การหาปริมาณรังสีเฉลี่ยที่ผิวหนังผู้ป่วยและปัจจัยที่มีผลต่อปริมาณรังสีจากการตรวจสวนหัวใจ

นายพัฒนพงษ์ แสนชนม์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต

สาขาวิชาฉายาเวชศาสตร์ ภาควิชารังสีวิทยา

คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ปีการศึกษา 2549

THE DETERMINATION OF THE AVERAGE PATIENT SKIN DOSE AND ITS FACTORS AFFECTING IN CARDIAC CATHETERIZATION PROCEDURES

Mr.Phattanapong Saenchon

A Thesis Submitted in Patial Fulfillment of the Requirements
for the Degree of Master of Science Program in Medical Imaging
Department of Radiology
Faculty of Medicine
Chulalongkorn University
Academic Year 2006

Title	THE DETERMINATION OF THE AVERAGE PATIENT SKIN DOSE AND ITS FACTORS AFFECTING IN CARDIAC CATHETERIZATION PROCEDURES
By	Mr. Phattanapong Saenchon
Field of study	Medical Imaging
Thesis Advisor	Associate Professor Anchali Krisanachinda,Ph.D.
Thesis Co-advisor	Associate Professor Somjai Wangsuphachart,M.D.

Accepted by the Faculty of Medicine, Chulalongkorn University in Partial Fulfillment of the Requirements for Master's Degree

....Dean of the Faculty of Medicine

(Professor Pirom Kamol-ratanakul, M.D., M.Sc.)

THESIS COMMITTEE

....Chairman

(Assistant Professor Sukalaya Lerdlum,M.D., M.Sc.)

....Thesis Advisor

(Associate Professor Anchali Krisanachinda,Ph.D.)

....Thesis Co-Advisor

(Associate Professor Somjai Wangsuphachart,M.D.)

....Member

(Associate Professor Somrat Lertmaharit, M.Sc.)

พัฒนพงษ์ แสนชนม์ : การหาปริมาณรังสีเฉลี่ยที่ผิวหนังผู้ป่วยและปัจจัยที่มีผลต่อปริมาณรังสีจากการตรวจสวนหัวใจ (THE DETERMINATION OF THE AVERAGE PATIENT SKIN DOSE AND ITS FACTORS AFFECTING IN CARDIAC CATHETERIZATION PROCEDURES) อ.ที่ปรึกษา : รศ. ดร. อัญชลี กฤษณจินดา, อ.ที่ปรึกษาร่วม : รศ. พญ. สมใจ หวังศุภชาติ, 50 หน้า.

การหาปริมาณรังสีเฉลี่ยและปัจจัยที่มีผลต่อปริมาณรังสีในผู้ป่วยตรวจสวนหัวใจโดยใช้แคพมิเตอร์ ปริมาณรังสีที่ผิวหนังผู้ป่วยคำนวณได้จากค่าที่อ่านได้จากแคพมิเตอร์และพื้นที่บนผิวหนังที่ได้รับรังสี จากการใช้พอร์ทอลฟิล์ม ปัจจัยต่างๆที่มีผลต่อปริมาณรังสีประกอบด้วย เวลาที่ใช้ในการตรวจขณะที่ใช้รังสี ความหนาแน่นมวลกายของผู้ป่วย ค่าเควีพี ค่าเอ็มเอเอส ประสบการณ์ของแพทย์ผู้ทำการตรวจรักษา และจำนวนเฟรม โดยได้ทำการศึกษาจากผู้ป่วยที่มารับการตรวจสวนหัวใจจำนวน 73 ราย ในโรงพยาบาลจุฬาลงกรณ์สภากาชาดไทย ผลการศึกษาพบว่าปริมาณรังสีเฉลี่ยที่ผิวหนังของผู้ป่วยที่ได้รับจากการตรวจโรคหลอดเลือดหัวใจด้วยรังสี (DCA) มีค่า 9.52 เซนติเกรย์ (95 % CI : 8.39-14.24) ในท่าตรง (PA) และ 18.67 เซนติเกรย์ (95 % CI : 13.97-23.85) ในท่าด้านข้าง (Lateral) ปริมาณรังสีเฉลี่ยจากการตรวจรักษาโรคหลอดเลือดหัวใจพร้อมการใส่สเตนท์ (PTCA/stent) มีค่า 35.95 เซนติเกรย์ (95 % CI : 24.50-49.92) ในท่าตรง และ 85.42 เซนติเกรย์ (95 % CI : 40.75-132.96) ในท่าด้านข้าง ค่าปริมาณรังสีเฉลี่ยจากการตรวจ RF ablation 64.82 เซนติเกรย์ (95 % CI : 42.27-87.43) ในหลอดท่าตรง และจากการศึกษาความสัมพันธ์ระหว่างปริมาณรังสีที่ผู้ป่วยได้รับกับปัจจัยต่างๆ พบว่าปัจจัยที่มีผลต่อปริมาณรังสีประกอบด้วย เวลาที่ใช้ในการตรวจขณะที่มีการใช้รังสี ค่าเควีพี ค่าเอ็มเอเอส และจำนวนเฟรม และพบว่าเวลาที่ใช้ในการตรวจขณะที่มีการใช้รังสี จะมีความสัมพันธ์กับปริมาณรังสีที่ผู้ป่วยได้รับสูง ที่ค่า r เท่ากับ 0.60, 0.83, 0.90 (95% CI : 2.41-8.19, 3.07-6.03, 1.54-2.52 และ p-value น้อยกว่า 0.05) จากการตรวจ DCA, PTCA/stent และ RF ablation ตามลำดับ การศึกษานี้พบว่าค่าปริมาณรังสีเฉลี่ยที่ผู้ป่วยได้รับจากการตรวจสวนหัวใจมีค่าน้อยกว่า 2 เกรย์ ซึ่งเป็นค่าปริมาณรังสีที่จะก่อให้เกิดผิวหนังเป็นผื่นแดง และพบว่ามีผู้ป่วยจำนวน 2 รายที่ได้รับปริมาณรังสีเฉลี่ยที่ผิวหนังเกินระดับที่กำหนดคือ จากการตรวจและรักษาโดยวิธี RF ablation และ PTCA/stent ปริมาณรังสีเฉลี่ยคือ 2.12 และ 4.51 เกรย์ ตามลำดับ ประโยชน์จากการศึกษานี้เป็นการรายงานถึงปริมาณรังสีเฉลี่ยที่ผู้ป่วยได้รับในการตรวจรักษา เพื่อเป็นการสร้างความตระหนักให้แพทย์ผู้ทำการตรวจและผู้ที่เกี่ยวข้องให้คำนึงถึงปริมาณรังสีที่ผู้ป่วยจะได้รับและปัจจัยที่มีผลต่อปริมาณรังสีเพื่อเป็นการป้องกันอันตรายที่จะก่อให้เกิดอันตรายจากรังสีแก่ผู้ป่วยในการตรวจสวนหัวใจ

ภาควิชา	รังสีวิทยา	ลายมือชื่อนิสิต	
สาขาวิชา	ฉายาเวชศาสตร์	ลายมือชื่ออาจารย์ที่ปรึกษา	
ปีการศึกษา	2549	ลายมือชื่ออาจารย์ที่ปรึกษาร่วม	

4874760330 MAJOR MEDICAL IMAGING

KEYWORD : PATIENT SKIN DOSE/ CARDIAC CATHETERIZATION PROCEDURES.

PHATTANAPONG SAENCHON: THE DETERMINATION OF THE AVERAGE PATIENT SKIN DOSE AND ITS FACTORS AFFECTING IN CARDIAC CATHETERIZATION PROCEDURES. THESIS ADVISOR: ASSOC. PROF.ANCHALI KRISANACHINDA, Ph.D., ASSOC.PROF. SOMJAI WANGSUPHACHART,M.D, 50 pp.

The patient dosimetry for cardiac catheterization and its factors affecting in this study were determined using Dose Area Product (DAP) method. The skin dose was calculated from DAP meter readout and information from portal film determination. The proposed potential factors affecting patient dose are fluoroscopic time, kVp, mAs, patient BMI, number of frames and experience of the cardiologists. The measurement was carried out from 73 patients who underwent the cardiac catheterization procedures such as Diagnostic Coronary Angiography (DCA), Cardiac intervention; Percutaneous Transluminal Coronary Angioplasty (PTCA)/stent and cardiac radiofrequency (RF) ablation at King Chulalongkorn Memorial Hospital. The result shows the average patient skin dose from DCA was 9.52 cGy (95 % confident interval (CI): 8.39-14.24) in tube A (Postero-Anterior) and 18.67 cGy (95 % CI: 13.97-23.85) in tube B (Lateral), PTCA/stent was 35.95 cGy (95 % CI: 24.50-49.92) in tube A and 85.42 cGy (95 % CI: 40.75-132.96) in tube B. For cardiac RF ablation the average patient skin dose was 64.82 cGy (95 % CI: 42.27-87.43) for single plane. Factors influencing the patient skin dose in this study were fluoroscopic time, kVp, mAs and number of frames. The patient skin dose is more dependent on the fluoroscopic time than other factors, especially from DCA, PTCA/stent and RF ablation which the correlation (r is 0.60, 0.83, 0.90, 95% CI : 2.41-8.19, 3.07-6.03, 1.54-2.52, $p\text{-value} < 0.05$) respectively. The average patient skin doses in this study were less than threshold dose of skin injury (2 Gy). Only two patients received the dose higher than the threshold dose (2.12, 4.51 Gy) from cardiac RF ablation and cardiac interventional studies respectively. The benefits of this study are the record and the establishment of the patient skin dose in order to protect the patient from skin injury and increase the cardiologist's awareness for cardiac catheterization procedure.

Department Radiology Student's signature Phattanapong Saenchon

Field of study Medical Imaging Advisor's signature ....

Academic year 2006 Co-advisor's signature Somjai Wangsuphachart

ACKNOWLEDGEMENTS

I would like to express gratitude and appreciation to Associate Professor Anchali Krisanachinda, Division of Nuclear Medicine, Department of Radiology, Faculty of Medicine, Chulalongkorn University, my advisor for her guidance, invaluable advice, constructive comments and English language proof in this research.

I would like to thank Associate Professor Somjai Wangsuphachart, Chief of Department of Radiology, Faculty of Medicine, Chulalongkorn University my co-advisor for her advice and comments in this research.

I would like to thank Associate Professor Sivalee Suriyapee, Head of Physicist, Division of Radiation Oncology, Department of Radiology, Faculty of Medicine, Chulalongkorn University for her advice and comments in this research.

I would like to extend my appreciation to all teachers, lecturers and staff in the Master of Science Program in Medical Imaging, Faculty of Medicine, Chulalongkorn University for their unlimited teaching of knowledge in Medical Imaging.

I would like to thank Associate Professor Somrat Lertmaharit, Department of Preventive and Social Medicine, Faculty of Medicine, Chulalongkorn University for her advice and comments with statistical analysis in this research.

I also would like to thank all the staff of the cardiac catheterization unit for their assistances.

Finally, I am grateful to my family for their financial support, valuable encouragement and entire care during the course of study.

CONTENTS

Page

LIST OF TABLES

Table **Page**

LIST OF FIGURES

Figure **Page**

LIST OF ABBREVIATIONS

BMI	Body Mass Index
cGy	Centigray
DA	Digital Angiography
DAP	Dose Area Product
DCA	Diagnostic Coronary Angiography
DF	Digital Fluorography
DSA	Digital Subtraction Angiography
Gy	Gray
HVL	Half Value Layer
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IQR	Inter Quartile Range
kVp	Peak kilo-Voltage
mAs	Miliampare second
mGy	Miligray
PA	Postero-Anterior
PTCA	Percutaneous transluminal coronary Angioplasty
r	Correlation coefficient
r^2	The coefficient of determination
RF	Radiofrequency
RFCA	Radiofrequency Cardiac Ablation
Sv	Sievert

TLD	Thermoluminescent Dosimetry
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background and rationale

Cardiac catheterization procedures such as Diagnostic Coronary Angiography (DCA), Cardiac Intervention; Percutaneous Transluminal Coronary Angioplasty (PTCA) / stent and cardiac radiofrequency ablation demonstrate lower risk than surgical procedures. Their wide acceptance has led to an increasing number being performed [1]. But the extensive use of this procedure increases risk of radiation induced effects in patients. The high entrance skin dose may be harmful as skin injury. This is recognized as a potential complication to rapidly proliferating complex fluoroscopically guided procedures involving long fluoroscopic time and sometimes multiple runs of serial imaging, considerably in excess of standard diagnostic procedures. Even so, many interventionalists still do not acknowledge that skin injuries could occur. Such denial has lead, in many cases, to uncertain and ill-directed care for some patients.

