR[15] and the NRPB introduced reference doses for common x-ray examinations in the UK following a patient dosimetry survey in 1985 (RCR & NRPB, 1990). The reference doses were determined at the third quartile values of the mean doses to a representative number of patients for a particular examination. In 1992, a DWP[16] established national protocols that would guide radiology departments in the use of these reference doses. The radiology departments were to carry out dose measurements on at least 10 adult patients per examination weighing between 50 kg and 90 kg. Such weight restrictions would ensure that the average weight of the patients studied would lie 5 kg on either side of 70 kg (65 kg -75 kg) which is the average weight of an adult man (DWP, 1992). In cases where the mean doses from such dose

[12] International Commission on Radiological Protection
[13] National Radiological Protection Board
[14] Diagnostic Reference Levels
[15] Royal College of Radiologists
[16] Dosimetry Working Party

measurements exceeded the reference doses and were not clinically justified, causes for the high doses are sought so as to undertake corrective actions (Wall, 2001).

Similar to reference doses in the UK, the ICRP adopted the term Diagnostic Reference Levels (DRLs) in 1996 (ICRP, 1996). DRLs were indicated as dose levels that were not to be exceeded by departments operating under standard and normal diagnostic and technical practices. The DRLs were also set at the third quartile value of mean dose obtained for standard sized adult patients or phantoms using a variety of equipment. While clarifying the use and setting of DRLs, the ICRP indicated that DRLs should be:

- easily measurable dose quantities such as absorbed dose in air and entrance surface dose for tissue equivalent phantoms or representative patients
- investigation levels above which equipment and procedures must be reviewed to ascertain whether dose optimisation measures were undertaken
- used as simple tests for identifying unusually high patient dose levels
- complementary to professional judgement and
- related to common types of diagnostic examination and widely defined equipment and not be used in a precise manner (ICRP, 1996; Matthews & Brennan, 2008).

Additionally, Wall (2001) stressed that dose data from 1 or 2 hospitals should be used to monitor local trends in patient dose with time and differences between x-ray rooms and practitioners. In situations where high DRLs or third quartile dose values are recorded, median dose values should be adopted as reference doses. This is because the median value is less affected by extreme outliers of under or overweight of the study sample as compared to the mean DAP value. When Yakoumakis et al (1999) included an overweight patient in the BaE patient sample, the mean DAP was greatly affected as compared to the median value. The use of the first quartile values as reference levels is not recommended as these dose levels may be too low that the image quality is compromised. First quartile values may therefore be adopted as dose levels for investigation of image quality in the radiology department (Roberts, 1992).

4.2.2 The need for DRLs

From the above indicators, it can be deduced that DRLs were primarily intended to avoid situations of high patient radiation exposure without clinical justification. DRLs can therefore be used to:

- identify techniques, equipment and departments delivering high dose and facilitate an investigation of such dose. McQuaruz & Tole (1992) found the absence of dose limits to continually impede radiation protection of patients in developing countries as poor and ill-maintained equipment were still in use due to the socio-economic pressures and reluctance to perform quality assurance programmes.
- obtain optimum dose ranges for particular examinations that represent good practice. In a dosimetry survey in the UK, reference doses for BaM and BaE were set at 25 $Gycm^2$ and 60 $Gycm^2$ respectively (DWP, 1992). With knowledge of specific effective dose, radiologists are capable of promoting dose optimisation as they influence image quality and radiation dose to the patients (Lampinen & Rannikko, 1999).
- promote progression towards lower dose and image quality procedures (ICRP, 2002; Matthews & Brennan, 2008). This is evidenced in the dose savings recorded in the UK dose studies of 40% (Hart et al, 1996) and further 20% (Hart, Hillier & Wall, 2002) as compared to the 1983 and 1985 (DWP, 1992) and 1995 (Hart et al, 1996) dosimetry studies respectively.

4.2.3 DRLs for barium meal and barium enema examinations

The regulations on adoption of local, regional and country based DRLs for the various x-ray examinations owing to the demographic variations such as body stature of individuals from different geographical locations led to dosimetry studies in the different countries (ICRP, 1996). Tables 4.1 and 4.2 show the mean and third quartile DAP values for BaM and BaE from various dosimetry studies respectively. The comparability of DAP values obtained in Spain and Serbia support the concept of country specific DRLs. In Spain, Ruiz-Cruces, Ruiz, Pĕrez-Martĭnez, Lŏpez et al (2000) obtained mean DAP values of 39.85 $Gycm^2$ and 56.87 $Gycm^2$ for BaM and BaE respectively that compared well with

those of Vano, Gonzalez, Morăn, Calzado et al (1992) who obtained mean DAP values of 39.90 $Gycm^2$ and 45.19 $Gycm^2$ for BaM and BaE respectively. Ciraj, Marković & Košutić (2005a) and Ciraj, Košutić, Kovacevic & Marković (2005b) in Serbia recorded mean DAP of 15 $Gycm^2$ and 23.3 $Gycm^2$ for BaM respectively in Serbia.

Contrary to the expectation that lower DAP values are recorded in subsequent dosimetry studies as in the UK (DWP, 1992; Hart et al, 1996; Hart et al, 2002) owing to adoption of dose saving procedures over time, higher DAP values were recorded in a later study in Greece (Delichas, Hatziioannou, Papanastassiou, Albanopoulou et al, 2004) as compared to an earlier study (Yakoumakis et al, 1999). Delichas et al (2004) however attributed this to investigating radiation dose in public hospitals where the radiological procedures were performed by radiologist registrars. Radiologist registrars are associated with longer fluoroscopy times that result in increased DAP readings. To support this, Hoskins & Williams (1992) reported decreased dose deliveries by radiologist registrars with increasing years of experience.

Table 4.1 The mean and third quartile DAP values ($Gycm^2$) recorded for BaM from various countries. D is digital fluoroscopy unit; C is conventional fluoroscopy unit

Author	***mean***	***3rd quartile***
DWP, 1992 (UK)		25
Broadhead et al, 1995 (UK)	7.62 (D)	
	15.45(C)	
Hart et al, 1996 (UK)		17.1
Warren-Forward et al, 1998 (UK)	11.39 (D)	
	21.26 (C)	
Hart et al, 2002 (UK)		13
Hart et al, 2007 (UK)		**13**
Carroll & Brennan, 2003 (Ireland)		17
Yakoumakis et al, 1999 (Greece)	23.3	
Delichas et al, 2004 (Greece)	25±11	
Geleijns et al, 1998 (Netherlands)	15 (D)	
	28 (C)	
Ruiz-Cruces et al, 2000 (Spain)	39.85±20.4	
Vano et al, 1992 (Spain)		39.90
Ciraj et al, 2005a (Serbia)	23.3	
Ciraj et al, 2005b(Serbia)	15±10	18
Verdun et al, 2005 (Switzerland)	67	

Barium meals

From table 4.1, the mean DAP values for conventional units ranged from 15.45 $Gycm^2$ to 28 $Gycm^2$ and 7.62 $Gycm^2$ to 15 $Gycm^2$ for digital units. For all the mean DAP values recorded, the digital units recorded lower mean DAP values as compared to the conventional units (Broadhead et al, 1995; Geleijns, Broerse, Chandie Shaw, Shultz et al, 1999; Warren Forward et al, 1998). When Broadhead et al (1995) compared the natural logarithms of the mean DAP values for both DF and CF units, they obtained 31 standard errors at the 95% confidence interval. Since the standard error lay outside the ±3 standard error of the mean, Broadhead et al (1995) confirmed presence of a significant difference between the dose delivered by the DF unit (7.62 $Gycm^2$) and the CF unit (15.45 $Gycm^2$). Where neither D nor C is indicated in table 4.1, the literature did not specify the fluoroscopy equipment type employed.

Ciraj (2005b), Delichas et al (2004) and Ruiz-Cruces et al (2000) recorded standard deviations of 10, 11 and 20.4 respectively about their mean DAP values. The other studies did not indicate the standard deviations of their means or whether the means they provided in their studies were corrected means with the errors removed.

The lowest and most recent DRL of 13 $Gycm^2$ for BaM was recorded in the UK (Hart et al, 2007).

Table 4.2 The mean and third quartile DAP values ($Gycm^2$) recorded for BaE from various countries. D is digital fluoroscopy unit; C is conventional fluoroscopy unit

Author	*mean*	*3rd quartile*
DWP, 1992 (UK)		60
Martin & Hunter, 1994 (UK)	24.4	
Broadhead et al, 1995	13.84 (D)	
	25.11 (C)	
Hart et al, 1996 (UK)		32.2
Hart et al, 2002 (UK)		31
Hart et al, 2007 (UK)		**24**
Warren-Forward et al, 1998 (UK)	25 (D)	
	28 (C)	
Engel-Hills, 1997 (SA)		**84**
Carroll & Brennan, 2003 (Ireland)		47
Yakoumakis et al, 1999 (Greece)	35.2 (C)	
Delichas et al, 2004 (Greece)	60±35(C)	
Ruiz-Cruces et al, 2000 (Spain)	56.87±32	
Vano et al, 1992 (Spain)	45.19	
Ciraj et al, 2005b (Serbia)	39±16	41
Verdun et al, 2005 (Switzerland)	102	
Kemerink et al, 2001 (Netherlands)	51±29 (D)	
Lampinen & Rannikko, 1999 (Finland)	35.8 (C)	

Barium enema

From table 4.2, the mean DAP values for conventional units ranged from 25.11 $Gycm^2$ to 60 $Gycm^2$ and 13.84 $Gycm^2$ to 51 $Gycm^2$ for digital units. For all the mean DAP values recorded, the digital units recorded lower mean DAP values as compared to the conventional units (Broadhead et al, 1995; Warren Forward et al, 1998). Broadhead et al (1995) further investigated the whether the difference in the dose delivered by DF and CF units for significant and obtained 26 standard errors at the 95% confidence interval between mean natural logarithm DAP of the 2 equipment types. The standard error being outside the ±3 standard error interval of the mean confirmed presence of a significant difference between the mean DAP delivered by the CF (25.11 $Gycm^2$) and DF (13.84 $Gycm^2$) units. In table 4.2, where neither D nor C is indicated, the literature did not specify the fluoroscopy equipment type employed.

Ciraj (2005b), Delichas et al (2004), Kemerink et al (2001) and Ruiz-Cruces et al (2000) recorded standard deviations of 16, 35, 29 and 32 respectively about their mean DAP values. The other studies did not indicate the standard deviations of their means or whether the means they provided in their studies were corrected mean with the errors removed.

The lowest and most recent DRL of 24 $Gycm^2$ for BaE was recorded in the UK (Hart et al, 2007). An earlier study in SA recorded a third quartile value of 84 $Gycm^2$ for BaE (Engel-Hills, 1997).

4.2.4 Factors affecting dose variations

During investigation of patient doses for BaM and BaE, Carroll and Brennan (2003) recorded individual patient variations of 90 $Gycm^2$ and 45 $Gycm^2$ and mean hospital dose variations of 4.2 $Gycm^2$ and 7.8 $Gycm^2$ for BaM and BaE respectively. On investigation of these variations, they developed a four and seven variable regression model for the BaM and BaE respectively. In decreasing order of importance, the fluoroscopy time (FT), patient's weight, fluoroscopy grid ratio and filtration accounted for the 53% DAP variation for BaM, while FT, number of films, level of filtration, fluoroscopy grid material, radiographic grid ratio, prior failed colonoscopy and fluoroscopy grid ratio were responsible for the 70% DAP variation for BaE. The fluoroscopy time, secondary radiation grid type and the level of filtration affected both BaM and BaE (Carroll & Brennan, 2003). Martin & Hunter (1994) found that 15% to 20% lower DAP values are achievable with optimisation of all equipment factors. When the same radiologist is operating the same equipment using a standard protocol for all patients, any arising variations are dependant on the patient such as the patient's weight (Ciraj et al, 2005a).

Besides equipment factors, the dynamic nature of the examination, preference of the examining radiologist and findings of the examination affect the variation in DAP values of patients (Yakoumakis et al, 1999; Ciraj et al, 2005a). Lampinen and Rannikko (1999) attributed the higher DAP values recorded at two university hospitals in Finland to the more complex BaE protocols that were employed. This is so because more images are

obtained to demonstrate the pathology especially for digital units where images are easily acquired. Warren-Forward et al (1998) found the DAP value for BaE decreasing by 15 % as compared to 50% DAP decrease for BaM because of the enormous number of images obtained for the former. Verdun, Aroua, Trueb, Vock et al (2005) found a strong correlation between FT and complexity of the examination.

Fluoroscopy time

The main contributor to dose during BaM and BaE examinations is fluoroscopy time making reduction of FT an intervention for reducing dose to patients referred for such procedures (Ciraj et al, 2005a). The fluoroscopy time is however affected by the dynamic nature and findings of the examination. Radiologists are able to control both the fluoroscopy time and number of radiographic exposures and should therefore justify the techniques used during BaM and BaE (Vehmas, Lampinen, Mertjarvi & Rannikko, 2000; Verdun et al, 2005). Radiology registrars have been found to register longer FT of the order of 6.45 minutes (BaM) and 9.1 minutes (BaE) as compared to qualified radiologists who recorded 3.1 minutes and 3.2 minutes for BaM and BaE respectively (Yakoumakis et al, 1999). A total DAP reduction of 11% is feasible by decreasing the FT and thus the fluoroscopy dose (Horton, Cook & Taylor, 1992).

Additional filtration

In fluoroscopy equipment, copper of 0.2mm to 0.5 mm is used to provide additional filtration of the x-ray beam. In this way, the beam is hardened and only the high energy x-rays reach the patient as the low penetrating x-rays are filtered out resulting in lower absorbed dose to the patient and therefore lower DAP values (Geleijns et al, 1998; Kemerink et al, 2001). This additional filtration does not however decrease the DAP and effective dose by the same proportion. Morrell, Rogers, Jobling and Shakespeare (2004) found the additional copper filtration to decrease the DAP by 54% and the effective dose by only 11% with 30% more x-ray tube loading. It is therefore recommended that fluoroscopy units with additional copper filtration must adopt lower DRLs than units devoid of such filtration (Martin, 2004).

Fluoroscopy equipment

During fluoroscopy examinations, continuous images of dynamic anatomical structures are visualised with acquisition of radiographic images or spot films for areas of interest to the radiologist. The use of fluoroscopy extends to the GIT, genitourinary tract and investigation of blood vessels or angiography. The two types of fluoroscopy equipment in use are conventional fluoroscopy (CF) and digital fluoroscopy (DF).

Conventional fluoroscopy equipment

Conventional fluoroscopy equipment record and display data in analogue format. The components of a CF unit are the x-ray tube, image intensifier (I.I), television camera; television monitor and patient couch (figure 4.1).

Figure 4. 1 The equipment set up of an over-table CF unit at one of the study sites.