Two types of radiation effect may occur are deterministic and stochastic effects.

1. Deterministic effects

Based on a large number of experiments involving animals and other researches, further supplemented by theoretical studies, it was discovered that severity of certain effects on human beings will increase with increasing doses. There exists a certain level, the "threshold", below which the effect is not observed. This kind of effects is called "deterministic effects" such as cataract, erythema, infertility etc.

The characteristics of deterministic effects are shown as the followings.

1. Damage depends on absorbed dose.
2. The existence of the threshold dose.

2. Stochastic effects

The severity of stochastic effects does not depend on the absorbed dose. Under certain exposure conditions, the effects may or may not occur. There is no threshold and the probability of having the effects is proportional to the dose absorbed such as radiation induced cancer and genetic effects.

The characteristics of stochastic effects are shown as the followings.

1. Severity is independent of absorbed dose.
2. The non existence of the threshold does.
3. The probability of occurrence depends on absorbed dose.

The risk for long-term stochastic effects may be assessed by effective dose [2]. The majority of instances reported by the United States Food and Drug Administration (FDA) results from the cardiac radiofrequency ablation and the coronary angioplasty [3-4].The FDA, the World Health Organization (WHO), the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) have published documents [5-6] to avoid deterministic effects in cardiology procedures. There is now general agreement that skin dose should be determined if there is a risk that doses approach or exceed the threshold levels for deterministic effects. A threshold level of concern is 2 Gray (Gy) for the onset of transient erythema and 3 Gy for hair loss.[5, 7].

Cardiologists should be aware of potential for serious radiation induced skin injury caused by long periods of fluoroscopy occurring with some of these procedures. The time that patient receives under fluoroscopic intervention procedures should be recorded. Even though the relationship between the fluoroscopic time and patient skin dose is not clear, the further factors influencing the patient skin dose, the complexity of procedures and factors affecting patient skin dose should be considered during procedures.

In September 1995, FDA of the United States issued a public health advisory entitled *Avoidance of Serious X-Rays Induced Skin Injuries to Patients During Fluoroscopy-Guided Procedure* [8]. The advisory recommended, among several items, that information be recorded in the patient's record which permits estimation of absorbed dose to the skin. The purpose of the recommendation is to encourage identification of those areas of the skin which are irradiated at levels of absorbed dose that approach or exceed a threshold for injury [9].

It was deemed important to assess the potential for unusual high skin doses in an effort to understand the potential causes and factors behind radiation skin injury and to make recommendations on how to avoid them.

1.2 Research objectives

1.2.1 To study the average patient skin dose in each cardiac catheterization procedure.

1.2.2 To study factors affecting and the correlation with the patient skin dose in cardiac catheterization procedures.

1.2.3 To report and establish the patient skin dose in order to protect the patient from skin injury and increase the cardiologist's awareness for catheterization procedures.

CHAPTER 2

REVIEW OF RELATED LITERATURES

Shope TB. [3] had studied radiation-induced skin injuries from fluoroscopy in the year 1996. Since 1992, the U.S. Food and Drug Administration (FDA) received reports of radiation induced injuries to the skin in patients who had undergone fluoroscopically guided interventional procedures. The procedures, the equipment and other related factors that may have contributed to the injury were investigated. The injuries range in severity from erythema to moist desquamation to tissue necrosis that required skin grafting as shown in Table1. They occurred after a variety of interventional procedures that required extended periods of fluoroscopy compared with those of typical diagnostic procedures. Medical facilities and physicians should be aware of the magnitude of radiation doses to the skin that can result from the long exposure times required by complex interventional procedures. The FDA recommends several steps for reducing these injuries, including establishing protocols for each procedure, determining radiation dose rates for specific fluoroscopy systems and operating modes, and monitoring cumulative absorbed doses to areas of the skin.

Table 2.1 The radiation-induced skin injuries adapted from L.K.Wagner et al [10].

Injury	Threshold Dose to Skin (Sv)	Weeks to Onset
Early transient erythema	2	<<1
Temporary epilation	3	3
Main erythema	6	1.5
Permanent epilation	7	3
Dry desquamation	10	4
Dermal atrophy	11	> 14
Telangiectasis	12	> 52
Moist desquamation	15	4
Late erythema	15	6-10
Dermal necrosis	18	> 10
Secondary ulceration	20	> 6

Betsou S., et al [11] studied patient radiation doses during cardiac catheterization procedures such as coronary angiography, percutaneous transluminal coronary angioplasty (PTCA) and stent implantation. Thermoluminescent dosemeters (TLDs), suitably calibrated, were used for the measurement of the dose received at four anatomical locations on the patient's skin. A dose-area product (DAP) meter was also used. The contribution of cinefluorography to the total DAP was higher than that of fluoroscopy. An effective dose to DAP conversion factor of 0.183 mSv Gy^{-1} cm^{-2} was estimated with the use of a Rando phantom. The range of DAP values are quite large for procedures such as coronary angiography, PTCA and stent implantation. This is reasonable, as several projections may be used, each one more or less than the rest. In addition, the effort and time needed to achieve the desirable outcome varies according to the location of the lesion, the severity of the situation, the number of stenotic lesions and the skills of the cardiologist performing the procedure. However, a typical procedure may be put forward, which will provide an average baseline for comparison.

Vano E. et al [12] studied the patient dosimetry in interventional radiology using slow films. The method requires the analysis of slow non-screen films such as those used in radiotherapy. Patient skin dose can be estimated with fair accuracy depending on the interventional procedure type. The agreement between the slow film method and Diamentor (DAP) measurement is better than 5% after the application of appropriate corrections. The cost is reasonable (£5 per film) making it a worthwhile option in patient dosimetry, especially when the X-ray equipment does not include any fixed dose area measuring device. Additional valuable information which may be applied to optimization of procedures *(e.g.* irradiated areas, number and types of projections, check of appropriate use of beam limiting devices) is achieved by examining the different irradiation fields on the film.

De Putte S.,et al [13] studied the correlation of patient skin dose in cardiac interventional radiology with dose area product. The use of X-rays in cardiac interventional radiology has the potential to induce deterministic effects on the patient's skin. Guidelines published by official organizations encourage the recording of information to evaluate this risk, and the use of reference values in terms of the dose-area product (DAP). Skin dose measurements were made with thermoluminescent dosemeters. In addition, DAP was recorded in 100 patients for four types of interventional radiology procedures. Mean, median and third quartile for these results were presented. Maximum skin dose values found were 412 mGy, 725 mGy, 760 mGy and 1800 mGy for coronary catheterization, coronary catheterization with left ventricle investigation, and percutaneous transluminal angiography without and with stenting, respectively. Median DAPs for these same procedures were 5,682 cGy cm^2, 10,632 cGy cm^2, 10,880 cGy cm^2 and 13,161 cGy cm^2 respectively. The relationship between DAP and skin dose was investigated. Poor correlation of DAP with maximum skin dose (r=0.77) and skin dose indicator (r=0.78) were reported. Using conversion factors derived from Monte Carlo simulations, skin dose distributions were calculated based on the measured DAPs. Agreement between the calculated skin dose distribution, using DAP values averaged over a group of patients who underwent coronary catheterization and left ventricle investigation, and the measured skin dose averaged over the same group of patients was very good.

However, there were large differences between the calculated skin doses using the individual DAP data per patient and measured skin doses for individual patients (r=0.66). Hence, calculation of individual skin doses based on the specific DAP data per patient is not reliable and therefore measuring skin dose is preferable

Koichi C., et al [14] reported the relationship between fluoroscopic time, Dose–Area Product, body weight, and maximum radiation skin dose in cardiac interventional procedures. The correlation between the maximum radiation skin dose with DAP is more striking than that with fluoroscopic time in both Cardiac Radiofrequency Catheter Ablation (RFCA) and percutaneous coronary intervention procedures. It was recommended that physicians record the DAP when it can be monitored and record the fluoroscopic time when DAP cannot be monitored for estimating the maximum patient skin dose. For estimating in percutaneous coronary intervention procedures, it was recommended that physicians record DAP when it can be monitored and record WFP(weight-fluoroscopic time product) when DAP is not available.

The objective of this study is to evaluate the average patient skin dose in cardiac interventional procedures and factors such as kVp, mAs, fluoroscopic time, patient body mass index (BMI), number of frames and the experience of the cardiologists which affect patient skin dose during cardiac catheterization procedures.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Design

This study is a cross sectional descriptive study.

3.2 Research Question

3.2.1 Primary research question

What is the average patient skin dose in each cardiac catheterization procedure performed at King Chulalongkorn Memorial Hospital?

3.2.2 Secondary research question

What are factors affecting the patient skin dose in cardiac catheterization procedures?