Currently, CF units with x-ray tubes above the patient couch, with options of operating the equipment close to or remote from the x-ray tube are available. In this case, the I.I is positioned below the patient couch. On activation of the x-ray tube, x-ray photons are transmitted through the patient and an image forming x-ray beam is incident on the input

phosphor of the I.I. In the I.I, each x-ray is multiplied into a large number of light photons resulting in a bright image that is visualised on the television monitor. Spot images of areas of interest are then acquired on spot films (Bushong, 2004:358-369). Images acquired with CF equipment cannot be manipulated or post-processed after acquisition to alter their image detail contrast. As such, strict exposure requirements need to be observed to allow acquisition of diagnostic quality images. Furthermore, the dose levels delivered in CF are dependant on the sensitivity of the image receptor and film latitude (Broadhead et al, 1995).

Digital fluoroscopy equipment

The configuration of DF equipment is similar to CF equipment except for the addition of an analog to digital converter (ADC), a computer, operator console and two television monitors. The ADC converts the analogue information from the image intensifier into digital information that is interpreted by the computer.

The advantages of DF over CF equipment include:

- The ability to acquire images using x-ray spectrums with exposure levels that result in dose saving.
- Flexibility for image processing and display resulting in recovery of any loss of image contrast.
- Easy acquisition and immediate display of images that may result in fewer radiographs being acquired and therefore reduced dose to the patient (Broadhead et al, 1995)

Dynamic flat panel solid state x-ray image detector DF systems

The current advancement in DF equipment has replaced the I.I, video camera and ADC system with direct digital conversion detectors or flat panel detectors. The flat panel detectors are composed of Caesium Iodide scintillators that absorb the x-ray photons and convert them to light photons. The light photons are absorbed by low noise photodiode arrays of amorphous Silicon panels that convert the light photons into an electronic charge. With each photodiode array representing a pixel, the charge on each pixel is read out by low noise electronics and turned into digital data that are sent to the image

processor. This type of DF equipment is currently predominantly used in cardiac and vascular systems offering:

- Improved image quality given the smaller pixel size and higher detection quantum efficiency of the detectors
- Greater contrast resolution and
- more room space for radiology personnel when carrying out examinations given the small size of the equipment (Cowen, Davies & Sivananthan, 2008).

DAP variation for conventional and digital equipment

Engel-Hills and Hering (2001) associated the hospital DAP variations to the different equipment used at the hospitals. The old under-couch unit recorded the lowest mean FT but high DAP values as compared to the digital unit with high FT but lowest DAP values. Geleijns et al (1998) recorded mean DAP values for digital units (15 $Gycm^2$) that were almost half those obtained for the conventional units (28 $Gycm^2$) attributing this to less spot films acquired during the digital imaging. Interestingly, digital equipment was also capable of maintaining DAP values below 15 $Gycm^2$ when over 28 projections were obtained. Though lower DAP values have been achieved in other studies, Geleijns et al (1998) proposed that a DAP value of 30 $Gycm^2$ for BaM can ensure that the effective dose is maintained below 15mSv.

The dose saving options of digital equipment such as pulsed fluoroscopy have allowed the recording of lower DAP values. The training of radiology personnel is however essential in realising these dose savings and care must be taken that the achievement of low doses is not through compromising the image quality (Martin, 2004).

Equipment set-up

The radiation dose delivered to patients is also dependant on the equipment set up. Equipment with the automatic exposure control (AEC) component can use dose saving techniques by selecting high tube potentials for radiography that result in less absorbed dose for the patients and therefore lower DAP values (Yakoumakis et al, 1999). The lower tube voltages in the investigation of patient doses resulted in high DAP values for

BaE (Kemerink et al, 2001). High kilovoltages of the order of 102 kV to 125 kV[17] during radiography and low kilovoltages (73 kV to 83 kV) and low tube currents (1.8 mA[18] to 2.4 mA) during fluoroscopy result in decreased DAP values. The low factors used during fluoroscopy result in poor image quality (Hart & Wall, 1994) but this can be manipulated during post-processing of the images with digital units (Broadhead et al, 1995).

Awareness of being monitored

Crawley, Shine and Booth (1998) and Horton et al (1992) recorded lower doses for patients when radiology personnel were aware of being monitored. The awareness of being monitored thereby served as an incentive in reducing radiation exposure to the patients.

With the understanding of the principle of dose limits and their need, a research methodology was adopted from the UK national protocols to investigate the radiation dose levels for BaM and BaE in the Western Cape, SA. The research methodology is systematically explained in the next chapter.

[17] Kilovoltage
[18] milliamperes

CHAPTER 5 RESEARCH METHODOLOGY

5.1 Introduction

Increasing efforts to reduce radiation dose to patients during fluoroscopy examinations, have led to a legal requirement that all fixed fluoroscopy equipment must have a DAP meter permanently installed from January 2008 in South Africa (DoH[19] SA, 2006). This allows for routine measurement of the radiation dose to patients referred for fluoroscopy examinations and estimation of national Diagnostic Reference dose Levels for SA when data from the different hospitals are collected and analysed. Known reference doses measured in $Gycm^2$ are needed to act as guiding principles to radiology personnel when exposing patients to ionising radiation and to maximise the benefits from the inclusion of DAP meters on all fluoroscopy equipment.

This study investigated and measured the radiation doses received by patients during BaM and BaE and in this chapter, the research methodology, research design, inclusion and exclusion criteria of sites and patients, tools for data collection, statistical analysis, validity and reliability of measurement tools, delimitation of the study, research assumptions and ethical considerations are discussed.

5.2 Research methodology

5.2.1 Descriptive quantitative survey research

A descriptive quantitative survey method correlated to the UK national protocols (DWP, 1992) was used to establish local DRLs for BaM and BaE. A descriptive quantitative survey method relies on collecting data through observation of participants in their present situation without any modifications to the characteristics under investigation (Leedy & Ormrod, 2001: 191,196). The UK protocols recommend that dose studies be carried out on patients rather than phantoms to give a clear indication of the radiation dose delivered in reality (DWP, 1992). Chapple, Broadhead & Faulkner (1995) used

[19] Department of Health

phantoms to estimate doses during barium studies and obtained lower doses in comparison to studies where real patients were used (DWP, 1992).

In this study, the radiation doses were recorded for the BaM and BaE as they were routinely performed at the research sites. In this way, a true indication of radiation dose received by patients referred for BaM and BaE was obtained.

5.2.2 Site and participant selection

Through telephone calls to state and private hospitals in the Western Cape, a list of hospitals with permanently installed DAP meters was developed by the researcher. The researcher further inquired about the number of BaM and BaE performed at the hospitals. This allowed for suitable sites with sufficient measurement data to be obtained so that the data collection process was completed within the allocated time frame.

Inclusion criteria

Research sites

Three state hospitals were selected as research sites for the study. In addition to having DAP meters permanently mounted to their fluoroscopy units, they routinely performed BaM and BaE. These sites also captured a large number of patients and had a variety of equipment that is; digital and conventional fluoroscopy units enabling investigation of doses with both types of the equipment. The specifications of the fluoroscopy units used at the study sites are given in Appendix 1[20].

Patient participants

The study included both male and female patients referred for BaM and BaE that were between 18 years and 85 years and weighed 50 kg to 90 kg. The 50 kg to 90 kg weight range was in order to effect a mean weight for the sample that would be not more or less than 5 kg from 70 kg that is to say; 65 kg to 75 kg. This is a good indication of the typical weight of an average adult patient (DWP, 1992) and therefore appropriate to the calculation of a reference dose for an adult population. The plan was that at least 10 BaM

[20] Fluoroscopy equipment specifications for equipment at the 3 study site (page 93)

and 10 BaE patients would be selected from each of 3 research sites with a total of 30 patients for each examination in this study (DWP, 1992).

Exclusion criteria

Research sites

Hospitals that did not have permanently fitted DAP meters on their fluoroscopy units were excluded from the study. Furthermore, hospitals with DAP meters but performed very few BaM and BaE were also excluded. The number of BaM and BaE performed by a hospital was forecasted from the number of patients that attended in the year prior (2007) to this research project.

Patient participants

The researcher excluded patient participants;

- younger than 18 and older than 85 years,
- weighing less than 50 kg or greater than 90 kg,
- in whom other contrast media other than barium sulphate was used for the investigation of the GIT and
- that were very frail.

5.2.3 Time frame

The intended time frame for data collection was June 2008 to February 2009. Data collection was extended to June 2009 so that adequate data could be collected.

5.2.4 Pilot study

A pilot study was conducted at one of the research sites. This tested the relevancy of the research variables included on the data capture sheet and allowed for the necessary changes to be made prior to the main study (Leedy & Ormrod, 2001:116).

5.2.5 Data collected

The data pertaining to the study objectives were recorded on the data capture sheet in Appendix 2[21]. These included the demographics of the patients, the indication for the BaM or BaE, equipment and exposure factors, DAP value, degree of difficulty of the examination, number of images obtained and grade or level of training of the radiologist performing the BaM or BaE. Only data from completed examinations were included in the data analysis.

Patient demographics

The demographics of the patients that were recorded were; age, gender, weight and the indication for the BaM or BaE.

- **Age**

The DWP (1992) recommends that adults rather than children be considered when setting reference doses. The age of the patients assisted in ensuring that only adult patients were recruited for the study.

- **Weight**

When obtaining reference doses, the patients' weights are determined to ensure the mean weight of the sample corresponds to that of an adult patient. Only then can reference doses be generalised to the adult population.

- **Indication**

The indication or reason for referral for the BaM or BaE was obtained from the patient's request form. Depending on the indication for the study, more images may be acquired and long FT recorded while establishing the radiological finding. The indication for their study may therefore be used to explain long FT and high number of images acquired during the study.

Exposure factors for radiography and fluoroscopy

All the fluoroscopy units in the study used the automated brightness control (ABC) where the exposure factors are automatically selected by the fluoroscopy unit for the anatomical area being irradiated. For each radiographic image acquired, the tube potential (kV), the

[21] Data capture sheet (page 94)

product of the tube current and time in milli ampere seconds (mAs) and time in seconds were recorded. For fluoroscopy, the tube potential (kV), the tube current (mA) and the fluoroscopy time in minutes were also recorded at the end of the examination.

The number of images

The number of images was the number of images recorded in the radiography phase for the digital units and the number of spot images for the conventional unit.

DAP value

The total DAP reading in Gray per square centimetre ($Gycm^2$) was recorded at the end of each examination from the DAP meter display.

Level of difficulty of the examination

This was ascertained by the radiologist performing the examination from his knowledge and experience of performing BaM and BaE. The radiation doses tend to be higher for difficult examinations as many images are acquired and long FT recorded.

Level of training of the radiologist

The level of training of the radiologist was obtained by the researcher through a verbal communication with the radiologists performing the BaM or BaE.

5.2.6 Validity and reliability of the measurement instruments

Jackson (2008) describes validity of a measurement instrument as the extent to which the instrument measures its intended variable whereas instrument reliability is the degree of consistency of measurement values in the same participant.

- **Error in measurement**

Errors in measurement of variables are divided into method and trait errors. Method errors arise from the researcher or practitioner and research environment, whereas trait errors stem from the participants. Though trait errors are difficult to control, method errors are minimised by the training of individuals in the use of the measuring instruments and the calibration of these instruments (Jackson, 2008:67).

- **Procedure for recording weight**

The weights of the patients were measured using calibrated digital bathroom scales (Safeway deviation ±100g) that were automatically reset to zero for every new weight measurement. Digital bathroom scales were employed in the study because they displayed a numerical value thereby eliminating inter-observer variation in recording of participants' weights. The patients' weights were obtained under similar conditions with the patients wearing hospitals gowns only and with shoes removed.

- **Fluoroscopy units and DAP meters**

Individual equipment records (IER) are documents that show the type of equipment and the quality control (QC) tests performed on the equipment in the radiology departments (DoH[22] SA, 2006). The IER were obtained for all the fluoroscopy units and DAP meters to establish that they passed the acceptance and QC tests. The medical physicist further examined these records to ensure that the fluoroscopy units and DAP meters operated within the prescribed accuracy and precision measurements (DWP, 1992). The DAP meters were always reset to zero at the beginning of each BaM and BaE. This was ensured by the responsible persons identified at each study site. At site 3, the in-charge radiographer of the fluoroscopy room was the responsible person while the researcher was the responsible person at sites 1 and 2.

- **Data capturing**

The radiographers involved in the data capture process in this study were trained in the acquisition and recording of data relevant to the study thereby improving the reliability of the data collected. Furthermore, the researcher verified the completeness of the data capture sheet before entering the data into the computer program.

5.2.7 Delimitation of research

This research measured the radiation doses received by both male and female patients between 18 years and 85 years weighing 50 kg to 90 kg referred for BaM and BaE at 3 hospitals in the Western Cape, SA. The radiation doses were measured using DAP meters that were permanently installed on either digital or conventional fluoroscopy

[22] Department of Health

equipment. The radiation doses were measured in $Gycm^2$ using DAP meters that were permanently installed onto the fluoroscopy units.

5.2.8 Research assumptions

The research assumptions were;

- the radiographers followed the procedure of recruiting patients into the study
- the radiographers accurately recorded all the relevant information on the data sheet
- all equipment were accurately calibrated.

5.3 Ethical consideration

Researchers are responsible for participants' welfare in surveys. They must; minimise the risks, reduce possible harm, ensure voluntary participation, maintain the ethical standard of confidentiality and anonymity, include an informed consent process and ensure privacy of the participants. An application was submitted to the Faculty of Health and Wellness Sciences Research Ethics Committee and approval was granted (Ref: CPUT/HW-REC 2008/010). The study sites accepted the ethics approval of the higher education institution. The heads of the radiology departments of the research sites signed letters of permission for the project to commence. In view of confidentiality, these letters and the ethics approval certificate from the university are not included as appendices but are available on request.

Walliman (2005), proposes two perspectives from which to view ethical issues in research; values of honesty and integrity of the researcher and ethical responsibility to the participants.

5.3.1 Ethical responsibility to the participants

The ethical responsibility to the participants included ensuring voluntary participation, good informed consent process, confidentiality, anonymity and privacy. After acquiring the age of the patient from the hospital folder, the research project was explained to the patient so as to obtain informed consent for participation in the study. Participation in the

study was completely voluntary with no prejudice against patients who declined their involvement at any stage during the data collection.

Since the study sites had patients from all ethnic backgrounds, the aims and objectives of the study were explained to the patients in English, Afrikaans or Xhosa. Consent forms were available in all these 3 languages. Appendix 3[23] shows the English consent form. On signing the consent form, the participants were assigned study codes to ensure anonymity of the information obtained from them. The weights of the participants were measured inside the x-ray room and the completed data capture sheets were stored in locked cabinets that only the researcher had access to.

5.3.2 Values of honesty and integrity of the researcher

The researcher has acknowledged all sources of information and the results of the study have been analysed without manipulation to draw false conclusions that are not derived from the research findings (Walliman, 2005).

5.4 Barium enema examination protocols

The patient preparation, contrast medium, equipment used and projections undertaken for the barium enema procedures at the study sites are discussed.

5.4.1 Study site 1

Site 1 used a CF unit with an over-couch x-ray tube.

Patient preparation

The patients were prepared 2 days before the BaE. Two days prior to the examination, the patients drank plenty of fluids and had their last solid meal at 18H00 two days before the examination. For example; a patient due for the BaE on Monday would have their last solid meal at 18H00 on Saturday.

On Sunday, the patient drank a bottle of sodium phosphate at 8H00 and swallowed 3 solflax tablets with a glass of water. These are laxatives. The patient then continued on a

[23] Consent form (page 95)

clear fluid diet that included fruit juice, water, jelly, black tea or coffee (no milk). The clear fluids were taken at intervals of one glass per hour. On the day of the examination; in this case Monday, the patient drank black tea or coffee or juice.

Barium enema contrast

Barium sulphate is an insoluble radio-opaque material that enables visualisation of the GIT. Barium sulphate is inert, not absorbed or metabolised by the body and is eliminated unchanged from the body (Axim pharmaceuticals, 2001; Brady & Holum, 1988: 896).

Composition

The barium sulphate at study site 1 was Axim Polibar ACB that constituted a dry white powder of 96% barium sulphate for every 100g of the Axim Polibar ACB. An amount of 397g of barium sulphate was used for the BaE.

Dosage and mixing instructions

The 397g of the contrast was mixed with 400 millilitres (mls) to 700 mls of warm water (40^0C) to give a contrast density of 76% mass per volume and 47% mass per volume respectively.

Contraindications

Barium sulphate is contraindicated in colon obstruction, presence of suspected or impending gastro-intestinal perforation, known hypersensitivity to Barium Sulphate, in patients at risk of perforation e.g. acute ulcerative colitis or diverticulitis and following rectal or colonic biopsy, sigmoidoscopy or radiotherapy (Axim pharmaceuticals, 2001; Caroline & Kendzierski, 2008: 630).

Barium enema equipment

The barium enema equipment used was;

- a miller disposable enema catheter with tube and inflatable cuff,
- hand air pump and balloon inflator
- 397g of barium sulphate dry powder,
- drip stand
- pair of forceps
- 2 ampoules of micro Hyoscine-N-butylbromide each 20mg

Barium enema procedure with the conventional fluoroscopy unit

The radiographer obtained the preliminary film of the abdomen of the patient. This was to ascertain adequate bowel preparation. The absence of faecal matter in the colon was an indication of adequate bowel preparation. In cases where faecal matter was seen in the colon, the procedure was cancelled and the patient was given more laxatives to allow bowel emptying.

The radiographer mixed the barium sulphate as explained above and suspended the barium sulphate bag on a drip stand that was approximately 2 meters high. With the patient in the left lateral decubitus position, the radiologist performed a rectal examination to exclude rectal obstruction, nodules, tenderness, irregularities, haemorrhoids, pre-sacral space and faecal impaction (Holmes, Tscheslog, Hendler, Morrel, et al, 1997: 443).

The radiologist then inserted the enema catheter that was connected by a tube to a 400 ml to 700 ml barium sulphate suspension infusion bag. The enema tube was clamped to prevent the barium suspension from flowing into the rectum at insertion of the catheter. A pair of forceps was used to clamp the hand pump. Using a balloon inflator, the radiologist then inflated the cuff on the enema catheter just distal to the point of insertion of the rectal catheter. This aided in retention of the catheter during the procedure. The enema tube was also connected to a hand pump that was used to inject air during the procedure.

With intermittent screening and the patient maintained in the left lateral decubitus position, the forceps were removed and the barium contrast suspension flowed freely into the rectum. An image of the lateral rectum was obtained at this stage to demonstrate the pre-sacral space. When the barium reached the hepatic flexure, 2 ml of micro Hyoscine-N-butylbromide were administered intravenously to the patient. Micro Hyoscine-N-butylbromide is a smooth muscle relaxant that regulates bowel movements.

The column of barium within the sigmoid colon was then run out by lowering the infusion bag to the floor. Air was then gently pumped into the bowel forcing the column of barium towards the caecum thereby producing a double contrast effect. From the prone position, the patient rolled onto the left side and over into the right anterior oblique position so that the barium coated the bowel mucosa (Chapman & Nakielny, 2001: 67-70). The fluoroscopy and radiography kV, mA, mAs, and time were selected automatically through the option of automatic brightness control. Table 5.1 shows the standard series of radiographs obtained at site 1.

Table 5.1 The standard series of radiographs obtained for BaE at study site 1.

Projection	***Film size***
Lateral rectum Single Contrast	18 x 24
Lateral rectum Double Contrast	18 x 24
Sigmoid oblique	24 x 30
Descending colon	24 x 30
Splenic flexure	24 x 30
Transverse colon	35 x 35
Hepatic flexure	24 x 30
Ascending colon	15 x 24
Caecum	15 x 24
Supine overview	35 x 43
Prone overview	35 x 43
Prone 30 degrees caudad	35 x 35

5.4.2 Study site 2

Site 2 employed a DF unit with an over-couch x-ray tube.

Patient preparation

Patients had an all fluid diet a day before the examination that included black tea or coffee, water and fruit juice. Patients were given 4 packets of Go-Lytely; laxatives powder with the 4 packets each containing 68.5775 g of the laxative. Each packet was mixed with one litre of cold water that had to be finished within an hour. On the morning of the examination, patients were allowed to drink black tea or coffee.

Barium contrast medium

The barium contrast medium used at site 2 was Baritop. Baritop is microfine barium sulphate with a carbon dioxide suspension in a 300ml container. For every 100ml there is

100g of barium sulphate. This is similar to the density of the barium contrast used at study sites 1 and 3.

Dosage and mixing instructions

For the BaE procedure, 2 containers of Baritop were mixed with 1300 mls of warm water (40 degrees Celsius) in an infusion bag.

Barium enema procedure

No preliminary film of the abdomen was obtained but rather screening to check for bowel preparation. The procedure was similar to that at site 1 except for the standard projection sequence.

Site 2 employs digital fluoroscopy and less or more images than those indicated in table 5.2 were usually undertaken. There were instances where the radiologist recorded two images and the rest were post-processed from the fluoroscopy images.

Table 5.2 The standard series of radiographs obtained for BaE at study site 2

Position	***Centred at***
RAO	Recto sigmoid colon
Prone	Recto sigmoid colon
LPO	Recto sigmoid colon
Left lateral	Recto sigmoid colon
LAO(tilt table erect)	Splenic flexure
RAO(tilt table erect)	Hepatic flexure
Left lateral(tilt table erect)	Rectum
LAO (tilt table horizontal)	Caecal pole
Supine	

5.4.3 Study site 3

Study site 3 used the same barium contrast and barium enema protocol as site 1. Table 5.3 shows the standard series of radiographs obtained for BaE at site 3. Depending on the indication for the study, more or less radiographic projections were obtained.

Table 5.3 The standard series of radiographs obtained for BaE at study site 3

Area of interest	*Projection*
Lateral rectum	Left lateral
Sigmoid	Right anterior oblique Left posterior oblique Prone 30 degrees caudal
Caecum	Right anterior oblique Left anterior oblique
Splenic flexure	Left anterior oblique
Transverse colon	Antero-posterior
Hepatic flexure	Right anterior oblique
Colon overview	Supine
Colon overview	Prone

5.5 Barium meal procedure at sites 1, 2 and 3

The barium meal procedure was similar at the 3 sites. There was a standard series of radiographs obtained for BaM at site1 which employed the CF unit. Depending on the examining radiologist, the number of images recorded at sites 2 and 3 that employed DF units varied. All the anatomical areas were however demonstrated.

5.5.1 Contrast medium and preparation

The contrast medium was barium sulphate. Site 1 and 3 used Axim E-Z-HD (96% barium sulphate). This was mixed with 50mls of cold water. Site 2 used 300ml of Baritop. Gastrigas, a gas forming agent was used at all 3 sites. Each tablet contained 21.25 milligrams (mg) of sodium bicarbonate and 12.25 mg tartaric acid.

5.5.2 Contraindication of barium meal

Barium meals are contraindicated in complete bowel obstruction (Chapman & Nakielny, 2001: 67-70)

5.5.3 Patient preparation

The patients had nothing to drink or eat 6 hours before examination and smokers were advised against smoking on the day of the examination (Simpkins, 1993: 789).

5.5.4 Technique

- The patient swallowed the gas producing agent with 5ml of water
- The patient then drank the barium suspension while lying on left side to prevent the barium from reaching the duodenum quickly and obscuring the greater curve of the stomach
- While lying in the supine position and slightly to the right side, the barium got up against the gastro-oesophageal junction. Such a position aided the radiologist to check for reflux
- An intravenous injection of micro Hyoscine-N-butylbromide (20 mg/ml) was administered to the patient to relax the smooth muscle
- The patient then rolled onto the right side and over in a complete circle to coat the gastric mucosa (Chapman & Nakielny, 2001: 67-70). The sequence of radiographs recorded for the BaM is shown in table 5.4.

Table 5.4 The sequence of radiographs obtained for BaM at the 3 study sites

Position	***Demonstrates***
RAO	Antrum and greater curve with barium in the fundus
Supine	Antrum and body
LAO	Lesser curve and face
Left lateral tilted head up 45 degrees	Fundus
Prone	Duodenal loop
Prone, RAO, supine, LAO	Spot views of cap x 4
Erect	Fundus
Erect caps; RAO, steep LAO	Caps x 2
Swallow RAO	Oesophagus x 2

5.6 Data analysis

The raw data were entered into and analysed using the Microsoft Excel computer program. The data included the number of patients at each study site, the patients' weights and ages, the DAP values for BaM and BaE, the fluoroscopy times in minutes, the number of radiographic images acquired for each patient and the level of training of the examining radiologist. The average weights and ages of the BaM and BaE patient participants were calculated. The mean, median, minimum, maximum, first and third quartile DAP values were also calculated for the samples of BaM and BaE participants at the study sites.

5.6.1 Rejection of data

While recording measurements of a variable such as DAP, values are recorded that are very different from the other data points in a set of data. In this research project, patients with lower body weight but complicated radiological findings resulted in high DAP values, long fluoroscopy times and a high number of images that were very different from those of the other patients with similar body weight. Such a high DAP value arising from a low body weight patient due to a complicated radiological finding is an outlier. Inclusion of this high DAP value may result in a higher mean DAP of the sample which is not the true mean of the sample. In order to ascertain how these DAP values differed from the rest of the values in the data set, the Q test (Stones & Ellis, 2006) was used to either reject or retain the DAP values that were very different from the other data points in the sets of data at each of the 3 study sites. And the Chauvenet's criterion test (Taylor, 1997: 165-172) was used to either reject or retain the DAP values that were very different from the other data points for the combined data sets of BaM and BaE respectively. The Q and Chauvenet's criterion tests were used to reject only a single data point in any set of data and only one of the tests was used for any data set.

Q test

The Q test is a statistical test employed in the rejection of a single data point that is very different from the other data points in a set of data. The Q test is used for small study

samples of 10 or less values with a normal parent distribution. The suspect value is either the highest or lowest DAP value in data set where;

$$Q = \frac{X_{suspect} - X_{closest}}{X_{highest} - X_{lowest}}$$

If the value of Q is larger that the critical value Q_c for the corresponding number of data points as shown in table 5.5, then the suspect value is discarded. A corrected mean and standard deviation are then calculated for the data set. The Q test must only be used to discard one suspect value for a particular data set (Stones & Ellis, 2006). The Q test was used in this research project to reject or retain suspected DAP values for BaM and BaE at the each of the 3 study sites individually and corrected means and standard deviations were calculated for each site.

Table 5.5 Critical Q values (Q_c) for rejection of a single discordant value at a 90% confidence interval

Number of data points	*Critical value Q_c*
3	0.94
4	0.76
5	0.64
6	0.56
7	0.51
8	0.47
9	0.44
10	0.41

Chauvenet's criterion test

The Chauvenet's criterion is a statistical test used in the rejection of a single data point for data sets of up to 1000 data values of any parent distribution. Unlike the Q test, one must have knowledge of the standard deviation and mean of the sample so as to use the Chauvenet's criterion test. For a study sample, only one data point may be discarded using the Chauvenet's test. A data point is discarded when the critical deviation d_c is larger than the observed deviation.

The critical deviation $d_c = S\ (d/\sigma)$;

where S is the standard deviation of the sample under study and

d is deviation of the distribution of a number of data points as per Chauvenet's criterion table.

σ is the deviation and the standard deviation of the distribution of a number of data points as per Chauvenet's criterion table.

The observed standard deviation is obtained by subtracting the suspected data point from the mean of the sample (Taylor, 1997: 165-172). In this research study, the Chauvenet's criterion test was used to reject or retain suspected data points when the DAP values for all the BaM and BaE from the 3 study sites were combined.

5.6.2 Sub-problem 1

This sub-problem required the measurement of the DAP values for patients referred for BaM and BaE using DAP meters that were permanently fitted to the fluoroscopy units at the 3 study sites. The DWP (1992) recommended that DRLs must be set at the third quartile value of a sample of at least 10 adult participants of average weight of 65 kg to 75 kg. The mean weights of the patient participants and the third quartile DAP values for BaM and BaE were calculated using the Microsoft Excel computer program.

5.6.3 Sub-problem 2

This sub-problem required the comparison of DAP values obtained in this study with those from similar studies. The mean DAP values and DRLs of BaM and BaE from other studies are shown in tables 4.1[24] and 4.2[25] respectively and are compared against the mean DAP and DRLs obtained in this study. As such, it was assessed whether the values obtained in this study were higher or lower than those from other BaM and BaE dosimetry studies.

5.6.4 Sub-problem 3

This sub-problem sought to determine the factors contributing to the inter- and intra-DAP level variations among participants at the same study site and among the three study sites respectively. Carroll & Brennan (2003) and Warren- Forward et al (1998) developed variable regression models to explain the dose variations among patients and

[24] Mean and third quartile DAP values for BaM from various countries (page 28)
[25] Mean and third quartile DAP values for BaE from various countries (page 30)

study sites. The factors contributing to dose variations for BaM in decreasing order were; FT, patient's weight, fluoroscopy grid ratio and x-ray beam filtration (Carroll & Brennan, 2003). These accounted for 53% of the dose variation for BaM. The factors that accounted for the 70% of BaE dose variation in decreasing order were; FT, number of images, level of filtration, fluoroscopic grid material, radiographic grid ratio, failed colonoscopy prior to BaE and the fluoroscopic grid ratio (Carroll & Brennan, 2003).

The variation regression model developed by Warren-Forward et al (1998) for BaE included FT, number of images, patient size, applied potential, difficulty of the examination and use of digital equipment in decreasing order of affecting dose variation. This model explained 58% of the dose variation for BaE with the FT, number of images, patient size and applied potential accounting for 50% of the 58% dose variation.