3.3 Conceptual framework

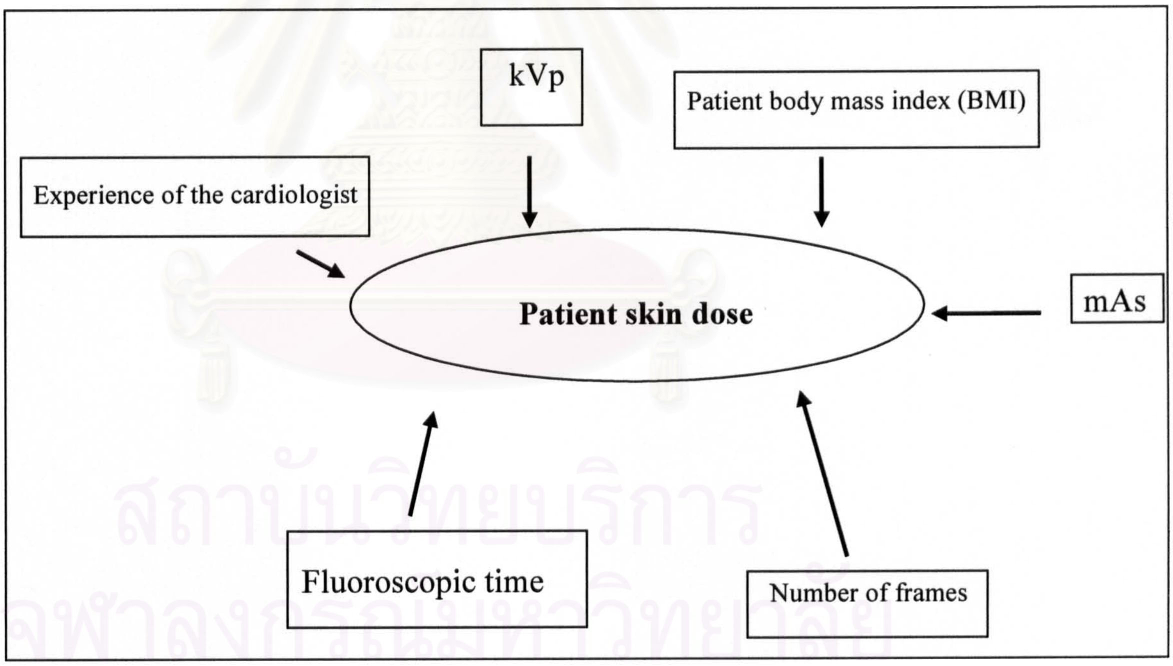

Figure 3.1 Conceptual framework of factors affecting patient skin dose

3.4 Research design model

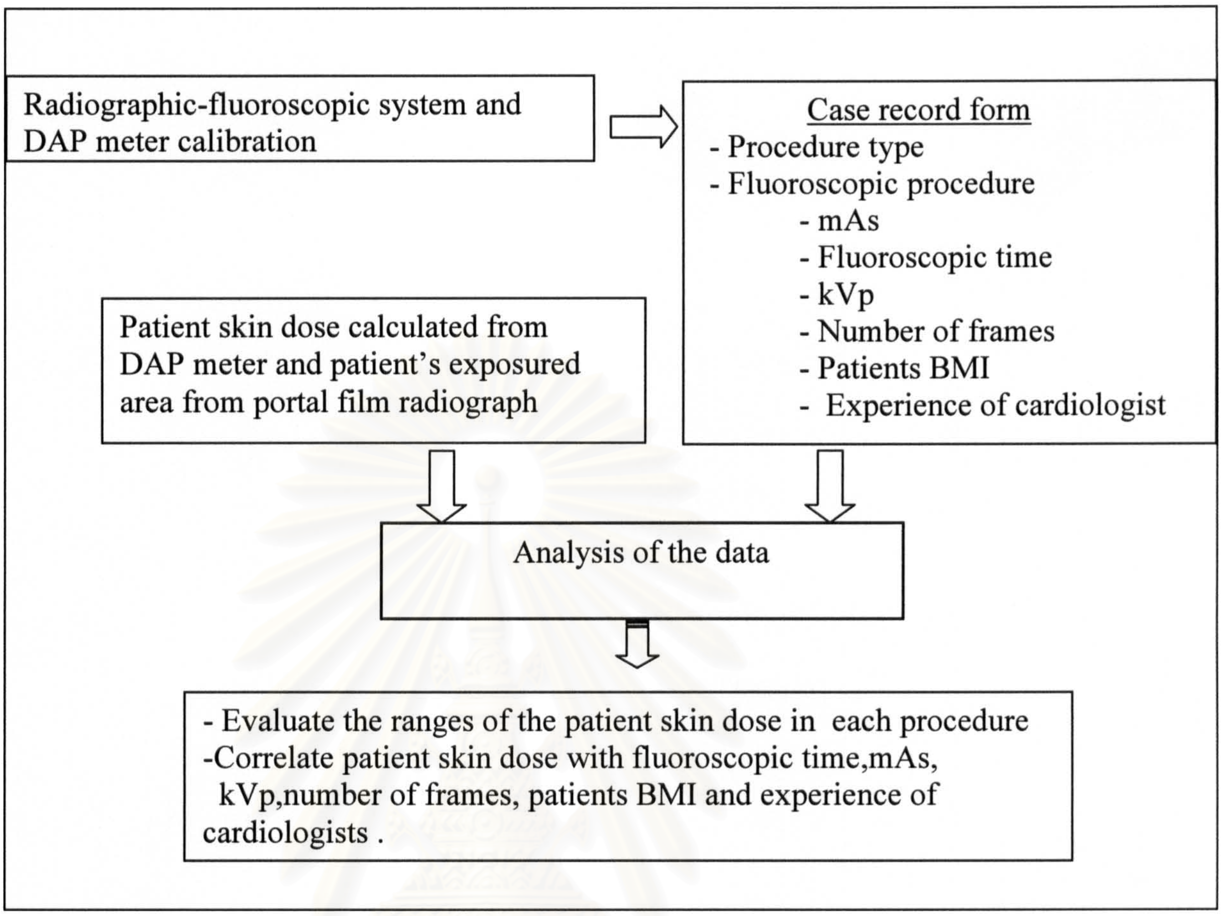

Figure 3.2 Research design model

3.5 Key words

Patient skin dose, Cardiac catheterization procedures

3.6 The sample

3.6.1 Target population

The patients who underwent cardiac catheterization procedures at King Chulalongkorn Memorial Hospital.

3.6.2 Sample population

This research was cross sectional descriptive study. The patients who underwent in cardiac catheterization procedures were recruited at King Chulalongkorn Memorial Hospital from period of February to June 2006. Seventy-three patients who underwent cardiac catheterization procedures i.e. 32 cases for Diagnostic Coronary Angiography (DCA), 21 cases for cardiac intervention; Percutaneous Transluminal Coronary Angioplasty (PTCA) / stent were recorded on every Monday and Tuesday and 20 cases for cardiac radiofrequency ablation were recorded on every Wednesday and Friday.

3.7 Outcome

3.7.1 The average patient skin dose in cardiac catheterization for each procedure.

3.7.2 Ranges of parameters used in this study such as fluoroscopic time, mAs, kVp, the number of frames, patients BMI and experience of the cardiologists.

3.7.3 Correlation between average patient skin dose and affecting factors.

3.8 Materials

3.8.1 Radiographic-fluoroscopic system

The following x-ray machines were used for cardiac catheterization procedures.

Table 3.1 The x-ray machines used for cardiac catheterization.

Procedures	Manufacturer	Model / Year
1. Diagnostic Coronary Angiography (DCA), Cardiac intervention; Percutaneous Transluminal Coronary Angioplasty (PTCA) / stent	Siemens	AXIOM-Artis/2004 Bi plane system
2. Cardiac radiofrequency ablation	GE	Advantx L/C/1994 Single plane system

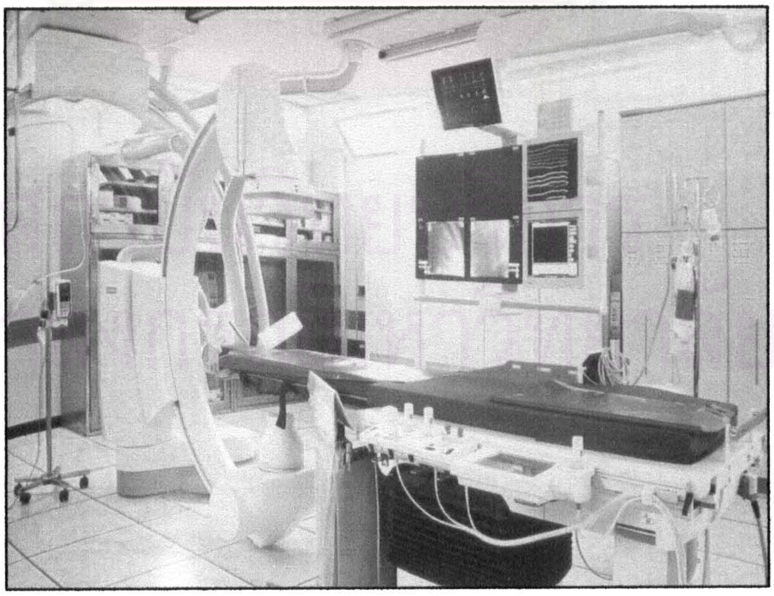

Figure 3.3 Radiographic-fluoroscopic machines for DCA, PTCA/stent procedures (Siemens, Axiom-Artis)

3.8.2 Radiation dosemeters

3.8.2.1 Ionization chamber and electrometer

Victoreen 4000 M^{+} ionization chamber was used for the determination of the table attenuation coefficient, the beam quality half value layer (HVL) and the equipment quality control.

Figure 3.4 Ionization chamber (Victoreen 4000 M^{+})

3.8.2.2 Portal film (Verification film) Kodak X – Omat V

The non screen ready packed film used for the radiation area verification.

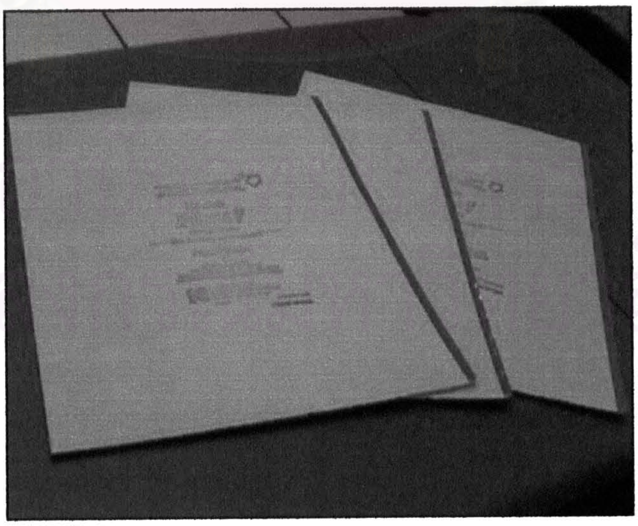

Figure 3.5 Portal film (Verification film) Kodak X – Omat V

3.8.2.3 Dose Area Product (DAP) meter (Model PTW-Diamentor E)

DAP meter is used to measure the KEMA (mGy), times the area of the x-ray field (cm^2), on patient skin. The relationship between DAP and exposure-area product (EAP) is essentially a single conversion factor that relates dose to exposure. EAP is expressed in roentgen-cm ($R\text{-}cm^2$) and DAP is expressed in gray–cm^2 ($Gy\text{-}cm^2$, usually read in $cGy\text{-}cm^2$).

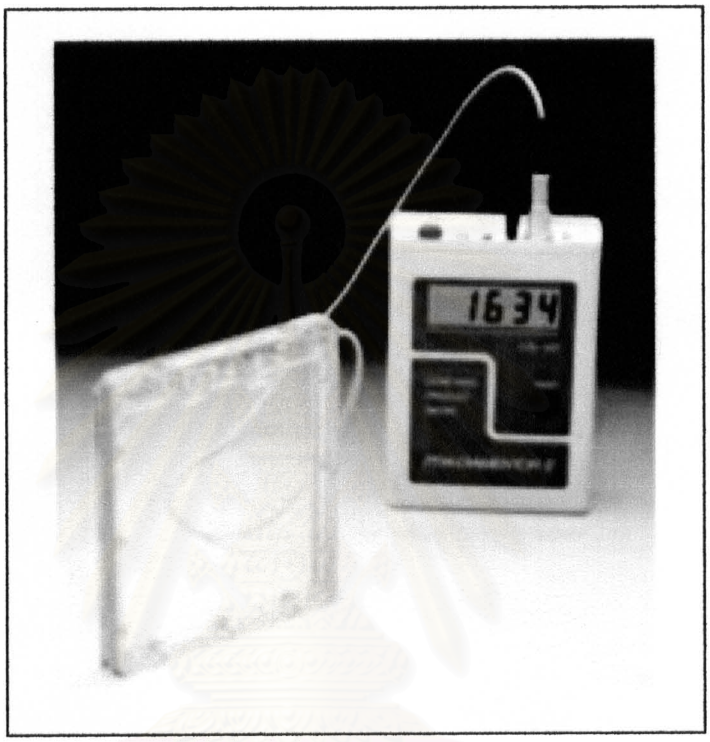

Figure 3.6 Dose Area Product (DAP) Meter (Model PTW-Diamentor E)

3.8.3 Equipment performance form (Appendix C)

3.8.4 Data recording form

Clinical data collection for cardiac intervention and cardiac ablation. (Appendix A)

3.9 Methods

The study was carrying out into 5 steps.

3.9.1 Quality control of radiographic-fluoroscopic system

The performance of the Radiographic-fluoroscopic system was evaluated with the following studies [15].

- Dose assessment
- Automatic brightness control test
- Maximum dose rate assessment
- Table attenuation
- Image size assessment
- Half value layer assessment
- Image quality assessment

The result was recorded in equipment performance form. (See Appendix C)

3.9.2 Recorded the patient data collection.

All measured outcomes were shown in case recording form (see Appendix A). The setting of the device for data collection is shown by the followings :

3.9.2.1 DAP chamber was placed on the collimator of the x-ray tube.

3.9.2.2 Portal film was placed on the couch under the patient around the patient's back at heart portion.

3.9.2.3 The data was recorded in case recording form.

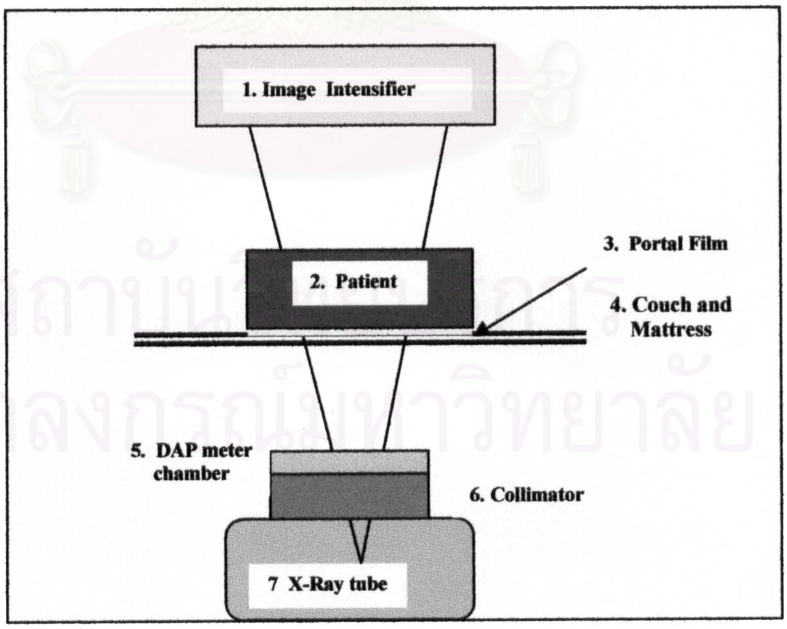

Figure 3.7 Setting of the devices for patient skin dose determination

3.9.3 Data analysis

3.9.3.1 Statistical analysis

Statistical analysis for affecting factors and patient skin dose were average, range, median, SD and 95% confidence interval (CI).This study involves the comparison and correlation of the data from independent variables and dependent variables. Simple regression is statistics of one independent variable and one dependent variable.