The factors that were examined to explain the dose variations for BaM and BaE for this research project were; the patient's weight, fluoroscopy time, number of images, level of training of the examining radiologist and type of equipment used that is; whether a digital or conventional fluoroscopy unit. The relationship between DAP values and patients' weights and fluoroscopy times were assessed using linear regression, linear correlation coefficient, R and the coefficient of determination, R^2.

5.6.5 Linear correlation coefficient, R

A regression line was drawn for the graphs comparing DAP with patients' weights and DAP with fluoroscopy times. The linear correlation coefficient, R was calculated using the Microsoft excel computer program where;

$$r = \frac{n\sum xy - \left(\sum x\right)\left(\sum y\right)}{\sqrt{n\left(\sum x^2\right) - \left(\sum x\right)^2}\sqrt{n\left(\sum y^2\right) - \left(\sum y\right)^2}}$$

n is the number of data points (Mathbits, 2009)

R is used to measure the strength and direction of the linear relationship between two variables such as DAP and patients' weights. R takes on values greater than or equal to

negative 1 and less or equal to positive 1 ($-1 \leq R \geq +1$). A positive correlation suggests that as values of x increase, the y values increase or x values decrease as y values decrease. A negative correlation suggests that as the values of x increase, the values of y decrease or as the x values decrease, the y values increase. There is a strong linear correlation between two variables when R is either positive or negative 1. When the R values tend towards zero, there is a weak or no linear correlation between the two variables being compared. A linear correlation coefficient, R of greater than 0.8 is described as strong whereas one at 0.5 is described as weak. There is no linear correlation when R is less than 0.5 (Mckillup, 2006: 186-204; Mathbits, 2009).

5.6.6 Coefficient of determination, R^2

The coefficient of determination R^2 is a measure of how well the regression line represents the data on the scatter graph. R^2 is also referred to as the ratio of the explained variation to the total variation. R^2 is therefore greater than or equal to 0 and less than or equal to 1 ($0 \leq R^2 \geq 1$). When the regression line passes through all data points on the scatter graph then R^2 is equal to 1. This suggests a strong linear correlation between x and y values. Additionally, R^2 represents the percentage of data closest to the regression line. For example, if $R = 0.77$ then $R^2 = 0.5929$; therefore 59.29% of total variation of y values can be explained by the linear relationship between x and y. The remaining 40.71% of the total variation of y values remains unexplained by the linear relationship between x and y (Mckillup, 2006: 186-204; Mathbits, 2009).

5.6.7 Significance of the linear correlation coefficient

The statistical significance of the linear correlation coefficient was ascertained by calculating the probability levels (p-value). When the p-value was less than 0.05, the correlation between the variables compared was statistically significant. And when the p-value was greater than 0.05, the linear correlation between the two variables was not statistically significant (Mckillup, 2006:55).

5.6.8 Error bars

In order to ascertain whether the differences in the mean DAP, mean FT and mean number of images among the 3 study sites were statistically different, error bars showing

the standard error were plotted about the graph with the mean values. When the error bars overlapped, the differences between the mean values were considered not to be statistically different. However, when the error bars did not overlap, the differences in the mean values were considered statistically different (Cumming, Fidler & Vaux, 2007).

The recommended protocol for obtaining DRLs for BaM and BaE is measuring the radiation dose using DAP meters for adult patients weighing 50 kg to 90 kg (DWP, 1992). This protocol was followed in this study and the results are discussed in the next chapter.

CHAPTER 6 RESEARCH FINDINGS

This research project investigated the radiation doses received by patients referred for BaM and BaE using Dose Area Product meters that were permanently fitted to the fluoroscopy units at three hospitals in the Western Cape, SA and recommended reference dose levels for these examinations. The data collection was undertaken between June 2008 and June 2009, commencing after the legalised deadline (January 2008) for permanent installation of DAP meters to all fixed fluoroscopy equipment in SA (DoH SA, 2006). Despite this, some hospitals did not have DAP meters installed on their fixed fluoroscopy units at the time of the research study citing other hospital and departmental budget priorities superseding the acquisition of expensive DAP meters. In order to calculate reference dose levels, the DWP (1992) recommended that dose measurements be carried out on at least 10 patients weighing 50 kg to 90 kg for any examination. Such a weight range would ensure that the mean weight of the study sample lay close to 70 kg (65-75 kg) which is the average weight of an adult.

In this chapter, the mean ages, mean weights and DAP values recorded for patients referred for BaM and BaE at 3 study sites are discussed. Furthermore, an assessment of the relationship between the DAP value recorded and the patients' weights, fluoroscopy time, number of images recorded, type of equipment that is; digital or conventional and the level of training of the radiologist performing the BaM or BaE was done using linear regression, correlation coefficient, R and coefficient of determination, R^2. The statistical significance of the linear relationships between the variables was ascertained by the probability value (p-value). Additionally, error bars were used to assess whether the difference in mean DAP values, mean FT and mean images recorded at the study sites were significantly different from each other.

6.1 Barium meals

A total of 25 BaM patients were investigated in this study with four, eleven and ten patients at sites 1, 2 and 3 respectively.

6.1.1 Age

The patients' ages for BaM ranged from 27 years to 81 years with an average age of 55 years.

6.1.2 Weight

The mean weight for the 25 BaM patients was 66.4 ±8.8 kg. Figure 6.1 is a graph comparing the DAP values with the patients' weights for BaM in the study. There was no direct linear correlation (R= -0.06) between the DAP recorded and the patients' weights when a regression line was drawn through the data points in figure 6.1 thereby suggesting absence of a direct correlation between patients' weights and DAP values recorded. The patients' weights only explained 0.36% (R^2 = 0.0036) of the DAP variation due to the patients' weights. The absence of a direct correlation between DAP and patients' weights was however not statistically significant (p = 0.387) for BaM patients.

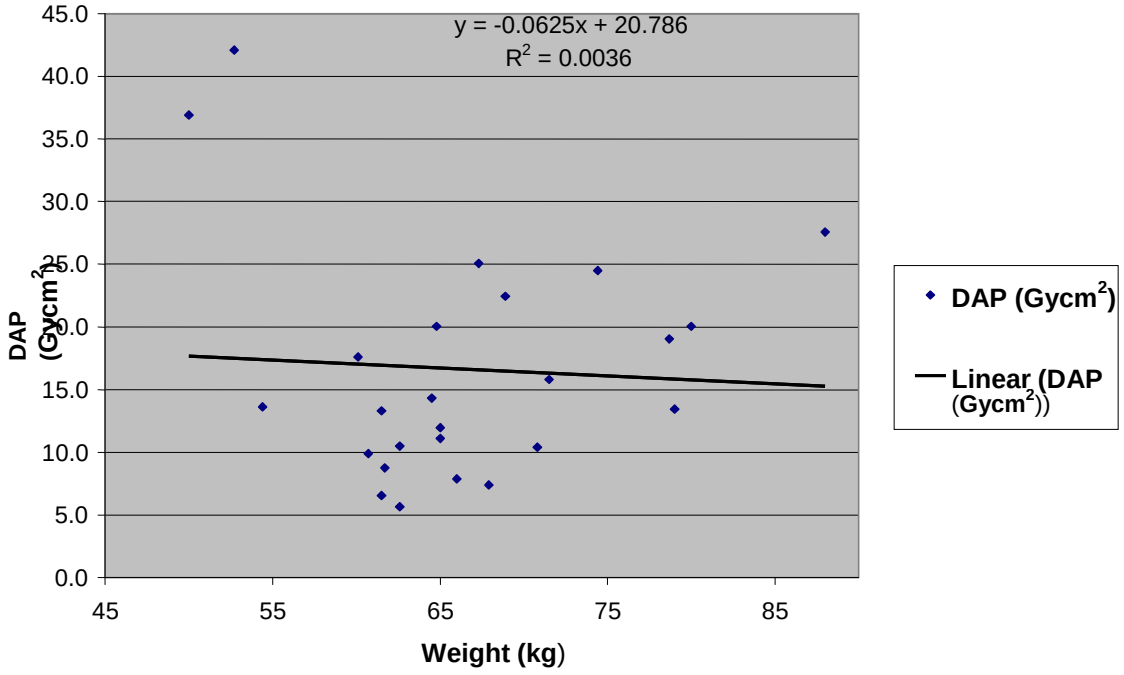

Figure 6. 1 DAP versus weight for all BaM patients

Additionally, graphs were plotted to determine the linear correlation of the DAP with patients' weights at sites 2 (figure 6.2) and 3 (figure 6.3). There were no direct linear correlations between DAP and patients' weights observed at sites 2 (R= 0.05; R^2= 0.0022; p= 0.45) and 3 (R= 0.31; R^2= 0.0979; p= 0.19). The absence of linear direct correlations between DAP and patients' weights at sites 2 and 3 were not statistically significant as the p values were greater than 0.05 (Mckillup, 2006:55).

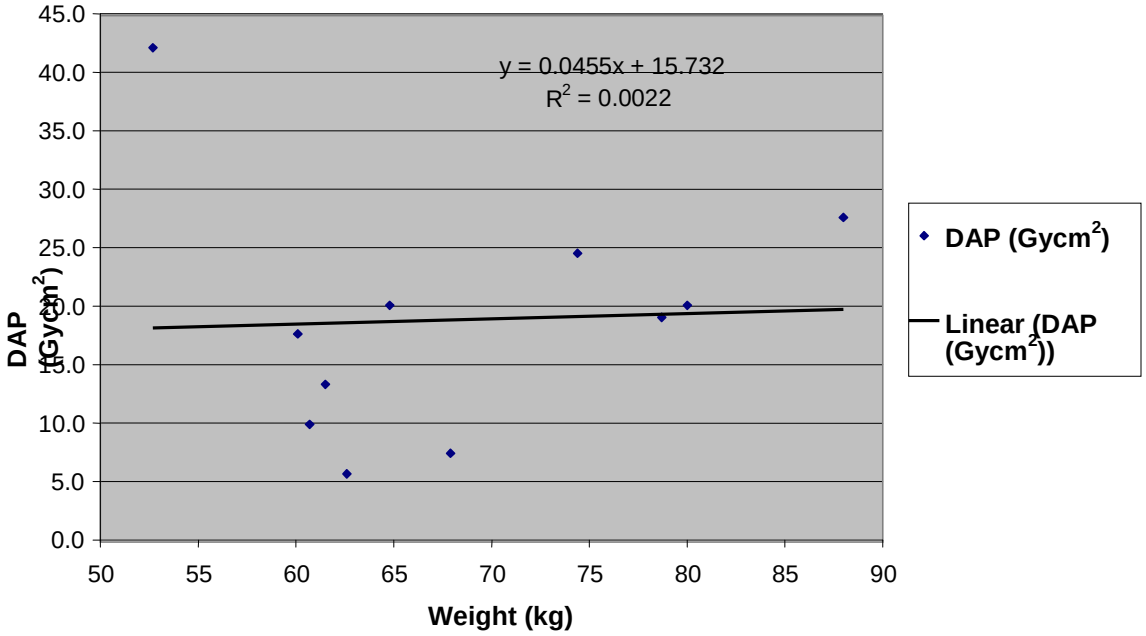

Figure 6. 2 DAP versus weight for BaM at site 2

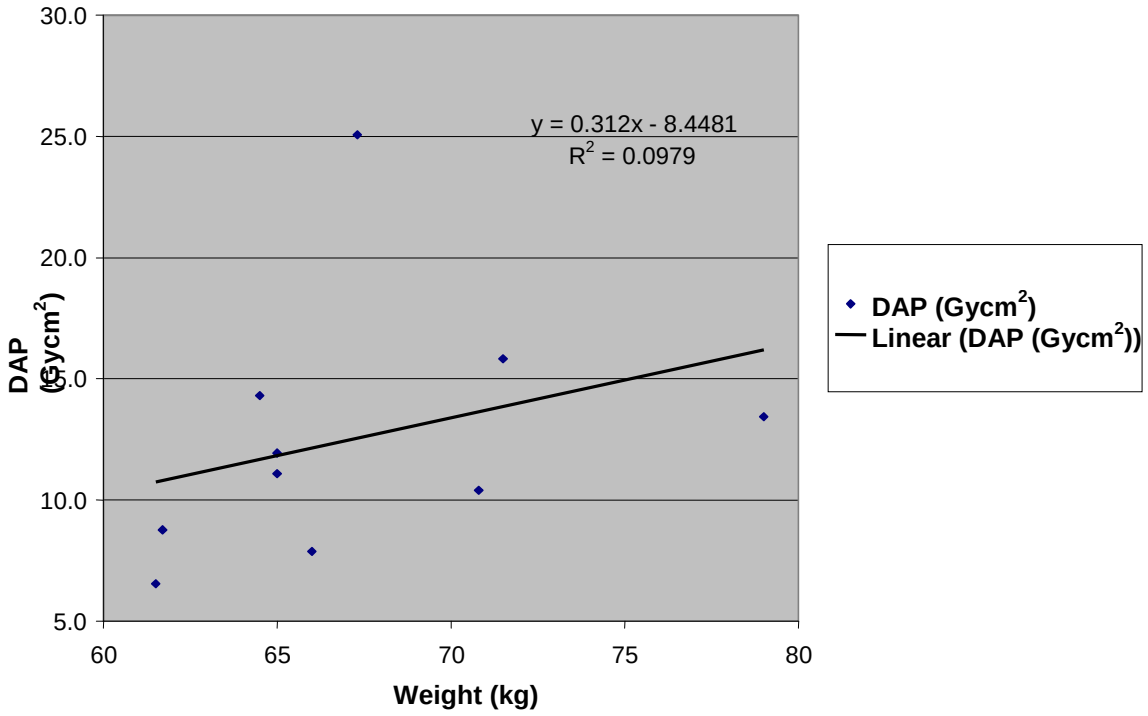

Figure 6. 3 DAP versus weight for BaM at site 3

6.1.3 DAP values

The lowest and highest DAP values for BaM were recorded at site 2 as shown in table 6.1.

Table 6.1 The mean, minimum, maximum, standard deviations, corrected mean DAP and corrected standard deviations for BaM at the 3 study sites

Study site	*n*	*Minimum*	*Mean*	*Maximum*	*STDEV*	*Corrected mean DAP*	*Corrected STDEV*
1	4	10.5	20.9	36.9	11.8	20.9	11.8
2	11	**5.7**	18.8	**42.1**	10.3	16.5	7.3
3	10	6.6	12.5	25.1	5.3	11.1	3.1
Combined	**25**	**5.7**	**16.6**	**42.1**	**9.2**	**15.6**	**7.7**

where; n is the number of patients

STDEV is the standard deviation

Corrected mean DAP and corrected STDEV were calculated after ascertaining and removing outlier points using the Q test (Stones & Ellis, 2006) for each study site data and the Chauvenet's criterion test when the data from all 3 sites were combined (Taylor, 1997: 165-172)

Site 3 recorded a mean DAP value lower than the combined mean whereas sites 1 and 2 recorded mean DAP values higher than the combined mean. The DWP recommends

dose measurements on at least 10 patients to allow comparison (DWP, 1992). The lower number of BaM patients studied at site 1 does not allow comparison of the DAP values with sites 2 and 3. The combined median, first and third quartile DAP values were 13.6 $Gycm^2$, 10.4 $Gycm^2$ and 20.1 $Gycm^2$ respectively as shown in Table 6.2.

Table 6.2 The combined median, first and third quartile DAP values for all BaM patients

n	***first quartile***	***median***	***third quartile***
25	10.4	13.6	20.1

The mean and corrected mean DAP for the 3 study sites were;

	Mean DAP	**corrected mean DAP**
1	20.9 ±11.8	20.9 ±11.8
2	18.8 ±10.3	16.5 ±7.3
3	12.5 ±5.3	11.1 ±3.1
Combined	**16.6 ±9.2**	**15.6 ±7.7**

6.1.4 Fluoroscopy time

The mean and ranges for fluoroscopy time in minutes for BaM at sites 1 and 3 sites were:

1 6.60 minutes (4.17 to 11.33 minutes)

3 8.74 minutes (4.92 to 12.85 minutes)

The combined mean fluoroscopy time for BaM at the 2 study sites was 7.67 minutes. Site 1 recorded mean FT lower than the combined mean FT whereas the mean FT at site 3 was higher than the combined mean FT. There were no FT recorded at site 2 as the fluoroscopy unit only indicated the time when a pulse of x-rays was activated. Figure 6.4 is a graph of DAP versus FT with a regression line drawn through the data points to determine presence of a direct linear correlation between the FT and the DAP recorded. There was no direct linear correlation between the DAP and FT ($R= 0.42$) with the FT explaining only 1.33% ($R^2= 0.0133$) of the variation in the DAP values. There is a weak linear correlation between two variables when the R is closer to zero than 1 (Mathbits, 2009). The absence of a direct linear correlation between DAP and FT was not statistically significant ($p= 0.067$) in this study. When p-value is greater than 0.05, there

is no statistical significance and a p-value less than 0.05 implies statistical significance (Mathbits, 2009).

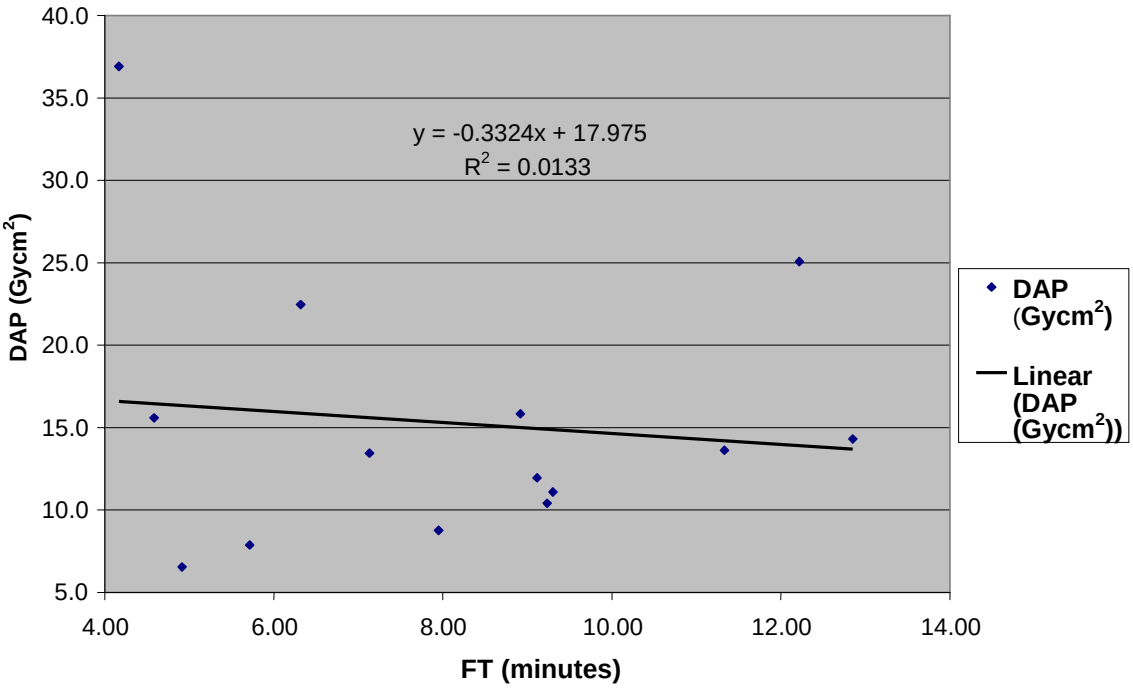

Figure 6. 4 DAP versus FT for BaM at sites 1 and 3

6.1.5 Number of images

The mean and the range number of images acquired for BaM at the 3 study sites were:

	Barium meal
1	12 (8 to 16)
2	5 (0 to 11)
3	15 (11 to 24)

The combined mean number of images recorded at the 3 sites was 10 images. Site 1 employed a conventional fluoroscopy unit and 12 images were normally acquired during a BaM procedure. The digital equipment used at sites 2 and 3 allowed for post-processing of images thereby reducing the number of images acquired in the radiographic mode of imaging. For one patient at site 2, there were no images acquired in the radiographic mode. However, the ease with which images are acquired with digital

equipment as compared with conventional equipment, allowed the acquisition of a maximum of 24 images at site 3 that employed digital fluoroscopy equipment.

6.1.6 Comparison of mean DAP, mean FT and mean number of images at the study sites

The mean DAP values, mean FT and mean number of images recorded for BaM at the 3 study sites are shown in figure 6.5. Site 1 recorded a mean DAP value higher than sites 2 and 3. Error bars plotted about the mean DAP values at the three study sites overlapped for sites 1 and 2 but not for site 3. The overlapping error bars suggested absence of a statistical difference between mean DAP values of sites 1 and 2. Since the mean DAP value error bars for either sites 1 or 2 did not overlap with that at site 3, the mean DAP value recorded at site 3 was statistically different from those recorded at sites 1 and 2.

Site 1 recorded lower mean FT than site 3 (figure 6.5). The difference in the mean FT was not statistically different as error bars plotted about the mean FT overlapped.

Of the three sites, site 2 obtained the lowest mean number of images that was statistically different from the mean images recorded at sites 1 and 3 since the error bar at site 2 did not overlap with those at sites 1 and 3. However, the mean image error bars for sites 1 and 3 overlapped suggesting absence of a statistical difference between the mean number images recorded at sites 1 and 3.

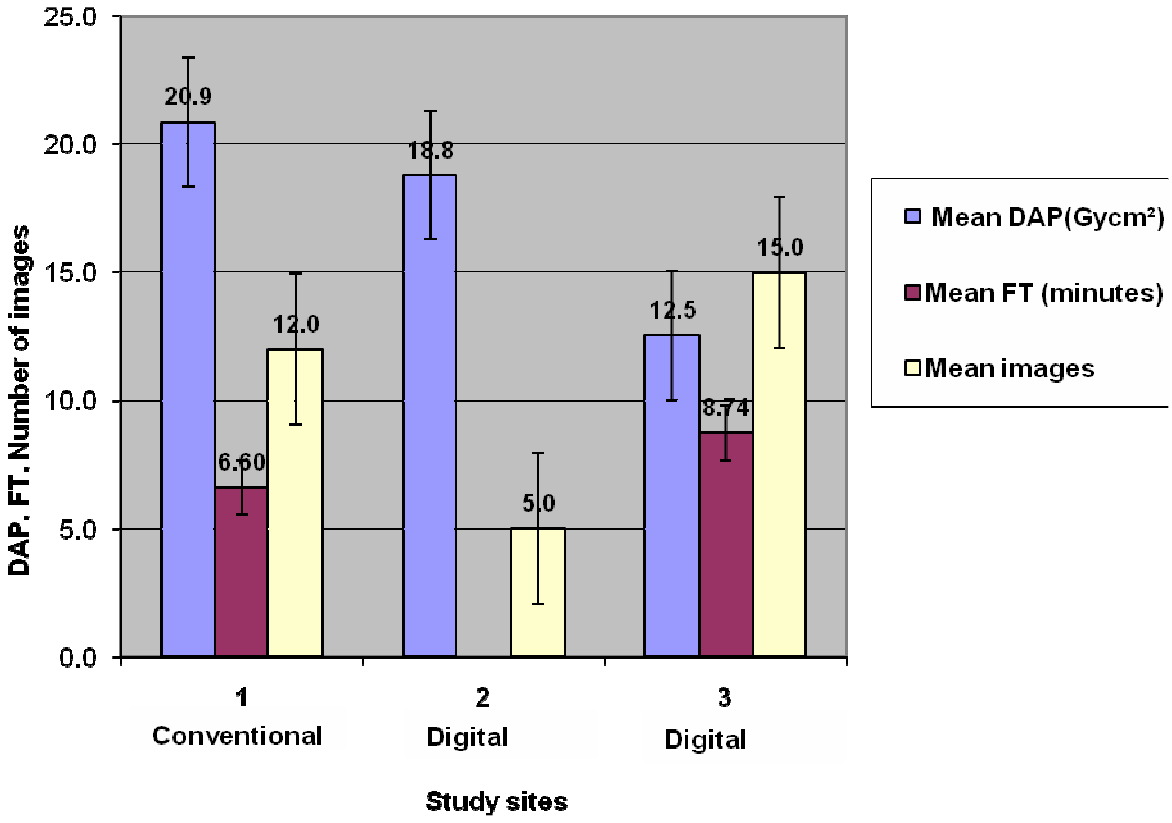

Figure 6.5 The mean DAP, mean FT and mean images obtained for BaM at the 3 study sites employing conventional and digital fluoroscopy equipment. Error bars with standard error.

6.2 Barium enemas

A total of 30 BaE patients were investigated in this study with 10 patients for each of the sites 1, 2 and 3.

6.2.1 Age

The patients' ages ranged from 36 years to 79 years with an average of 58.3 years.

6.2.2 Weight

The mean weight for the 30 BaE patients was 68.8 ±9.3 kg. Figure 6.6 is a graph comparing the DAP values with the patients' weights for all BaE in this study. There was a weak linear correlation (R= 0.55) between patients' weights and DAP values recorded when a regression line was drawn through the data points in figure 6.6. The patients' weights explained 30.35% (R^2 = 0.3035) of the DAP variation. The weak correlation between DAP and patients' weights was statistically significant (p = 0.00082) for BaE patients.

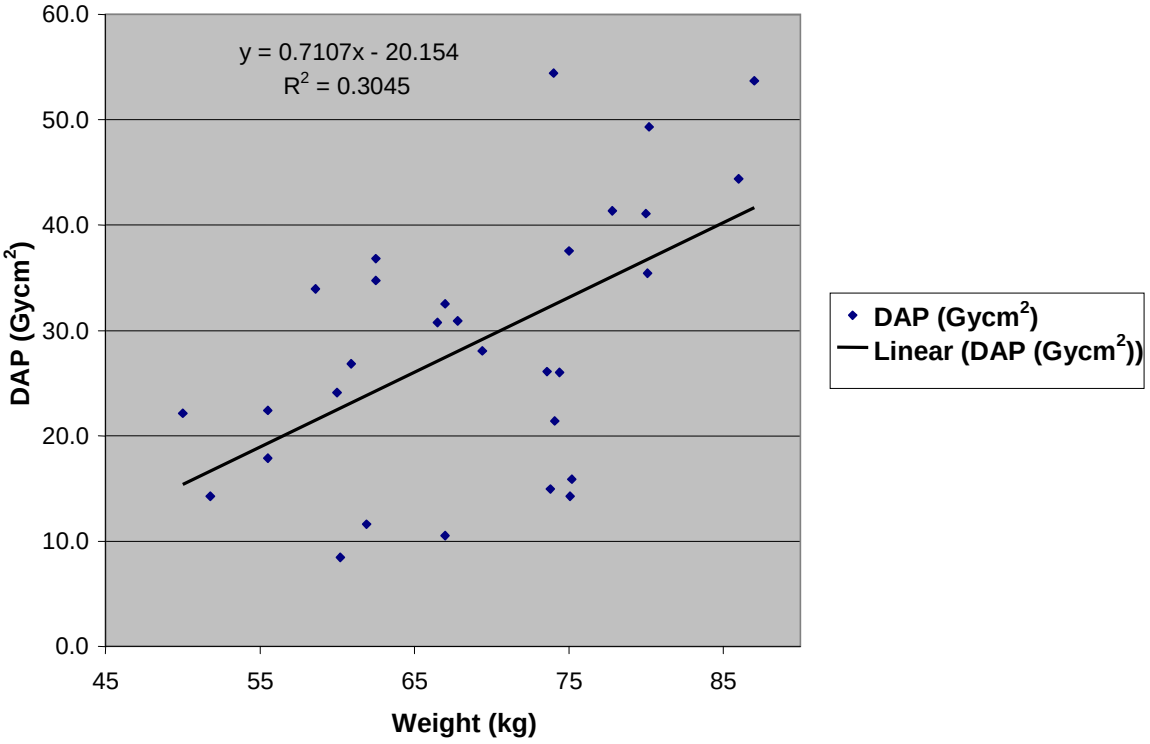

Figure 6. 6 DAP versus weight for all BaE patients

Additionally, graphs were plotted to determine the linear correlation of the DAP with patients' weights at sites 1 (figure 6.7), 2 (figure 6.8) and 3 (figure 6.9). Strong direct linear correlations were observed at sites 1 (R= 0.77; R^2= 0.596; p= 0.0046), 2 (R= 0.78; R^2= 0.6072; p= 0.0039) and 3 (R= 0.62; R^2= 0.3815; p= 0.0279) and these were statistically significant.