Simple regression equation is

$$Y = a + b x$$

a. is constant
b. is regression coefficient

This determination was analyzed using SPSS 15.0 for windows evaluation version.

3.9.3.2 Sample size determination

Sample size for this study was calculated from continuous data used for estimating the population means based on the formula and constructs 95 % confidence interval (CI) for mean of the population.

$$n = \frac{Z^2_\alpha \sigma^2}{d^2}$$

n is sample size = 60
σ^2 is true variance (from 15 samples pilot study $\sigma^2 = 297$)
d is precision (10% of precision = 4.4)
Z_α is 95% CI =1.96 from table ($\alpha = 0.05$)

3.9.3.3 Patient skin dose calculation

3.9.3.3.1 Develop the portal film to determine the radiation area (cm^2), calculate the absorbed dose (cGy) from the DAP meter reading ($cGy.cm^2$).
3.9.3.3.2 Determine the absorbed dose in cGy using the data from the DAP meter readout in $cGy.cm^2$ divided by the area from portal film in cm^2.
3.9.3.3.3 Apply the correction factors from table transmission and DAP Meter calibration and DAP correction factor.

3.9.3.4 Outcome measurement

The measurement of this study consists of 2 types of variables such as:

3.9.3.4.1 Dependent variables: DAP meter readouts.
3.9.3.4.2 Independent variables: Procedure type, fluoroscopic time, kVp, mAs, patients size (BMI), number of frames and experience of the cardiologists.

3.9.4 Evaluation of the factors affecting the patient skin dose in cardiac catheterization procedure.

3.9.5 Evaluation of the correlation between the patient skin dose and the potential related factors such as fluoroscopic time, mAs, kVp, experience of the cardiologists, number of frames and patient BMI for cardiac catheterization procedures.

3.10 Data presentation

3.10.1 Table presentation such as the table attenuated patient dose determination, demographic data of the patient, the patient skin dose, factors affecting in cardiac catheterization procedures and Pearson correlation coefficient.

3.10.2 Bar chart presentation was the average patient skin dose in cardiac catheterization procedures.

3.10.3 Scattered diagram presentation such as the correlation between patient skin dose and affecting factors.

3.11 Ethical considerations

This research covers the determination of the average patient skin dose and its factors affecting the cardiac catheterization procedure. The dose area product (DAP) meter was used for the measurement of absorbed dose at the skin of the patient. DAP meter was attached on collimator of x - ray tube before the examination began, it did not disturb the cardiac catheterization procedures or caused any pain to the patients. The proposal was approved by Ethics Committee of Faculty of Medicine, Chulalongkorn University.

3.12 Expected benefits

3.12.1 Optimization of patient dose. In cardiac catheterization procedures, the patient skin dose is high, the factors affecting patient skin dose are very important for cardiologists and operators to know how to optimize the patient dose using the correlation between patient skin dose and affecting factors.

3.12.2 Increasing the awareness of cardiologists in performing cardiac catheterization procedures.

CHAPTER 4

RESULTS

4.1 The equipment calibration

Radiographic-fluoroscopic system performance test

The performance of the Radiographic/Fluoroscopic system was evaluated with the following topics.

- Dose assessment
- Automatic brightness control test
- Maximum dose rate assessment
- Table attenuation determination
- Image size assessment
- Half value layer assessment
- Image quality assessment

The results of equipment calibration values are shown in APPENDIX C.

4.2 Table attenuation determination

Table 4.1 shows the percentage of table attenuation (k, percent) which is directly affecting the average patient skin dose. The correction was applied to the readout from DAP meter in all data collection. This effect decreases patient skin dose in cardiac catheterization procedures.

Table 4.1 The results of table attenuated patient dose determined by DAP meter.

Radiographic/ Fluoroscopic manufacturer	Model	Submode/ Image quality	Dose rate C-arm at 0^o * (mGy/min)	Dose rate C-arm at 90^o (mGy/min)	Absorber	% Table attenuation (k)
Siemens	AXIOM-Artis	Normal	17.2	17.7	2mmCu	2.8
GE	Advantx L/C	Normal	8.8	9.8	2mmCu	9.9

* X-ray beam transmitted the examination couch for (PA) position.

4.3 Patient studies

Seventy three patients who underwent cardiac catheterization procedures consist of 32 cases for DCA, 21 cases for PTCA/stent and 20 cases for cardiac radiofrequency ablation. Those are summarized Table 4.2.

Patients of DCA have age range from 48 to 79 years (average (± SD), 63 (±8.58)). 14 cases were male and 18 cases were female. Patient height ranged from 147 cm to 177 cm (average (±SD), 159.73 (±7.82)). Patient weight ranged from 42 kg to 94.20 kg (average (±SD), 61.98 (±13.21)).

PTCA/stent patients have age range from 50 to 84 years (average (±SD), 66 (±10.69)). 15 cases were male and 6 cases were female. Patient height ranged from 150 cm to 175 cm (average (±SD), 163.90 (±5.40)). Patient weight ranged from 55 kg to 85 kg (average (±SD), 65.58 (±8.68)).

Cardiac radiofrequency ablation patients have age range from 24 to 71 years (average (±SD), 52 (±15.82)). 7 cases were male and 13 cases were female. Patient height ranged from 147 cm to 179 cm (average (±SD), 161.55 (±7.33)). Patient weight ranged from 45 kg to 80 kg (average (±SD), 60.68 (±9.85)).

Table 4.2 Demographic data of the patients in each procedure.

Procedures	**Number of studies (cases)**	**Sex**		**Age (Year) Average(± SD), range**(min-max)	**Patient BMI (kg/m^2) Average(± SD), range**(min-max)
		Male	**female**		
DCA	32	14	18	63 (±8.58), 48-79	24.29 (±4.80), 15.43 - 38.09
PTCA/stent	21	15	6	66 (±10.69), 50-84	24.42 (±3.05), 18.82 - 30.85
RF ablation	20	7	13	52 (±15.82), 24-71	23.21 (±3.20), 18.37 - 29.38
Total	**73**	**36**	**37**	-	-

4.4 Patient skin dose in cardiac catheterization procedures

The result of patient skin dose for 73 cases are presented in table 4.3 and Figure 4.1. The average patient skin dose from DCA was 9.52 cGy in tube A (Postero-Anterior) and 18.67 cGy in tube B (Lateral), PTCA/stent was 35.95 cGy in tube A and 85.42 cGy in tube B and cardiac radiofrequency ablation was 64.82 cGy for single plane.

Table 4.3. Patient skin dose in cardiac catheterization procedures

Procedures	Patient skin dose (cGy)											
	Bi planes								Single plane			
	Tube A				Tube B							
	Average (± SD)	95% CI**	Median (IQR)*	Range (min-max)	Average (± SD)	95% CI**	Median (IQR)*	Range (min-max)	Average (± SD	95% CI**	Median (IQR)*	Range (min-max)
)CA (32 cases)	9.52 (± 6.08)	8.39 – 14.24	7.75 (10.50)	2.13 - 23.94	18.67 (± 14.46)	13.97-23.85	16.36 (17.02)	2.47 – 77	-			
'TCA/stent 21 cases)	35.95 (± 27.09)	24.50-49.92	23.86 (41.96)	3.58 - 97.72	85.42 (± 96.24)	40.75-132.96	53.42 (56.06)	20.4 – 451	-			
Cardiac RF ablation 20 cases)	-								64.82 (± 48.25)	42.27-87.43	50-78 (37.38)	11.9-212

* IQR is inter quartile range (Q3-Q1), ** 95% confidence interval (CI)

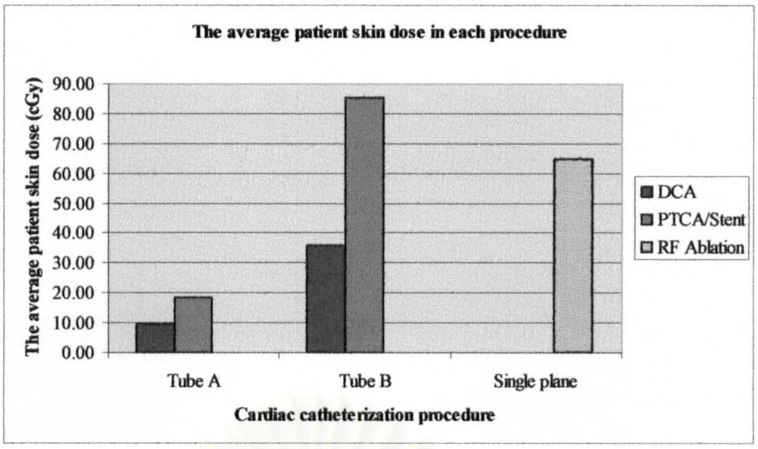

Figure 4.1 The average patient skin dose (cGy) in cardiac catheterization procedures

4.5 DAP meter readout in cardiac catheterization procedures

The DAP meter readout (cGy.cm^2) for 73 cases is presented in Table 4.4. The average DAP meter readout from DCA was 861.06 cGy.cm^2 in tube A (Postero-Anterior) and 1,653.59 cGy.cm^2 in tube B (Lateral), PTCA/stent was 3,478.43 cGy.cm^2 in tube A and 7,595.67 cGy.cm^2 in tube B and cardiac radiofrequency ablation was 10,652.70 cGy.cm^2 for single plane.

Table 4.4 DAP meter readout in cardiac catheterization procedures

Procedures	DAP meter readout (cGy.cm^2)					
	Biplanes				Single plane	
	Tube A		Tube B			
	Average (± SD)	Range (min-max)	Average (± SD)	Range (min-max)	Average (± SD)	Range (min-max)
DCA (32 cases)	861.06 (±515.75)	171-2287	1,653.59 (±913.75)	166-7902	-	
PTCA/stent (21 cases)	3,478.43 (±2,529.40)	263-9,263	7,595.67 (±8,021.75)	1,507-36,044	-	
RF ablation (20 cases)	-				10,652.70 (±10,047.30)	1,775-44,702

4.6 Factors affecting patient skin dose in cardiac catheterization procedures

Factors affecting patient skin dose such as fluoroscopic time, patient body mass index (BMI), the number of frames, kVp and mAs are shown in Table 4.5 and 4.6 from 32 DCA and 21 PTCA/stent patients.

The results of the study shown as the data in Table 4.7 performed on 20 patients of cardiac radiofrequency ablation, show factors affecting patient skin dose such as fluoroscopic time, patient body mass index (BMI), kVp and mAs.