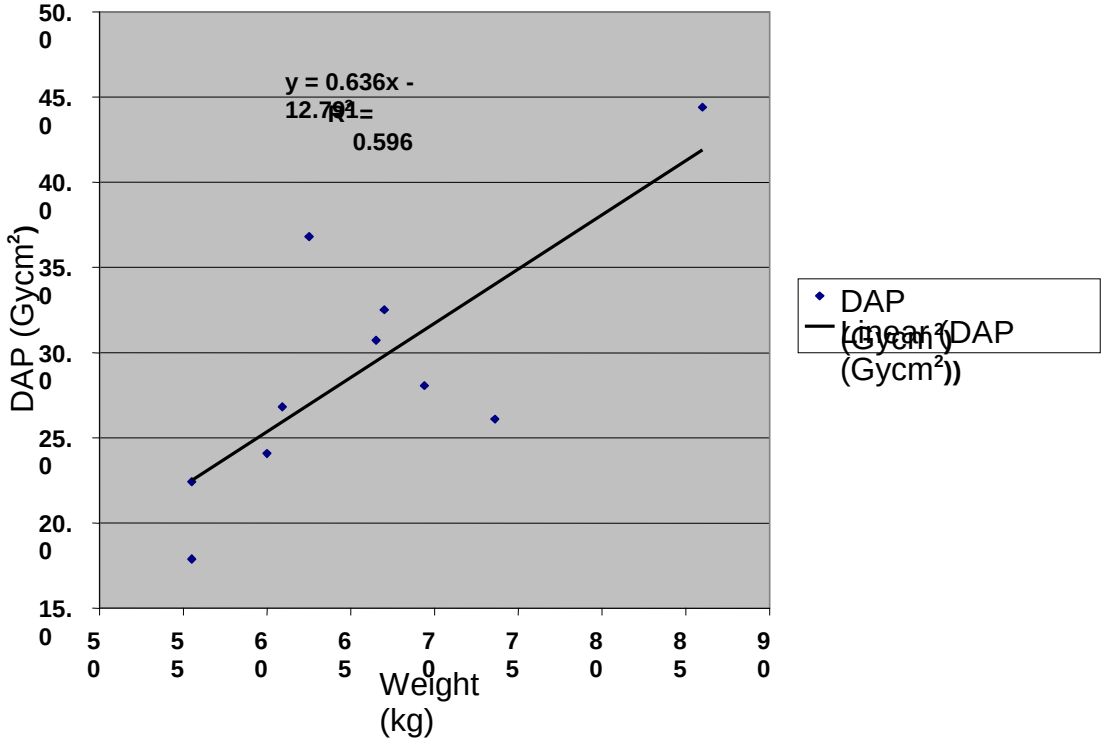

Figure 6.7 DAP versus weight for BaE at site 1

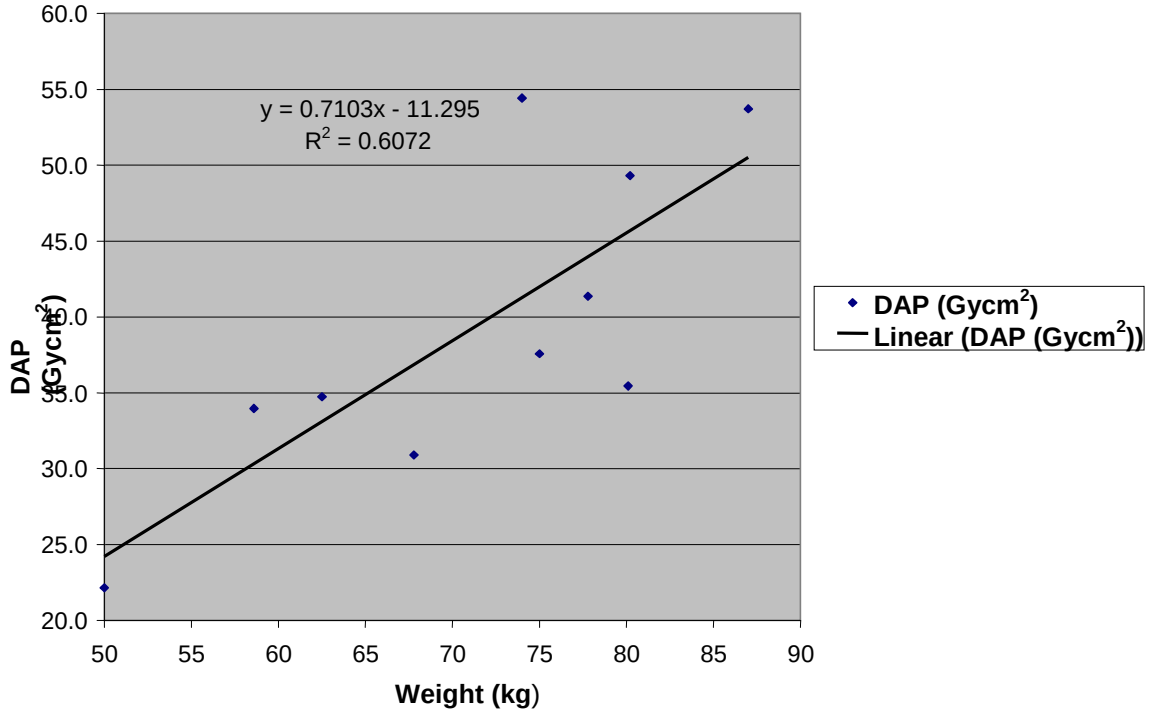

Figure 6. 8 DAP versus weight for BaE at site 2

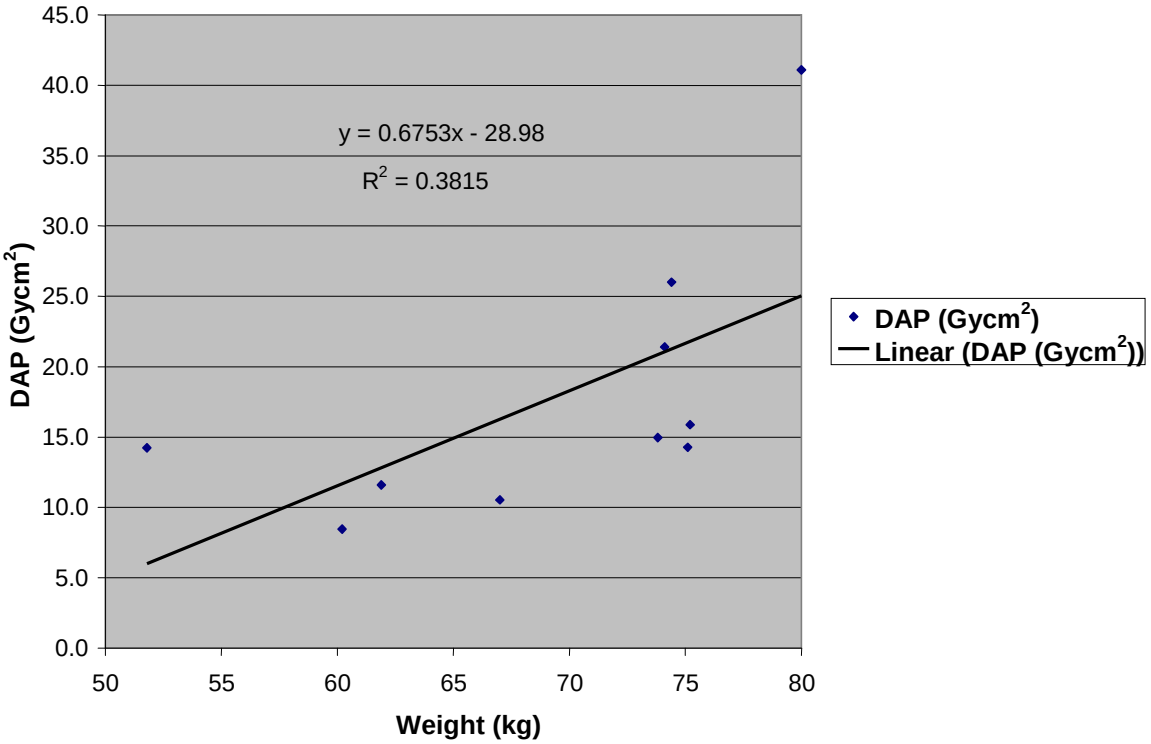

Figure 6. 9 DAP versus weight for BaE at site 3

6.2.3 DAP values

The lowest and highest DAP values for BaE were recorded at site 3 and site 2 respectively as shown in table 6.3.

Table 6.3 The mean, minimum, maximum, standard deviations, corrected mean DAP and corrected standard deviations for BaE at the 3 study sites

Study site	*n*	*Minimum*	*Mean*	*Maximum*	*STDEV*	*Corrected mean DAP*	*Corrected STDEV*
1	10	17.9	29.0	44.4	7.6	29.0	7.6
2	10	22.1	39.4	**54.4**	10.4	39.4	10.4
3	10	**8.5**	17.9	41.1	9.7	15.3	5.5
Combined	**30**	**8.5**	**28.7**	**54.4**	**12.7**	**28.7**	**12.7**

The combined mean DAP value was 28.7 Gycm^2. Site 3 recorded a mean DAP value lower than the combined mean while sites 1 and 2 recorded mean DAP values higher than the combined mean. The combined median, first and third quartile DAP value are 27.4 Gycm^2, 18.8 Gycm^2 and 36.5 Gycm^2 respectively as shown in table 6.4.

The mean and corrected mean DAP for the 3 study sites were;

	Mean DAP	**corrected mean DAP**
1	29.0 ±7.6	29.0 ±7.6
2	39.4 ±10.4	39.4 ±10.4
3	17.9 ±9.7	15.3 ±5.5
Combined	**28.7 ±12.7**	**28.7 ±12.7**

Table 6.4 The combined median, first and third quartile DAP values for all the BaE

n	*First quartile*	*Median*	*Third quartile*
30	18.8	27.4	36.5

6.2.4 Fluoroscopy time

The mean and ranges for fluoroscopy time in minutes for BaE at sites 1 and 3 sites were:

1 3.93 minutes (2.75 to 5.95 minutes)

3 6.63 minutes (4.43 to 8.53 minutes)

The combined mean fluoroscopy time for BaE at the 2 study sites was 5.28 minutes. There were no fluoroscopy times recorded at site 2 as the fluoroscopy unit only indicated the time when a pulse of x-rays was activated which were not representative of the total FT. Site 1 recorded mean FT lower than the combined mean FT while site 3 recorded a mean FT higher than the combined mean FT.

Figure 6.10 is a graph of DAP versus FT with a regression line drawn through the data points to determine presence of a direct linear correlation between the FT and the DAP recorded. There was no direct linear correlation between the DAP and FT (R= -0.26) with the FT explaining only 6.9% (R^2= 0.0133) of the variation in the DAP values. There is no linear correlation between two variables when the R is closer to zero than 1 (Mathbits, 2009). The absence of a direct linear correlation between DAP and FT was not statistically significant (p= 0.134) in this study. When p-value is greater than 0.05, there is no statistical significance and a p-value less than 0.05 implies statistical significance (Mathbits, 2009).

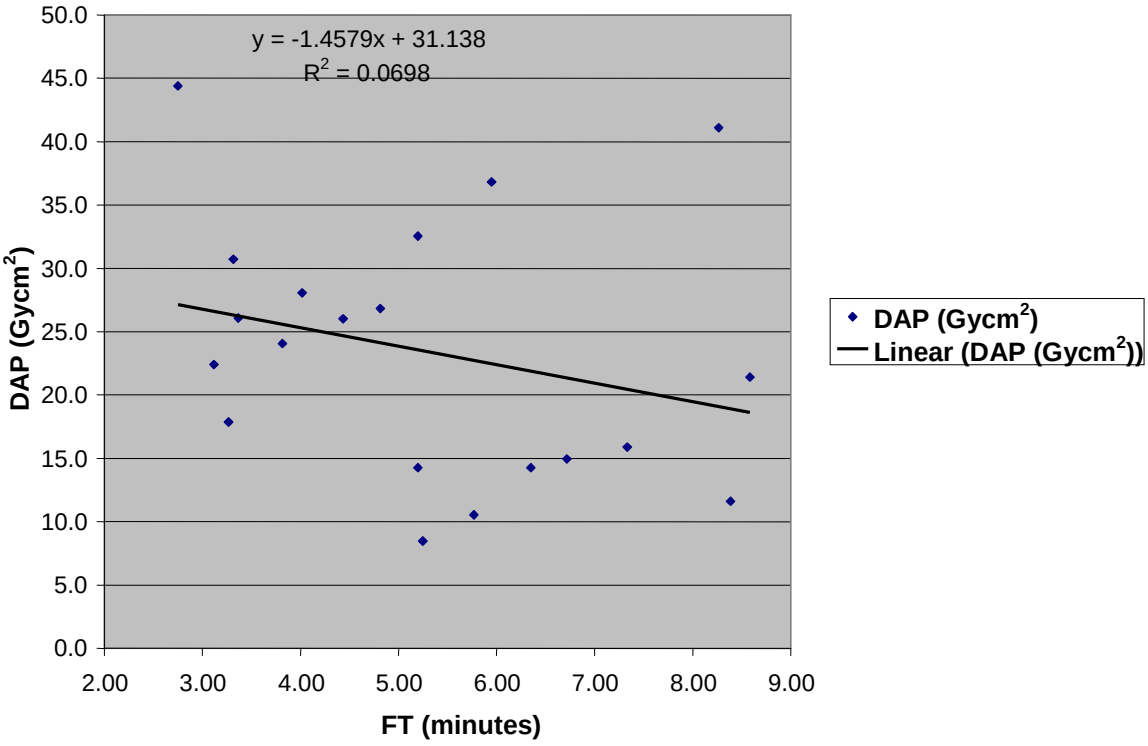

Figure 6. 10 DAP versus FT for BaE at sites 1 and 3

6.2.5 Number of images

The mean and the range number of images acquired for BaE at the 3 study sites were:

1	12 (12 to 14)
2	11 (1 to 18)
3	13 (9 to14)

The combined mean number of images recorded at the 3 sites was 12. At site 1, a conventional fluoroscopy unit was employed and 12 radiographic images are the norm for BaE. Due to repeat radiographs resulting from exclusion of the required anatomy on prior radiographs, one patient at site 1 had a total of 14 images recorded. The digital equipment used at sites 2 and 3 allowed for post-processing. A patient at site 2 had only one image recorded in the radiographic mode.

6.2.6 Comparison of mean DAP, mean FT and mean number of images at the study sites

The mean DAP values, mean FT and mean number of images recorded for BaE at the 3 study sites are shown in figure 6.11. Site 2 recorded the highest mean DAP value of the three study sites. Error bars plotted about the mean DAP values at the three study sites overlapped for sites 1 and 2 and sites 1 and 3 thereby suggesting absence of statistical differences between the mean DAP values recorded for sites 1 and 2 and also for sites 1 and 3. Since the mean DAP value error bar for site 2 did not overlap with that of site 3, the mean DAP value recorded at site 2 was statistically different from the mean DAP value at site 3.

Site 1 recorded lower mean FT than site 3 (figure 6.11). The difference in the mean FT was not statistically different as error bars plotted about the mean FT overlapped.

Of the three study sites, site 2 obtained the lowest mean number of images that was statistically different from the mean images recorded at sites 3 since the error bar at site 2 did not overlap with that at site 3. However, the mean image error bars for sites 1 and 2 overlapped thereby suggesting absence of a statistical difference between the mean number images recorded at sites 1 and 2.