Table 4.5 Data of the potential factors affecting patient skin dose in DCA

Parameter	Biplanes			
	Tube A		Tube B	
	Average (± SD)	Range (min-max)	Average (± SD)	Range (min-max)
Fluoroscopic time (min)	2.08 (±1.36)	0.50 – 6.0	1.51 (±1.53)	0.30 - 7.10
Patients Body Mass Index (BMI: kg/m^2)	24.29 (±4.80)	15.43 - 38.09	24.29 (±4.80)	15.43 - 38.09
Number of frames	495 (±204.99)	216 – 1141	480 (±199)	216 – 1144
Frame rate (frame/sec)	15			
kVp for DA and DF	66.50 (±6.08)	56.50 - 90.40	74.73 (±9.66)	64.50 - 101.90
mAs for DA and DF	143.82 (±18.44)	102.8 - 172.8	156.65 (±17.75)	109.7 - 179.8
kVp for DSA	74.11 (±9.10)	62.20 - 99.60	79.28 (±10.57)	63.50 - 110.8
mAs for DSA	781.37 (±44.03)	602.70 -814.70	786.77 (±37.84)	649.50-816.60

Table 4.6 Data of the potential factors affecting patient skin dose in PTCA/stent

Parameter	Biplanes			
	Tube A		Tube B	
	Average (± SD)	Range (min-max)	Average (± SD)	Range (min-max)
Fluoroscopic time (min)	7.76 (±5.80)	0.80 - 22.50	13.64 (±17.50)	0.70 - 61.50
Patients Body Mass Index (BMI: kg/m^2)	24.42 (±3.05)	18.82 - 30.85	24.42 (±3.05)	18.82 - 30.85
Number of frames	941 (±468.82)	334 – 1927	936 (±460.24)	336 – 1854
Frame rate (frame/sec)	15			
kVp for DA and DF	69.15 (±5.32)	60.70 - 87.70	76.83 (±8.30)	67.60 - 92.90
mAs for DA and DF	160.85 (±12.89)	122.50 - 180.90	165.86 (±12.37)	141.40 - 182.10
kVp for DSA	72.69 (±7.86)	64 - 95.90	80.58 (±8.63)	67.40-92.10
mAs for DSA	774.95 (±59.34)	549 – 845.30	801.70 (±20.73)	718.70 - 820

Table 4.7 Data of the potential factors affecting patient skin dose in cardiac radiofrequency ablation

Parameter	Cardiac radiofrequency ablation	
	Single plane	
	Average (± SD)	Range (min-max)
Fluoroscopic time (min)	24.64 (±21.28)	7.00 - 96.70
Patients Body Mass Index (BMI: kg/m^2)	23.21 (±3.20)	18.37 - 29.38
kVp for DA and DF	76.60 (±4.93)	75.00 - 92.00
mAs for DA and DF	2.58 (±1.50)	1.00 - 6.20

4.7 The experience of the cardiologists in cardiac catheterization procedures

The experience of the cardiologists in cardiac catheterization procedures are shown in Table 4.8 from 32 DCA, 21 PTCA/stent and 20 cardiac radiofrequency ablation patients.

Table 4.8 Experience of the cardiologists in cardiac catheterization procedures

Procedures	Experience of the cardiologists (Years)	
	Average	Range (min-max)
DCA	11	8-14
PTCA/stent	10	8-14
RF ablation	7	5-9

4.8 The correlation between patient skin dose and factors affecting in cardiac catheterization procedures

Figures 4.2 to 4.12 are scattered diagram showing the correlation between the average patient skin dose and its factor affecting patient skin dose of cardiac catheterization procedures. The y-axis represents the average patient skin dose in cGy. The x-axis shows factor affecting patient skin dose. It can be seen that most of the correlation are positive. However, in Table 4.9- to 4.11 showing Pearson correlation coefficient (r) between patient skin dose and affecting factors all of each procedure tend to be positive, except Figure 4.11 and 4.12.

4.8.1 Scattered diagrams show the correlation between the average patient skin dose and fluoroscopic time

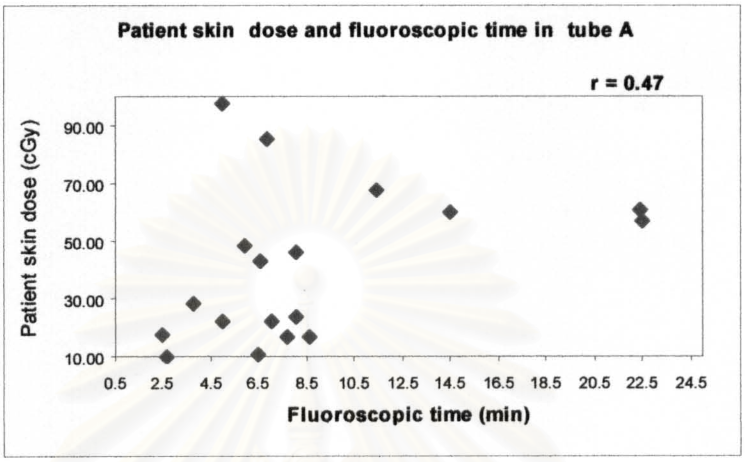

Figure 4.2 The correlation between patient skin dose (cGy) and fluoroscopic time in tube A of PTCA/stent (n = 21)

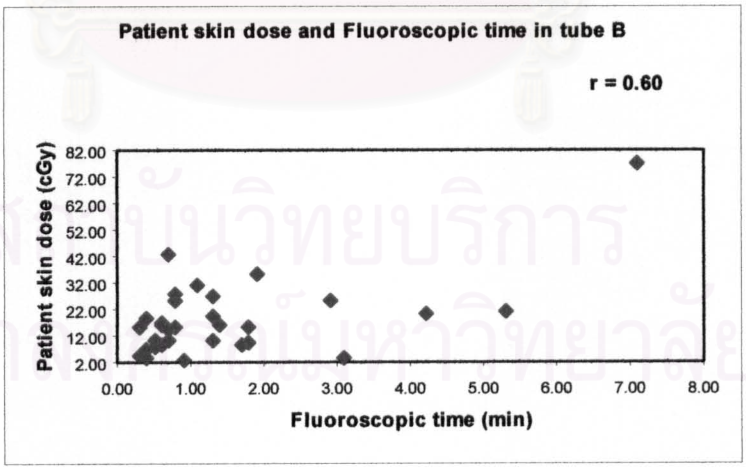

Figure 4.3 The correlation between patient skin dose (cGy) and fluoroscopic time (min) in tube B of DCA (n = 32)

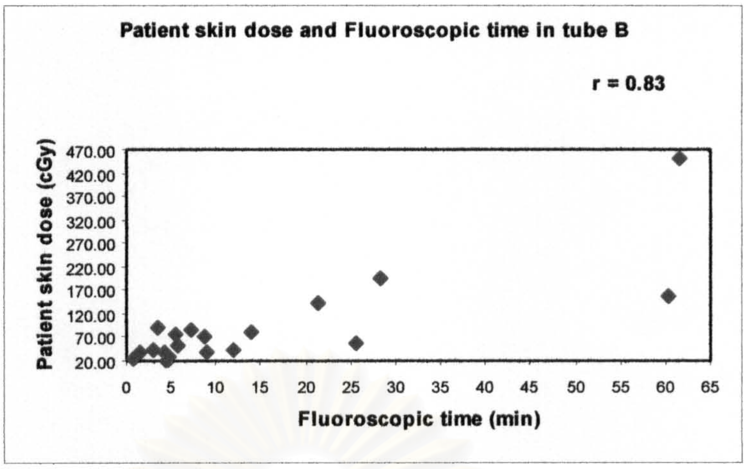

Figure 4.4 The correlation between patient skin dose (cGy) and fluoroscopic time in tube B of PTCA/stent (n = 21)

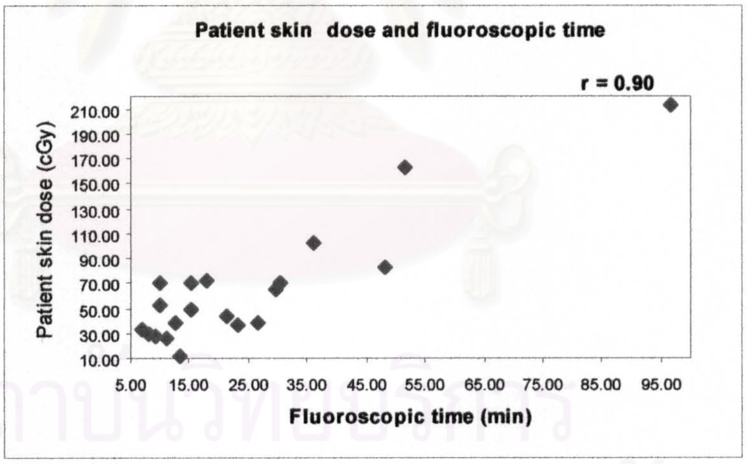

Figure 4.5 The correlation between patient skin dose (cGy) and Fluoroscopic time of cardiac radiofrequency ablation (n = 20)

4.8.2 Scattered diagrams show the correlation between the average patient skin dose and the number of frames

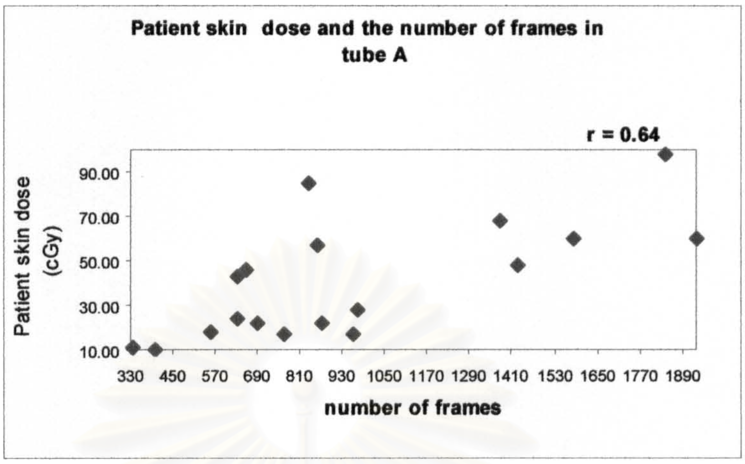

Figure 4.6 The correlation between patient skin dose (cGy) and the number of frames in tube A of PTCA/stent (n = 21)

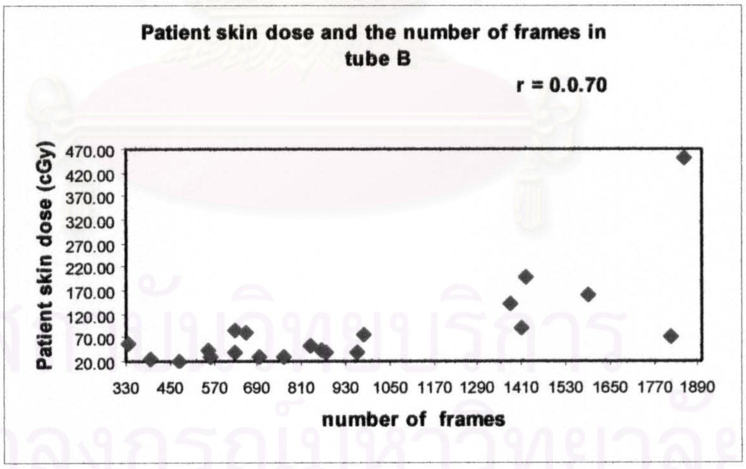

Figure 4.7 The correlation between patient skin dose (cGy) and the number of frames in tube B of PTCA/stent (n = 21)

4.8.3 Scattered diagrams show the correlation between the average patient skin dose and peak kilovoltage; kVp

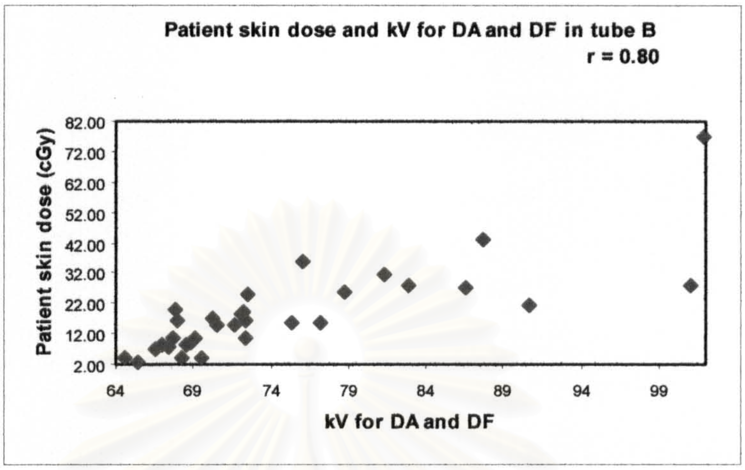

Figure 4.8 The correlation between patient skin dose (cGy) and kVp for DA and DF in tube B of DCA (n = 32)