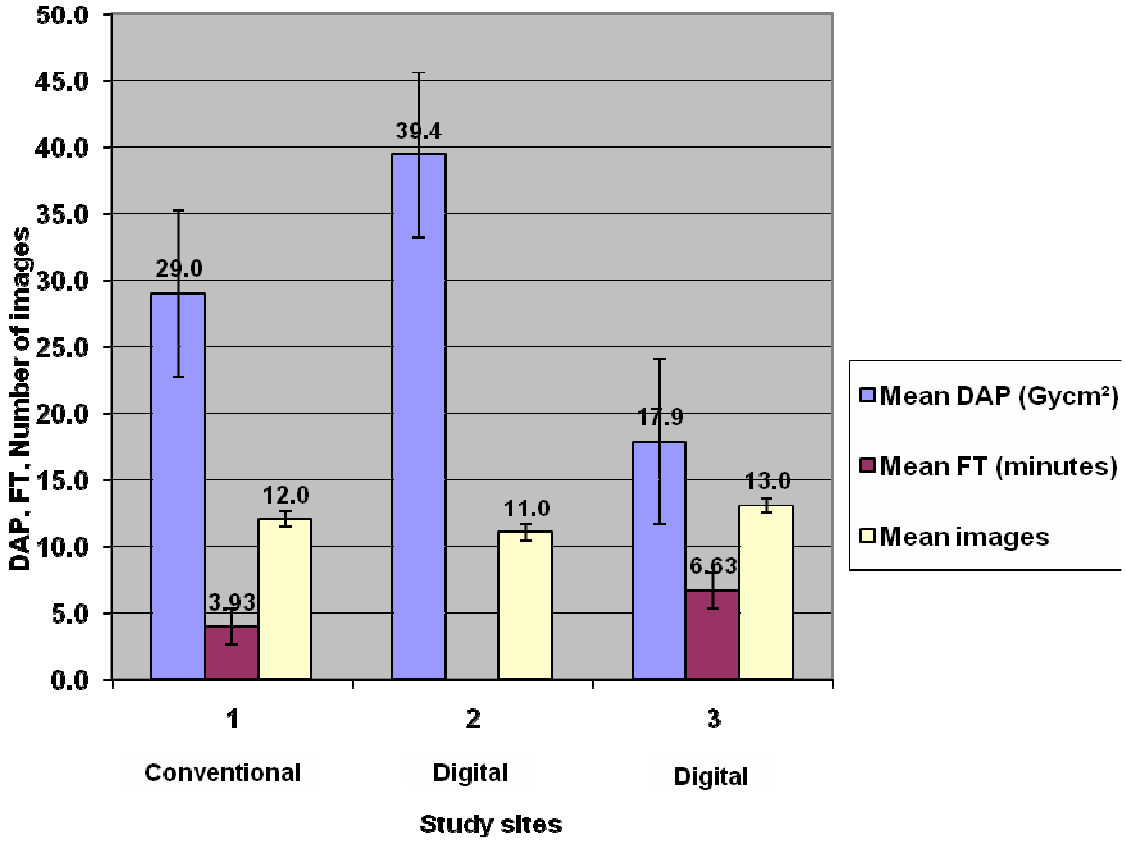

Figure 6. 11 The mean DAP, mean FT and mean images obtained for BaE at the 3 study sites employing conventional and digital fluoroscopy equipment. Error bars with standard error.

6.3 Level of training of the radiologist

The BaM and BaE at site 1 were performed by the same consultant radiologist using a standard technique. At sites 2 and 3, the BaM and BaE were performed by radiology registrars at various levels of training. In order to compare the resultant DAP value with the level of training of the radiologist performing the examination, the same fluoroscopy unit is considered to eliminate equipment related factors affecting the DAP reading. Two radiology registrars at different levels of training performing BaE that both described as standard examinations were compared at site 2. In addition to obtaining a higher number of images (18 images), the first year registrar recorded a higher DAP value (37.57 $Gycm^2$) than the registrar in the fourth year of training (1 image; 22.15 $Gycm^2$). With the exception of factors such as difficulty of the examination, patient's weight and the radiological finding influencing the DAP reading, the level of training of the radiologist

performing the BaM or BaE affected the dose delivered to patients referred for BaM or BaE in this study.

6.4 Digital versus conventional fluoroscopy units

In this research project, site 1 employed a CF unit and sites 2 and 3 utilised DF units. While site 1 recorded mean DAP values of 20.9 $Gycm^2$ and 29.0 $Gycm^2$ for BaM and BaE respectively, mean DAP values of 12.5 $Gycm^2$ and 17.9 $Gycm^2$ were recorded at site 3 for BaM and BaE respectively (figures 6.5[26] and 6.11[27]). Despite the DF unit at site 3 recording lower mean DAP values than the CF unit at site 1 for both BaM and BaE, overlapping error bars were obtained for BaE (figure 6.11) but not for the BaM (figure 6.5). The overlapping error bars for the BaE suggested absence a statistical difference between the mean DAP values of the BaE at sites 1 and 3. For BaM, the error bars about the mean DAP values did not overlap for sites 1 and 3 thereby suggesting presence of statistical difference between the mean DAP values (Cumming et al, 2007). However, it must be noted that only 4 BaM patients were investigated at site 1 compared to the 11 BaM patients at site 3. It is therefore unknown whether collection of more data at site 1 would have given the same results

[26] The mean DAP, mean FT and mean images obtained for BaM at the 3 study sites employing CF and DF units (page 64)
[27] The mean DAP, mean FT and mean images obtained for BaE at the 3 study sites employing CF and DF units (page 72)

CHAPTER 7 DISCUSSION

This study determined the radiation doses received by patients referred for BaM and BaE at 3 hospitals in the Western Cape, SA and obtained potential Diagnostic Reference dose Levels for these examinations. Additionally, the factors responsible for the variation in radiation doses among the study sites were investigated and are discussed in this chapter.

Barium meals

The mean age of the patients was 58.7 years with mean weight of 66.4 kg. This mean weight is within the 65 kg to 75 kg weight range recommended by the DWP (1992) for the sample from which DRLs are determined. The first and third quartiles, mean and median DAP values for BaM were 10.4 $Gycm^2$, 20.1 $Gycm^2$, 16.6 $Gycm^2$ and 13.6 $Gycm^2$ respectively. The DRL for BaM from this study is 20.1 $Gycm^2$ following the recommendation to set DRLs to the third quartile DAP value (DWP, 1992). This DRL is higher than those obtained in the UK: 13 $Gycm^2$ (Hart et al, 2007), Ireland: 17 $Gycm^2$ (Carroll & Brennan, 2003) and Serbia: 18 $Gycm^2$ (Ciraj et al, 2005b) as shown in table 4.1[28]. The mean DAP value of 16.6 $Gycm^2$ recorded in this study was lower than those recorded internationally except in the UK (Hart et al, 2007) and Ireland (Carroll & Brennan, 2003) as shown in table 4.1.

Barium enemas

The mean age of the patients was 58.3 years with mean weight of 68.8 kg. The mean weight obtained in this study is within the 65 kg to 75 kg weight range recommended by the DWP (1992) from which DRLs are determined. Engel-Hills and Hering (2001) recorded mean age of 55.6 years and mean weight of 69.5 kg while investigating radiation doses for BaE in the Western Cape, SA. The first and third quartiles, mean and median DAP values for BaE in this study were 18.8 $Gycm^2$, 36.5 $Gycm^2$, 28.7 $Gycm^2$ and 27.4 $Gycm^2$. The DRL for BaE from this study is 36.7 $Gycm^2$ following the DWP (1992) to set the DRL to the third quartile DAP value. Though this DRL is higher than that

[28] The mean and third quartile DAP values recorded for BaM from various countries (page 28)

obtained in the UK: 24 $Gycm^2$ (Hart et al, 2007), there was a 56.5 % radiation dose reduction when compared with a similar study in SA (Engel-Hill & Hering, 2001). The trend to record lower DAP values in subsequent dosimetry studies in the same geographical location (Hart et al, 2007; Hart et al, 2002; Hart et al, 1996) owing to improved radiation protection procedures and installation of dose saving fluoroscopy equipment was observed in this work. The mean DAP values recorded in this study were lower than those recorded internationally except in the UK (Hart et al, 2007) as shown in table 4.1.

Though third quartile DAP values have been recommended as the dose levels at which DRL must be set, the median DAP values provide dose levels that are less affected by extreme outliers such as under and over weight of the patients (Yakoumakis et al, 1999). For this reason, the median DAP values recorded for BaM (13.6 $Gycm^2$) and BaE (27.7 $Gycm^2$) in this study are recommended as the DRL for the Western Cape, SA. The adoption of the first quartile values as the DRLs is not recommended as these dose levels may be too low that the image quality is compromised (Roberts, 1992). The first quartile values of 10.4 $Gycm^2$ for BaM and 18.8 $Gycm^2$ recorded in this study can therefore be adopted as dose level for investigation of image quality in the radiology department.

During this study, radiology personnel were very keen on knowing how DAP is converted into effective dose so that they can actively monitor the radiation doses delivered to the patients during BaM and BaE. This suggests that radiology personnel are concerned about the radiation doses they deliver to their patients and are interested in keeping them as low as reasonably achievable. The DRLs recommended in this study will therefore serve as quick dose references for radiology personnel not to exceed when operating under normal diagnostic and technical conditions (ICRP, 1996). The ability of the DAP meter to integrate the absorbed dose over whole beam area for the total exposure to the patient and provide a single measurement for BaM and BaE (DWP, 1992) allows the exclusive use of DAP measurements without converting them to effective dose (Matthews & Brennan, 2008). This saves the radiology personnel time spent converting DAP values to effective dose. It was however noted during the research study period that most radiology personnel were more familiar with radiation dose being measured in milli

Sievert than Dose Area Product. The radiology personnel constantly sought additional information from the researcher on how to calculate the effective dose from the DAP to ascertain the quantity of radiation they delivered to the patients. Hart et al (1994) found 0.2 and 0.28 were suitable conversions coefficients for DAP to effective dose for BaM and BaE respectively. For example, for a DAP of 12 $Gycm^2$ recorded for a BaM; this value is multiplied by 0.2 to obtain the effective dose to the patient. In this case, the effective dose is 2.4 Sieverts. Radiology personnel need to be made aware of the DAP so that they can use it without converting it to effective dose.

Patients' weight for Barium meal

In this study, there were no direct linear correlations between patients' weight and DAP recorded for BaM with the 3 sites combined (figure 6.1[29]) and when sites 2 (figure 6.2[30]) and 3 (figure 6.3[31]) were individually investigated. The correlation coefficients were R less than 1 (Mathbits, 2009). The absence of direct linear correlations between patients' weight and DAP recorded for BaM were however not statistically significant with p values of greater than 0.05 (Mathbits, 2009) as shown in table 7.1.

Table 7.1 The correlation coefficient R, coefficient of determination R^2 and p values for BaM at the study sites

Study sites	***R***	***R^2***	***p value***
2	0.05	0.0022	0.45
3	0.31	0.0979	0.19
1, 2, 3	-0.06	0.0036	0.387

The variation of DAP with patients' weight was not determined for site 1 as only 4 BaM patients fitted the research project inclusion criterion of weighing 50 kg to 90 kg. Furthermore, a minimum of 10 patients is recommended to allow comparison and development of DRLs (DWP, 1992). The absence of a direct linear correlation between patients' weight and DAP in this study can be attributed to the high degree of emaciation

[29] DAP versus weight for all BaM patients (page 58)
[30] DAP versus weight for BaM at site 2 (page 59)
[31] DAP versus weight for BaM at site 3 (page 60)

in gastric and oesophageal cancer patients who report for BaM in the late stages of the disease. Carroll and Brennan (2003) found patients' weight to contribute to the 58% DAP variation in their BaM dosimetry study.

Patients' weight for Barium enema

In this study, a weak linear correlation R, 0.55 (R^2= 0.3035) between DAP and patients' weight was observed with BaE when the 3 sites were combined and this weak correlation was statistically significant (p=0.00082). Furthermore, when the study sites were individually investigated, strong linear correlation between the patients' weight and the DAP were observed at the 3 sites as shown in figures 6.7[32], 6.8[33] and 6.9[34]. These strong linear correlations between patients' weight and DAP were statistically significant with p values of less than 0.05 as summarised in table 7.2. When sites are individually investigated, equipment differences among the sites that may affect the DAP value are minimised as the same fluoroscopy unit was used for all the patients at a study site. The strong correlations observed between DAP and patients' weight for BaE at sites 1, 2 and 3 are in agreement with Carroll and Brennan (2003) and Warren-Forward et al (1998)'s findings of the patient's weight contributing to the 70% and 58% variation in DAP for BaE respectively.

Table 7.2 The correlation coefficient R, coefficient of determination R^2 and the p values for BaE at the study sites

Study sites	***R***	***R^2***	***p values***
1	0.77	0.596	0.0046
2	0.78	0.6072	0.0039
3	0.62	0.3815	0.00279
1,2,3	0.55	0.3035	0.00082

[32] DAP versus weight for BaE at site 1 (page 66)
[33] DAP versus weight for BaE at site 2 (page 67)
[34] DAP versus weight for BaE at site 3 (page 67)

Fluoroscopy time

In this study, the mean FT for BaM and BaE were 7.67 minutes and 5.28 minutes respectively. Sites 2 and 3 employed DF[35] units with pulsed fluoroscopy capability. Unlike site 3 that recorded the complete FT, the DF unit at site 2 only recorded the time for emission of each pulse of x-rays. Such time measurements were not a true reflection of the total FT. As such, only FT recorded at sites 1 and 3 were considered for this study. Site 1 recorded lower mean FT for both BaM and BaE than site 3. The lower FT at site 1 is attributed to the consultant radiologist with more than 5 years experience performing the BaM and BaE in contrast to the registrars at site 3. Yakoumakis et al (1999) found radiologist registrars to register FT of the order of 6.45 minutes (BaM) and 9.1 minutes (BaE) as compared to qualified radiologists who recorded 3.1 minutes (BaM) and 3.2 minutes (BaE). Though the FT may be affected by the dynamic nature and findings of the examination, radiologists are capable of controlling the FT by modifying the technique used for BaM and BaE (Vehmas et al, 2000; Verdun et al, 2005).

Fluoroscopy time has been identified as one of the factors responsible for DAP variation (Carroll & Brennan, 2003) with total DAP reduction of 11% possible with decreased FT (Horton et al, 1992). In this study however, there were no direct correlations between DAP and FT for BaM (R=0.42) and BaE (R=-0.26). The correlation coefficients R, were less than 1 (Mathbits, 2009). The absence of these direct correlations between the FT and DAP were however not statistically significant for BaM (p= 0.067) and BaE (0.134). The absence of direct correlations between DAP and FT for BaM and BaE in this study may be attributed to comparing radiologists with different levels of experience using different equipment types. At site 1, a consultant radiologist performed the examinations using a CF[36] unit whereas registrars using DF units performed the BaM and BaE at site 3. Warren-Forward et al (1998) recorded lower FT with DF (1.63 minutes: 2.63 minutes) as compared with CF (1.97 minutes: 2.47 minutes) for BaM and BaE respectively.

[35] Digital fluoroscopy
[36] Conventional fluoroscopy

Digital versus conventional fluoroscopy units

Site 1 employed a CF unit while sites 2 and 3 employed DF units. Site 3 recorded mean DAP values lower than those at site 1 for both BaM and BaE. There was no statistical difference between the mean DAP values for BaE at sites 1 and 3. Although, there was statistical difference between the mean DAP value for BaM at sites 1 and 3, only 4 BaM patients were investigated at site 1 compared to the 11 patients at site 3. It is therefore not known whether investigating an equal number of patients at both sites would have resulted in absence of a statistical difference between of mean DAP values.

Nevertheless, the capacity of DF units to maintain lower doses than CF units was realised in this study. Radiology registrars associated with long FT and high number of images maintained lower mean DAP values using the DF unit at site 3 compared to the radiology consultant with more than 5 years experience employing the CF unit at site 1. Dose savings of over 50% have been recorded with DF for BaM and BaE as compared to CF as shown in table 7.3 (Broadhead et al, 1995; Geleijns et al, 1998; Warren-Forward et al, 1998). Broadhead et al (1995) found the doses delivered by DF units to be significantly lower than those of CF units with standard errors of more that ±3 at the 95% confidence interval. Warren-Forward et al (1998) realised 15% dose savings for BaE and attributed these low DF dose savings to the enormous number of images obtained during BaE.

Table 7.3 Mean DAP values recorded for DF and CF units for BaM and BaE

	Mean DAP (Gycm^2)	
	DF	***CF***
BaM	**7.75**	24.18 **(Broadhead et al, 1995)**
	15	28 **(Geleijns et al, 1998)**
	11.39	21.26 **(Warren-Forward et al, 1998)**
	12.5	20.9 (This study)
BaE	***13.88***	*25.35* ***(Broadhead et al, 1995)***
	25	*28* ***(Warren-Forward et al, 1998)***
	17.9	*29 (This study)*

Despite employing a DF unit with pulsed fluoroscopy capability and acquiring images at low mean frame rates of 7.5, dose saving of only 10% was realised at site 2 for BaM when compared with site 1 (figure 6.5). For BaE, site 2 recorded mean DAP higher by

26.4% (figure 6.11) than that at site 1 in spite of the dose saving associated with low frame rates (Trapp & Kron, 2008). The shortcoming of imaging at low frame rates is increased image noise. In order to compensate the image noise arising from low frame rates, manufacturers increase the mA[37] setting of the DF unit. With high mA settings, the resultant dose does not decrease by the same amount as the frame rate. For example, decreasing the frame rate from 30 to 15 frames per second will not result in a 50% dose saving but rather 25% to 28% (Mahesh, 2001). At site 2, high mA ranges of 82 mA to 150 mA were used for fluoroscopy. Such high mA settings among other factors such as registrars performing the BaM and BaE may have caused the high DAP readings at site 2.

A step in realising the dose saving possibilities of DF is the training of radiology personnel in the dose saving capabilities of such units without compromising image quality (Martin, 2004). The increasing advancement in DF without additional training to radiology personnel using these units results in the under utilisation of the dose saving features of the equipment.

Awareness of being monitored

The awareness of being monitored serving as an incentive to reducing radiation doses to the patients (Crawley et al (1998); Horton et al (1992)) was observed in this study. Radiologists were concerned about the radiation doses they delivered to the patients and constantly inquired whether the dose delivered to the patients was within acceptable limits. However, without indication of which radiologist delivered what amount of radiation dose to the patient, some registrars became reluctant about the radiation doses they delivered to the patients. The adoption of dose measurement practices by radiology departments and nationally with identification of departments delivering high radiation doses may therefore result in radiology personnel minimising radiation dose to patients citing their dose delivery being constantly monitored.

[37] milliampere (tube current)

CHAPTER 8 CONCLUSION

Diagnostic reference levels were primarily introduced to avoid situations of high patient radiation exposure without clinical justification. Furthermore, these dose levels were not to be exceeded when departments were operating under normal diagnostic and technical practices (ICRP, 1996). The DRLs were set at the third quartile level with the first quartile serving as a dose level at which the image quality is monitored. In cases where the third quartile DAP values are high, the median DAP values are adopted as these are less affected by outliers such as under and over weight of patients (Yakoumakis et al, 1999).

This project investigated the radiation doses received by patients referred for BaM and BaE so as to obtain potential diagnostic reference dose levels for these examinations in the Western Cape, SA. The DRLs developed from this study were compared with those obtained from similar dosimetry studies and causes of dose variation among the study sites were determined.

The third quartile DAP values obtained in this study were 20.1 $Gycm^2$ and 36.5 $Gycm^2$ for BaM and BaE respectively. Though these DAP values are higher than the DRLs recorded in the UK (Hart et al, 2007) of 13 $Gycm^2$ and 24 $Gycm^2$ for BaM and BaE respectively, they are lower than those obtained an earlier study in SA (Engel-Hills, 1997). Following the ICRP (1996) recommendations on country and regional specific DRLs, comparison with the Engel-Hills (1997) study provides an indication of doses delivered to patients in Western Cape, SA.

Since the median values are less affected by outliers such as patients' weight, 13.6 $Gycm^2$ and 27.4 $Gycm^2$; the median values obtained in this study are the recommended DRLs for BaM and BaE respectively in the Western Cape, SA.

There was no direct correlation between patients' weight and DAP recorded for BaM. This was attributed to the emaciation of patients reporting for BaM. The absence of

direct linear correlation between DAP and patients' weight was not statistically significant.

Investigation of linear correlation between DAP and patients' weight for BaE with measurements from the 3 sites combined resulted in a weak positive correlation which was statistically significant. When the correlation between DAP and patients' weight for each site for BaE was investigated, strong positive correlations that were statistically significant were obtained suggesting that; as the patients' weight increased, the DAP also increased and DAP decreased with decreased patients' weight for BaE.

There were no direct correlations between the FT and DAP recorded in this study for BaM and BaE at sites 1 and 3. These correlations were however not statistically significant. This was attributed to comparing radiologists with different levels of training using different types of equipment. A consultant radiologist with more than 5 years experience, recording short FT at a CF unit at site 1 was compared with registrars recording high FT at a DF unit at site 3. The dose saving features of the DF unit maintained lower DAP values despite the high FT recorded at site 3.

In this study, there was no statistical difference between the mean DAP values recorded for the DF and CF units at sites 1 and 3 for BaE as the error bars overlapped. There was however a statistical difference between the mean DAP values for DF and CF units for BaM at sites 1 and 3. The difference in the number of patients investigated at sites 1 and 3 creates an uncertainty of whether a statistical difference between the mean values of the two equipment units would have existed with equal number of patients at the study sites. It is therefore recommended that more data be collected on DF and CF units so as to allow dose comparisons for these units.

Despite this, the capacity of DF units to record lower radiation dose than CF units was realised with radiology registrars associated long FT and high number of images maintaining lower mean DAP values on the DF unit compared to a radiologist with more than 5 years experience. However, training of radiology personnel in the dose saving

features of DF units may raise the dose savings to over 50% as recorded in other dosimetry studies (Geleijns et al, 1998; Warren-Forward et al, 1998; Broadhead et al, 1995).

Limitations of the study

The results of this study provided information on the dose levels for BaM and BaE in the Western Cape, SA. The study was however limited to public hospitals as the private sector did not perform sufficient BaM and BaE to allow the data collection process to be completed within the allocated research project time frame. Additionally, the private sector employed newer advanced equipment such as multi-detector CT that was opted for investigating of the GIT as compared to BaM and BaE.

Another limitation was the low number of BaM patients investigated at site 1. Only 4 patients were included in the study from site 1. Most patients were emaciated weighing less than 50 kg which was the lower weight limit for inclusion in this study.

There was no FT recorded for the digital fluoroscopy unit at site 2. This was because this unit indicated time for each pulse of x-rays that were not a representation of the complete FT of the BaM or BaE. Since sites 2 and 3 employed DF units with the pulsed fluoroscopy feature and registrars performed the BaM and BaE, recording the FT at the site 2 would have allowed comparison of the DF units at the two sites.

Recommendations

Since there are currently no national Diagnostic Reference Levels for BaM and BaE in SA, a copy of this work is going to be forwarded to the Department of Radiation Control, SA proposing the use of 13.6 $Gycm^2$ and 27.4 $Gycm^2$ for BaM and BaE respectively as initial reference doses for these examinations in the radiology departments. These DRLs must however not be used in precise manner. Radiology departments where qualified radiologists perform the BaM and BaE and DF units where dose saving features are employed must achieve lower DAP readings while maintaining good image quality.

Furthermore, it is recommended that research with larger numbers of participants and radiologists at the same level of training operating the two units be undertaken so as to assess the dose delivered by DF and CF units.

The research method used to develop DRLs in this study is a standard protocol recommended by the DWP (1992) that can be adopted by radiology departments in developing departmental reference dose levels for radiological procedures. As such, radiology departments will be able to investigate high radiation dose in their departments and implement corrective action when the reference doses are exceeded without clinical justification.

Radiation protection is an important aspect of the radiology department with the ultimate purpose to deliver As Low As Reasonably Achievable radiation dose to patients referred for radiological examinations so as minimise the effects and risks of over exposure to ionising radiation. In addition to allowing active monitoring of the radiation dose received by patients, establishing reference doses can serve as a quality assurance measure that assesses the practises and techniques used during radiological examinations.

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APPENDICES

Appendix 1: Fluoroscopy equipment specifications for equipment employed at the 3 study sites

	Site 1 (conventional)	Site 2 (digital)	Site 3 (digital)
Manufacturer	Phillips	Mecall	
Model		Superix RL180N	
X-ray tube	over-couch	over-couch	over-couch
Generator waveform	80kW		150kV/80kW
Total filtration	2.7mm Al at 100kV	3.07mm Al at 70kV	2.5mm Al at 80kV
Leakage radiation	100mR/h		<0.8mSv/h at 150kV/ 450W in 1m distance
Intensifier screen			SIRECON 33-4HDR SIRECON 40-4HDR
TV system			Videomed DHC
TV matrix			1024 x 1024
TV frame rate			max. 25frames/second
Collimator			
Inherent filtration	0.35mm Al-Equ	> 1.7mm/Eq	1.0mm Al at 70kV
Motorised filters	0.1mmCu+1mmAl (100kV) 0.2mmCu+1mmAl (100kV)	0.1mmCu+0.5mm Al 0.2mm Cu+0.5mm Al	0.1mmCu+3.5mmAl(80kV) 0.2mmCu+7.1mmAl(80kV)
Film processor	chemical processor	laser printer	laser
Film screens	200	-	-
Standard grid	12:1	12:1	
Grid vibration speed		120c/min (±10%)	
DAP meter	PTW, Diamentor	KermaX plus IDP	

Appendix 2: Data capture sheet

Date Study site:

Patient data

Study code Gender: Weight:

Age:

Examination data

Type of examination:

Indication:

Image data

Projection	applied kV	mAs	time	film size	film speed

Number of images:

Fluoroscopy data

Fluoroscopy time:

Applied potential range:……..kV

Dose data

Total dose-area product:…….. $Gycm^2$

Degree of difficulty of examination:

Easy Textbook: difficult

Appendix 3 Consent Form

PARTICIPANT INFORMATION AND INFORMED CONSENT FORM FOR RESEARCH PROJECT INVOLVING MEASUREMENT OF RADIATION DOSES RECEIVED BY PATIENTS DURING BARIUM MEAL AND BARIUM ENEMA EXAMINATIONS

TITLE OF RESEARCH PROJECT:
Investigation of radiation doses received by patients during barium meals and enemas to develop potential reference values for the Western Cape

PRINCIPAL INVESTIGATOR: Caroline Nabasenja
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CONTACT NO: 0781762911

Dear Participant,
Thank you for choosing our institution to take care of your health needs. As it is our goal to continuously offer quality medical care to our clients, we request your participation in a research study that involves investigating the radiation doses received by patients referred for barium meal and barium enema examinations. Please take some time to read the information presented here which will explain the details of this project. Kindly ask the principal investigator/attending radiographer about any part of the project that you do not fully understand. It is very important that you fully understand what the research will mean for you. Your participation is **entirely voluntary** and you will still receive our excellent services whether you agree to us using your information for this project or not.

The head of the radiology department of …… hospital has approved the research project. The Research Ethics Committee of the university has reviewed the research proposal and granted approval for the study.

What does this research study involve?

In the radiology department, x-rays are used to produce images of the body. These x-rays must however be actively monitored to maximise their benefits to patients, that is to produce a diagnostic image of the x-rayed area of the body for the doctor to make an accurate diagnosis.

In this study, we intend to determine the dose of x-rays our patients receive, compare it with what patients in other departments receive and identify the reasons for variations in radiation doses for different radiology departments and patients.
Your voluntary participation is therefore sought. Besides measuring body weight, your x-ray examination will be no different to what is routinely done in this department. Your body weight and x-ray dose measurement during the examinations will be used for this research.

Why have you been invited to participate?

We are looking for patients referred for barium meal and barium enema examinations at this radiology department between the ages of 18 and 85 years. Since you fit these criteria, we are inviting you to participate in this research.

What procedures will be involved in this research?

In the research project, the weights of all volunteers will be measured and recorded using a bathroom scale. You will then proceed to the x-ray examination as planned. The radiation dose will be measured during the examination using a dose area product (DAP) meter. This meter will be mounted to the diaphragm housing of the x-ray equipment. The DAP meter will not interrupt the procedure or cause any discomfort to you. All data will be stored in a locked cabinet before being transferred into the Microsoft Excel computer program by the principal investigator. We are calculating average doses so a code and not your name will be linked to the measurements. Confidentiality is therefore assured.

Are there any risks involved in this research?

There are no risks to the volunteer as a result of the research project since no additional procedures will be done other than measuring your weight.

Are there any benefits to your taking part in this study?
There are no direct benefits to you as a volunteer. The use of your body weight and amount of radiation dose received during the procedure will however assist us in determining the dose a patient can expect to receive when referred for barium meal or barium enema examinations.

How will your confidentiality be protected?

The volunteer information will be assigned study codes and stored in locked cabinets before being transferred into the Microsoft Excel computer program by the principal investigator only.

Will you or the researcher benefit financially from this research?
You will not be paid to take part in this study.

The benefit to the researcher is that this research is towards a Masters degree.

Declaration by participant

By signing below, I…….agree to take part in a research study entitled "Investigation of radiation doses received by patients during barium meals and enemas to develop potential reference values for the Western Cape"

I declare that:

- I have read or had read to me this information and consent form and it is written in a language that I can understand easily. I have had a chance to ask questions and all my questions have been adequately answered
- I understand that taking part in this study is voluntary and I have not been pressurized to take part.
- I understand that my information will be protected using a study code to ensure confidentiality.

Signed at (place)……on (date)……

……

…….

Signature of participant Signature of witness

Declaration by investigator:

I (name) ……declare that:

- I explained the information in this document to …….
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research as discussed above.
- I did/did not use a translator. *(if a translator is used then the translator must sign the declaration below)*

Signed at (place)……on (date)……

……

…….

Signature of investigator Signature of witness

Declaration by Translator

I (name) ……declare that:

- I assisted the investigator (name) ……..to explain the Information in this document to (name of participant) ……..using the medium of Afrikaans /Xhosa.

- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place)……on (date)……

……
……
Signature of translator Signature of witness