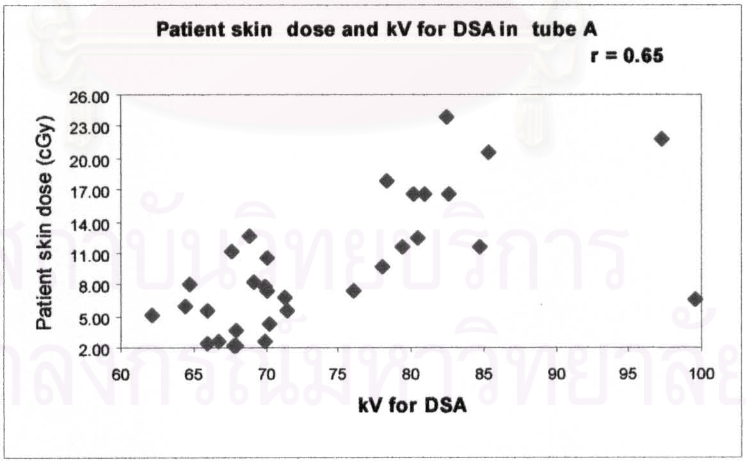

Figure 4.9 The correlation between patient skin dose (cGy) and kVp for DSA in tube A of DCA (n = 32)

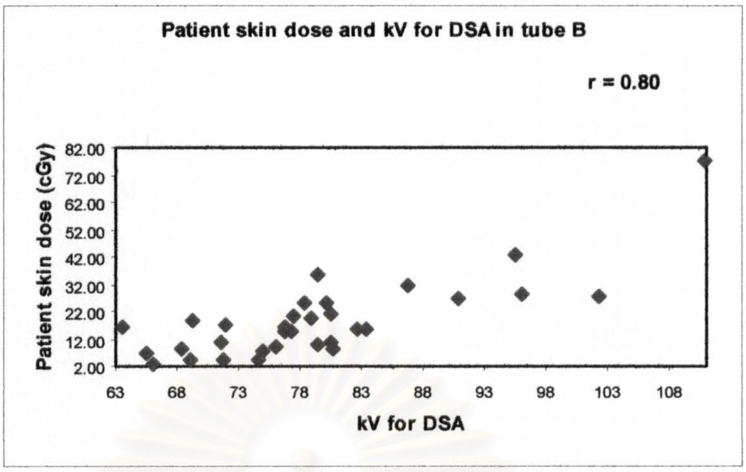

Figure 4.10 The correlation between patient skin dose (cGy) and kVp for DSA in tube B of DCA (n = 32)

4.8.4 Scattered diagrams show the correlation between the average patient skin dose and tube current – Time; mAs

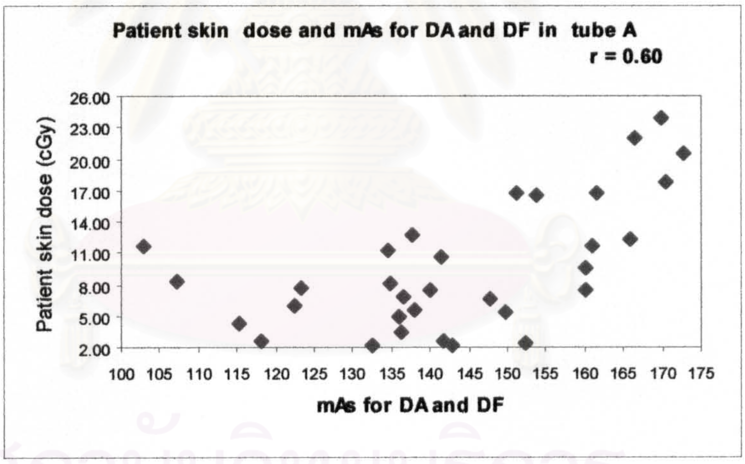

Figure 4.11 The correlation between patient skin dose (cGy) and mAs for DA and DF in tube A of DCA (n = 32)

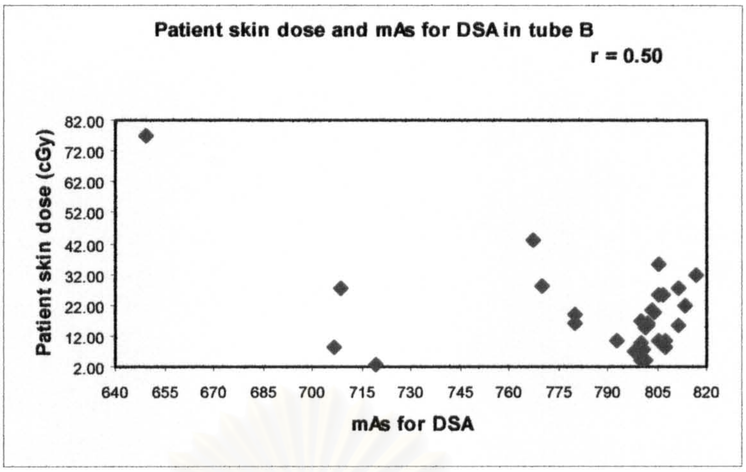

Figure 4.12 The correlation between patient skin dose (cGy) and mAs for DSA in tube B of DCA (n = 32)

Table 4.9 to 4.11. show Pearson correlation coefficient (r) between the average patient skin dose and the kVp, mAs, fluoroscopic time, number of frames, the patient body mass index and the experience of the cardiologists.

Table 4.9. Pearson correlation coefficient (r) between the average patient skin dose and factors affecting patient skin dose in DCA.

Parameters	Pearson correlation coefficient (r)			
	DCA			
	Bi plane			
	Tube A	95% CI**	Tube B	95% CI
Fluoroscopic time (min)	0.30	(-0.25)-2.92	**0.60*** **(r^2 = 0.32)**	2.41-8.19
Patient Body Mass Index (BMI: kg/m^2)	0.28	(-0.09)-0.81	0.30	(-0.24)-1.91
number of frames	0.30	(-0.002)-0.02	0.10	(-0.02)-0.03
kVp for DA and DF	0.20	(-0.16)-0.56	**0.80 *** **(r^2 =0.65)**	0.87-1.53
mAs for DA and DF	**0.60 *** **(r^2 =0.33)**	0.09-0.29	0.004	0.27-0.33
kVp for DSA	**0.65 *** **(r^2 =0.42)**	0.24-0.62	**0.80*** **(r^2 =0.63)**	0.77-1.39
mAs for DSA	0.31	(-0.06)-1.53	**0.50*** **(r^2 =0.22)**	(-0.31)-(-0.05)
Experience of cardiologists	0.32	0.73-0.39	0.16	(-1.09)-2.87

*** $p< 0.05$, r^2 is the coefficient of determination**
**** 95% confidence interval**

Table 4.10. Pearson correlation coefficient (r) between the average patient skin dose and factors affecting patient skin dose in PTCA/stent.

Parameters	Pearson correlation coefficient (r) PTCA/stent Bi plane			
	Tube A	95%CI**	Tube B	95%CI
Fluoroscopic time (min)	**0.47*** **(r^2 =0.21)**	0.20-4.16	**0.83 *** **(r^2 =0.67)**	3.07-6.03
Patient Body Mass Index (BMI: kg/m^2)	0.04	(-3.90)-4.60	0.13	(-10.91)-19.10
number of frames	**0.64 *** **(r^2 = 0.41)**	0.01-0.05	**0.70 *** **(r^2 =0.49)**	0.07-0.21
kVp for DA and DF	0.34	(-4.12)-0.42	0.18	(-0.53)-9.69
mAs for DA and DF	0.19	(-0.99)-1.02	0.12	(-4.65)-2.75
kVp for DSA	0.001	(-1.65)-1.65	0.34	(-1.24)-8.82
mAs for DSA	0.41	(-0.18)-0.09	0.15	(-1.51)-2.89
Experience of cardiologists	0.16	(-3.78)-7.64	0.15	(-21.91)-19.17

*** $p< 0.05$, r^2 is the coefficient of determination**
**** 95% confidence interval**

Table 4.11 Pearson correlation coefficient (r) between the average patient skin dose and factors affecting patient skin dose in cardiac RF ablation.

Parameters	Pearson correlation coefficient (r) Cardiac RF ablation Single plane	
		95%CI**
Fluoroscopic time (min)	**0.90 *** **(r^2 = 0.81)**	1.54-2.52
Patient Body Mass Index (BMI: kg/m^2)	0.35	(-1.72)-12.23
kVp for DA and DF	0.14	(-6.14)-3.44
mAs for DA and DF	0.04	(-17.07)-14.66
Experience of cardiologists	0.30	((-27.90)-6.32

*** $p< 0.05$, r^2 is the coefficient of determination**
**** 95% confidence interval**

4.9 Estimated patient skin dose from DAP meter readout in cardiac catheterization procedures

Figures 4.15 and 4.16 show the correlation between DAP meter readout and patient skin dose of PTCA/stent.

Figure 4.17 shows the correlation between DAP meter readout and patient skin dose of cardiac radiofrequency ablation. The x-axis represents the average patient skin dose in cGy. The y-axis shows DAP meter readout ($cGy.cm^2$). The curve shows the linear relation between DAP meter and the average patient skin dose.

4.9.1 DCA procedure

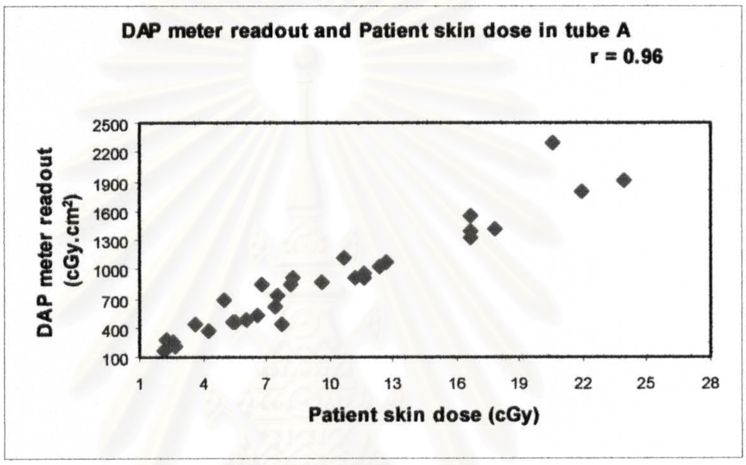

Figure 4.13 The correlation between DAP meter readout ($cGy.cm^2$) and patient skin dose (cGy) in DCA for tube A.

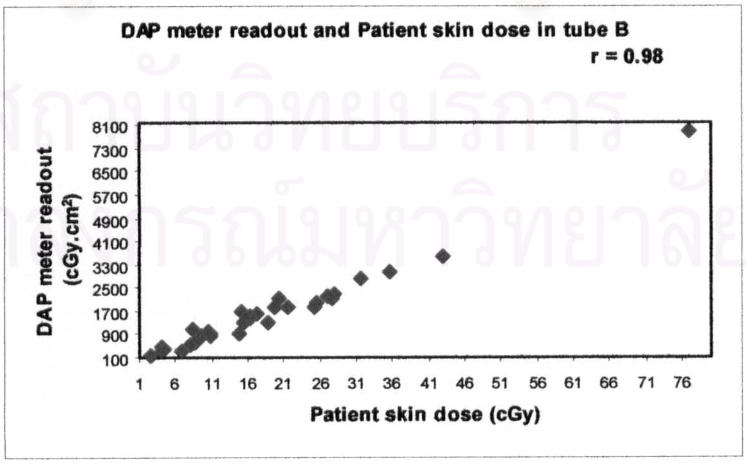

Figure 4.14 The correlation between DAP meter readout ($cGy.cm^2$) and patient skin dose (cGy) in DCA for tube B.

4.9.2 PTCA/stent procedure

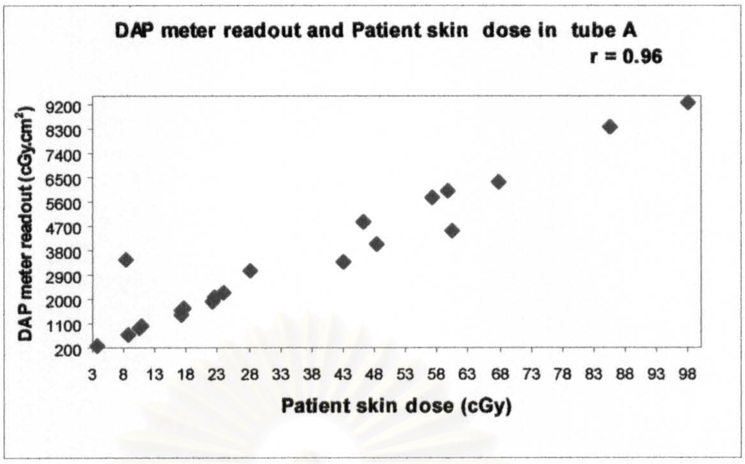

Figure 4.15 The correlation between DAP meter readout (cGy.cm^2) and patient skin dose (cGy) in PTCA/stent for tube A.

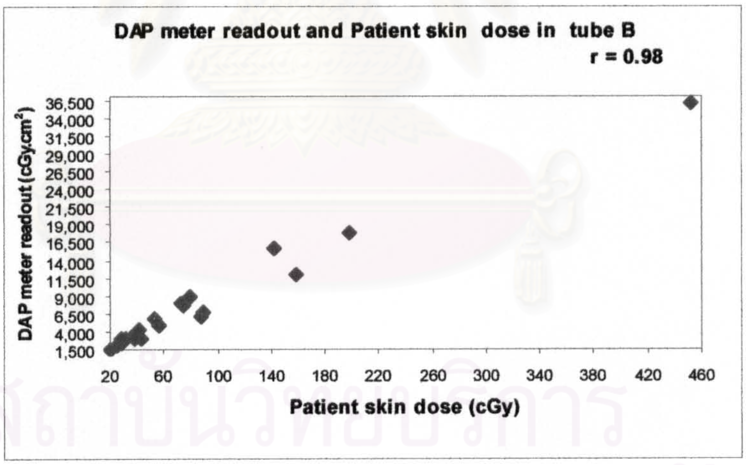

Figure 4.16 The correlation between DAP meter readout (cGy.cm^2) and patient skin dose (cGy) in PTCA/stent for tube B.

4.9.3 Cardiac radiofrequency ablation procedure

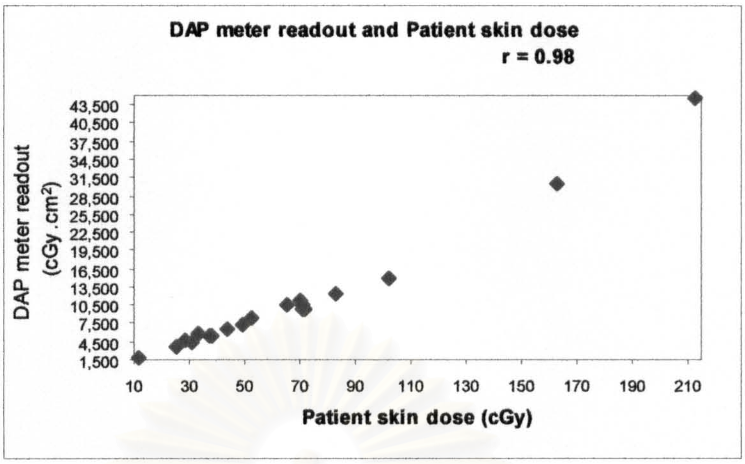

Figure 4.17 The correlation between DAP meter readout ($cGy.cm^2$) and patient skin dose (cGy) in cardiac radiofrequency ablation for single plane.

Table 4.12 shows Pearson correlation coefficient (r) between the average patient skin dose and DAP meter readout ($cGy.cm^2$) in cardiac catheterization procedures. Figures 4.13-4.14 are scattered diagram showing the correlation between DAP meter readout and patient skin dose of DCA.

Table 4.12 Pearson correlation coefficient (r) between the average patient skin dose and DAP meter readout ($cGy.cm^2$) in cardiac catheterization procedures.

Procedures	Pearson correlation coefficient (r)					
	Bi planes				Single plane	
	Tube A	95% CI**	Tube B	95% CI	Single plane	95% CI
DCA	**0.96*** (r^2 = 0.92)	0.010-0.012	**0.98 *** (r^2 = 0.96)	0.009-0.011	-	-
PTCA/stent	**0.96*** (r^2 = 0.92)	0.009-0.012	**0.98*** (r^2 = 0.97)	0.011-0.013	-	-
Cardiac RF ablation	-	-	-	-	**0.98*** (r^2 = 0.97)	0.004-0.005

*** $p< 0.05$, r^2 is the coefficient of determination**
**** 95% confidence interval**

CHAPTER 5

DISCUSSION AND CONCLUSION

Discussion

The average patient skin dose and its affecting factors were carefully studied in cardiac catheterization procedures during the year 2004-2006 at King Chulalongkorn Memorial Hospital . Among 73 patients who underwent cardiac catheterization procedures there are 32 cases of diagnostic cardiac angiography (DCA), 21 cases of cardiac intervention and 20 cases of cardiac radiofrequency ablation. The average patient skin dose from DCA was 9.52 cGy (range (min-max), median (IQR), 2.13 - 23.94, 7.75 (10.50)) in tube A (Postero-Anterior) and 18.67 cGy (range (min-max), median (IQR), 2.47 – 77, 16.36 (17.02)) in tube B (Lateral), PTCA/Stent was 35.95 cGy (range, median (IQR), 3.58 - 97.72, 23.86 (41.96)) in tube A and 85.42 cGy (range, median (IQR), 20.4 – 451, 53.42 (56.06)) in tube B and cardiac radiofrequency ablation was 64.82 cGy (range, median (IQR), 11.9 – 212, 50.78 (37.35)) for single plane. Two patients received dose higher than threshold erythema dose level of PTCA/Stent (4.51 Gy) and cardiac radiofrequency ablation (2.12 Gy).

DAP meter readout ($cGy.cm^2$) were recorded for all patients who underwent cardiac catheterization procedures. The average from DCA was 861.06 $cGy.cm^2$ (range, 171-2,287) in tube A (Postero-Anterior) and 1,653.59 $cGy.cm^2$ (range, 166-7,902) in tube B (Lateral), PTCA/stent was 3,478.43 $cGy.cm^2$ (range, 263-9,263) in tube A and 7,595.67 $cGy.cm^2$ (range, 1,507-36,044) in tube B and cardiac radiofrequency ablation was 10,652.70 $cGy.cm^2$ (range, 1,775-44,702) for single plane.

The results were compared with other studies as shown in Table 5.1 for the number of patients and DAP meter readouts.

Table 5.1. Comparison DAP readouts with other studies from cardiac catheterization procedures

Procedures	Study	Number of Patients	DAP meter readout ($Gy.cm^2$) Average	Range or Maximum	Median
DCA	De Putte, S., 2000	62	60.6	144	56.82
	Clark, A. L., 2000	117	14.2	1.1-11.3	-
	Neofotistou, V., 1998	198	72	27-79	-
	Vano, E., 1995	288	66.5	11.6 – 482	45.75
	This study	**32**	**12.57**	**1.66-79.02**	**9.52**

Procedures	Study	Number of Patients	DAP meter readout (Gy.cm^2)		
			Average	Range or Maximum	Median
PTCA/stent	Karambatsakidou et al, 2005	10	35.0	16-115	-
	Bazli et al, 2004	32	111	22.4-477	111
	Delichas, M. G., 2003	47	63	13-122	-
	Zorzetto, M., 1997	31	91.8	-	-
	Padovani, R., 1997	54	102	-	-
	Vano et al, 1995	45	66.8	12.8-345	66.8
	This study	**21**	**55.37**	**2.63-360.44**	**35.93**
Cardiac RF ablation	McFadden, S. L., 2002	50	123	21-430	-
	Webster, C. M., 2001	23	105	14-341	-
	Neofotistou, V., 1998	21	-	2.9-134	-
	Broadhead, D. A., 1997	81	95	-	-
	This study	**20**	**106.52**	**17.75-447.02**	**78.74**

Factors affecting dose

A. The fluoroscopic time

The patient skin dose is increasing as the fluoroscopic time increases for each procedure. The correlation was good in tube B but poor in tube A because tube B is lateral position. It is more affected than tube A, where high mAs , high kVp and more scatter radiation were obtained while increasing fluoroscopic time.

Table 4.5 and 4.9 and Figures 4.2 to 4.5 show fluoroscopic time and the correlation with the average patient skin dose for cardiac catheterization procedures. The fluoroscopic time for DCA was 2.08, 0.50-6.00 min (average, range (min-max)) in tube A and 1.51, 0.30-7.10 min (average, range(min-max)) in tube B. The correlation between patient skin dose and fluoroscopic time was good correlated in tube B (r =0.60) but the relationship in tube A was poorly correlated (r = 0.30).

Table 4.6 and 4.10 show fluoroscopic time and the correlation with the average patient skin dose for PTCA/stent. The fluoroscopic time was 7.76, 0.80-22.50 min (average, range (min-max)) in tube A and 13.64, 0.70-61.50 min (average, range (min-max)) in tube B. The correlation between patient skin dose and fluoroscopic time was good correlated in tube B (r =0.83) but the relationship in tube A was fair correlated (r = 0.47). The fluoroscopic time at tube B for PTCA/stent was the longest at tube B of 61.5 min when compared to DCA of 6-7 min fo tube B.

Table 4.7 and 4.11 shows fluoroscopic time and the correlation with the average patient skin dose for cardiac radiofrequency ablation. The fluoroscopic time was 24.64, 7.00-96.70 min (average, range (min-max)) for single plane. The correlation between patient skin dose and fluoroscopic time were good correlated for sigle plane (r =0.90).

B. Patient BMI

The body mass index (BMI) of patients undergoing cardiac procedures in this study was shown in Table 4.5 to 4.7. The patient skin dose increases with increasing BMI for cardiac catheterization procedures.

The patient BMI for DCA was 24.29, 15.43-38.09 kg/m^2 (average, range (min-max)). The correlation between patient skin dose and patient BMI in DCA were poor correlation in tube A (r = 0.28) and B (r = 0.30).

The patient BMI for PTCA/stent was 24.42, 18.82 - 30.85 kg/m^2 (average, range, (min-max)). The correlation between patient skin dose and patient BMI in PTCA/Stent were very poor correlation in tube A (r = 0.04) and B (r = 0.13).

The patient BMI for cardiac radiofrequency ablation was 23.21, 18.37-29.38 kg/m^2 (average, range (min-max)). The correlation between patient skin dose and patient BMI in cardiac radiofrequency ablation was poor (r = 0.35).

The maximum BMI was found in DCA procedures of 38.09 kg/m^2. The body mass index of a patient is also weakly related to the risk for high skin dose in the cardiac catheterization procedures of this study. This means that the size of a patient is less an important predictor of the dose to be delivered than other factors, such as the complexity of a procedure. A large patient will contribute to the elevation of a high dose delivery during a difficult procedure.

C. The number of frames

The number of frames in this study was shown in Table 4.5 and 4.6. Figure 4.6 and 4.7 showed the correlation between patient skin dose and the number of frames. The correlation was good for PTCA/stent but poor in DCA. The more number of frame was used in PTCA/stent, which was more affected with patient skin dose because of the long fluoroscopic time.

The number of frames in DCA was 495, 216-1141 (average, range (min-max)) in tube A and 480, 216-1144 (average, range (min-max)) in tube B. The correlation between the average patient skin dose and the number of frames were poor correlation (r = 0.10) in tube B and in tube A (r = 0.30)

The number of frames in PTCA/stent was 941, 334-1927 (average, range (min-max)) in tube A and 936, 336-1854 (average, range (min-max)) in tube B. The correlation between the average patient skin dose and the number of frames was good correlation in tube A (r = 0.64) and B (r = 0.70)

D. The kVp for DA and DF

The kVp for DA and DF in this study was shown in Table 4.5 to 4.7. The correlation between patient skin dose and kVp for DA and DF of DCA, PTCA/stent and cardiac radiofrequency ablation were shown in Figures 4.8. This studies shows good correlation in tube B of lateral position, higher kVp was used. For PTCA/stent, poor correlation was obserbed for both tubes.

The kVp for DA and DF in DCA was 66.50, 56.50-90.40 (average, range (min-max)) in tube A 74.73, 64.50-101.90 (average, range (min-max)) in tube B. The correlation between patient skin dose and kVp for DA and DF of DCA was poor in tube A (r = 0.2) but good in tube B (r = 0.80).

The kVp for DA and DF in PTCA/Stent was 69.15, 60.70-87.70 (average, range (min-max)) in tube A 76.83, 67.60-92.90 (average, range (min-max)) in tube B. The correlation between patient skin dose and kVp for DA and DF of PTCA/Stent was poor in tube A (r = 0.34) and very poor correlation tube B (r = 0.39). The high kVp was used in PTCA/stent for tube B than tube A.

The kVp for DA and DF in cardiac radiofrequency ablation were 76.60, 75.00-92.00 (average, range (min-max)) for single plane. The correlation between patient skin dose and kVp for DA and DF of cardiac radiofrequency ablation was poor (r = 0.14).

The kVp for DSA

The kVp for DSA and the correlation between patient skin dose and kVp of DCA and PTCA/stent were shown in Table 4.5 and 4.6.

The kVp for DSA was 74.11, 62.20-99.60 (average, range(min-max)) in tube A 79.28, 63.50-110.80 (average, range(min-max)) in tube B. The correlation between patient skin dose and kVp for DSA of DCA was good correlated in tube A (r = 0.65) and tube B (r = 0.80).

The kVp for DSA was 72.69, 64.00-95.90 (average, range(min-max)) in tube A 80.58, 67.40-92.10 (average, range(min-max)) in tube B. The correlation between patient skin dose and kVp for DSA of PTCA/stent was poor correlated in tube A (r = 0.001) and tube B (r = 0.34).

E. The mAs for DA and DF

The mAs for DA and DF in this study was shown in Table 4.4 to 4.7. The correlation between patient skin dose and mAs for DA and DF of DCA was shown in Figures 4.10.

The mAs for DA and DF in DCA was 143.82, 102.80-172.80 (average, range(min-max)) in tube A 156.65, 109.70-179.80 (average, range) in tube B. The correlation between patient skin dose and mAs for DA and DF of DCA was good correlation in tube A (r = 0.60) but very poor in tube B (r = 0.04).

The mAs for DA and DF in PTCA/stent was 160.85, 122.50-180.90 (average, range(min-max)) in tube A 165.86, 141.40-182.10, 170 (average, range(min-max)) in tube B. The correlation between patient skin dose and mAs for DA and DF of PTCA/stent was very poor in tube A (r = 0.008) and tube B (r = 0.12).

The mAs for DA and DF in cardiac radiofrequency ablation was 2.58, 1.00-6.20 (average, range(min-max)). The correlation between patient skin dose and mAs for DA and DF of cardiac radiofrequency ablation was very poor correlation for single plane (r = 0.04).

The mAs for DSA

The mAs for DSA in this study was shown in Table 4.5 and 4.6. The correlation between patient skin dose and mAs for DSA of DCA was shown in Figure 4.11 and 4.12. The correaltion between mAs and dose was poor in DCA and PTCA/stent. The mAs was automatic exposure control from machine system during procedure.

The mAs for DSA was 781.37, 602.70-814.70 (average, range(min-max)) in tube A 786.77, 649.50-816.60 (average, range(min-max)) in tube B. The correlation between patient skin dose and mAs for DSA of DCA was poor in tube A (r = 0.31) and fair in tube B (r = 0.50).

The mAs for DSA was115.43, 67.40-799.80 (average, range(min-max)) in tube A 801.70, 718.70-820.00 (average, range(min-max)) in tube B. The correlation between patient skin dose and mAs for DSA of PTCA/stent was poor in tube A (r = 0.41) and very poor tube B (r = 0.15).

F. The experience of the cardiologist

The detail of experience of the cardiologists was shown in Table 4.8. The experience of the cardiologists in DCA was 11, 8-14 years (average, range(min-max)). The correlation between the average patient skin dose and the experience of the cardiologist was poor (r = 0.32) with dose from tube B and it was very poor with dose from tube A (r = 0.16).

The experience of the cardiologists in PTCA/Stent was 10, 8-14 years (average, range(min-max)) in tube A and 10, 8-14 (average, range(min-max)) in tube B. The correlation between the average patient skin dose and the experience of the cardiologist was very poor in tube A (r = 0.16) and B (r = 0.15).

The experience of the cardiologists in cardiac radiofrequency ablation was 7, 5-9 (average, range(min-max)). The correlation between patient skin dose and the experience of the cardiologists of cardiac radiofrequency ablation was poor (r = 0.30).

The experience of cardiologists is a major factor in dose management but showing poor correlation with the patient skin dose. Fellows training in interventional cardiac procedures could cause a significant increase in patient exposure during fluoroscopy. Exposure can be further reduced by limiting the number of procedures performed with or by cardiology fellows. It would be important to decide if a cardiology fellow or only who will eventually become cardiologist should receive enough practical training.

Conclusion

Two patients from PTCA/stent and cardiac radiofrequency ablation procedures received skin dose over threshold level for erythema (2 Gy) of 4.51 Gy (fluoroscopic time 96.70 min on 04/05/06) and 2.12 Gy (fluoroscopic time 61.50 min on 16/04/06) respectively.

Fluoroscopic time is a factor showing high correlation with dose to the patient in cardiac catheterization procedures especially in the cardiac radiofrequency ablation of single plane.

The number of frames were good correlation with the skin dose only in tube A (r = 0.64) and tube B (r = 0.70) of PTCA/stent. The number of frames has little effects in DCA because of a short time procedure and small number of frames, while PTCA/stent took longer time and more number of frames during procedure.

One of the important factor affecting the patient skin dose is the use of frame rate. For this study it was fixed at 15 frame/sec, which was not influenced the skin dose. Nevertheless, it is necesssary to optimize the patient skin dose to low number of frames to avoid radiation induced skin injuries in patients who underwent cardiac catheterization procedures. Nowadays the number of frame is dependent on the cardiologists to manage the procedures.

The kVp for DA and DF was good correlation with the average patient skin dose only in tube B of DCA (r = 0.80). The kVp for DSA were good correlation in tube A (r = 0.65) and tube B (r = 0.80) of DCA. Tube B is at lateral position, as high kVp was used in tube B.

The mAs for DA and DF was good correlation with the average patient skin dose only tube A of DCA (r = 0.60). The mAs for DSA was fair correlation only in tube A of DCA (r =0.50).

The radiographic-fluoroscopic equipment is automatic brightness control system, the quality control (QC) program is necessary for the fluoroscopic x-ray output measurement. The calibration of the equipment, condition of the x-ray tube and any potential changes of the filtration were evaluated. A low radiation output could mean either the kVp or mAs was too low, the average patient skin dose is optimized for cardiac catheterization procedures.

DAP meter was recorded dose when the exposure was on, the readouts show the amount at different position on skin as the tube moved most of the time. The calculated dose does not account at single position. Furthermore different beam geometries and output modes of operation had be selected. Therefore, the dose determined was average skin dose rather than the peak skin dose.

Summary

The patient skin dose is an important during the cardiac catheterization procedures. Cardiologists and staff should be aware of several parameters influencing dose, therefore the case record form should be conducted. In case of the over exposure leading to skin injury, the cardiologists should inform the clinician to follow up and proper treatment for such the late effectes. The radiation risk is usually outweighed by the benefit of the procedure. Both patients and staff are at risk of radiation injury, appropriate equipment and training are needed to minimize this risk. Patient counselling should be undertaken routinely, and follow up when appropriated.

Recommendations

The average patient skin dose from DAP meter is more significant. It may be estimated from DAP meter readout but the dose was dependent. on the procedure, the direction of the tubes and the experience of the cardiologist. The calibration of DAP meter is necessary as the routine quality control.

The correlation factors should be posted for the staff awareness such as fluoroscopic time by keep beam-on time to a minimum, keep tube current (mAs) as low as possible and tube potential (kVp) as high as applicable, keep x-ray tube at maximum and the image intensifier at minimum distance from patient and prolonged procedures: reduce dose to the irradiated skin e.g. by changing beam angulation.

Controlling radiation dose for staff such as wear protective apron & glasses, use shielding, monitor hand dose is often important and correct positioning to machine to minimise the patient skin dose is recommended.

REFERENCES

1. Grossman W. Historical perspective and present practice of cardiac catheterization. In: Baim DS, Grossman W, eds. Grossman's cardiac catheterization, angiography and intervention,6th ed. Philadelphia. PA:Lippincott Williams&Wilkins,2000:3-14.
2. International Commission on Radiological Protection. Recommendations of the International Commission on Radiological Protection, ICRP publication 60. Oxford:Pergamon,1991.
3. Shope TB. Radiation – induced skin injuries from fluoroscopy. Radiographics. 1996;16:1195-1199.
4. Koeing TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 2, review of 73 cases and recommendations for minimizing dose delivered to the patient. Am J Roentgenol. 2001; 177: 13-20.
5. US Food & Drug Administration (FDA): Avoidance of serious x-ray induced skin injuries to patients during fluoroscopically-guided procedures. Medical Bulletin 1994; 24:7-17.
6. Joint WHO/ISH/CE workshop on efficacy and radiation safety in interventional radiology;1995 October9-13; Munich Neuremberg, Germany. Bundesamt fur Strahlenschutz, Bfs-ISH-178/97,1997.
7. Koeing TR, Wolff D,Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures:part 1. Characteristics of radiation injury. Am J Roentgenol. 2001;177:3-11.
8. Food and Drug Administration, "Important Information for Physicians and Other Health Care Professionals." Recording information in the patient's medical record that identifies the potential for serious X-Ray induced skin injuries following fluoroscopically guided procedures (September 15th 1995).
9. Shope TB. "Regulations and recommendations relevant to interventional radiology" in Syllabus:categorical course in physics:physical and technical aspects of angiography and interventional radiology Oak Brook, Radiological Society of North America.1995;195-205.
10. Wagner LK, Eifel PJ, and Geise RA Potential biological effects following high X-ray dose interventional procedures. Journal of Vascular and Interventional Radiology 994; 5:71-84.
11. Betsou S, Efstathopoulos EP, Katritsis D, Faulkner K, Panayiotakis G. Patient radiation doses during cardiac catheterization procedures. The British Journal of Radiology1998; 71:634-639.
12. Vano E, Guibelalde E, Fernandez JM, Gonzalez L, Ten JI. Patient dosimetry in interventional radiology using slow films. The British Journal of Radiology 1997; 70:195-200.
13. De Putte S, Verhaegen F, Taeymans Y, Thierens H. Correlation of patient skin dose in cardiac interventional radiology with dose – area product. The British Journal of Radiology 2000; 73: 504-513.
14. Koichi C, Haruo S, Hiroki O, Masahiro K, et al. Relationship between fluoroscopic time, Dose–Area Product, body weight, and maximum radiation skin dose in cardiac interventional procedures. American Journal of Roentgenology 2006; 186: 774-778.

15. Kumkrua C. The patient skin dose determined by radiochromic film and DAP meter method in cardiac catheterization and interventional radiology. Thesis for the Degree of Master of Science in Medical Imaging, Department of Radiology Faculty of Medicine Chulalongkorn University. ISBN : 974-17-6527-4.2004.

APPENDICES

APPENDIX A
Case record form

Clinical Data Collection for

( ) **DCA**
( ) **Cardiac Intervention**
( ) **RF Ablation**

Facility identification	
Equipment	
Plane for bi-plane system, if applicable	
Procedure	
Initial DAP setting	
Initial cumulative fluoroscopic time	
Patient Number	
Patient Height	
Patient Weight	
Patient Gender/Age	
Portal film in place?	
Superior position marked on film?	
Patient left marked on film	
Start time	
Fluoroscopy dose mode setting initially and at 10 minute interval	
End time	
DAP readout at end(cGy.cm2)	
Cumulative fluoroscopic time at end	
DA or digital fluorography frames	
DA or digital fluorography frame rate	
Dose mode setting for DA and fluorography	
Typical kVp, mAs, for DA or DF	
DSA frames(number)	
Dose mode setting for DSA	
Typical kVp, mAs, for DSA	
Cine frames rate	
Cine frames (number)	
Equipment setting for Cine	
Number of Cine run offs	
Typical kVp, mAs for Cine	
Calculate patient skin dose	
Date/month/year	
DAP Calibration factor =	
Display dose from system	
Experience of the cardiologist	
Cardiologist	
Cardiologist exposure/Case (Pocket dosemeter)	
Data collector	

APPENDIX B

ข้อมูลสำหรับผู้เข้าร่วมวิจัย (Patient information sheet)

การศึกษา : การหาปริมาณรังสีเฉลี่ยที่ผิวหนังผู้ป่วยและปัจจัยที่มีผลต่อปริมาณรังสีจากการตรวจสวนหัวใจ

เรียน ผู้เข้าร่วมวิจัยทุกท่าน

ท่านเป็นผู้ที่ได้รับเชิญให้เข้าร่วมการศึกษาเพื่อวัดปริมาณรังสีเฉลี่ยที่ผิวหนังผู้ป่วยและปัจจัยที่มีผลต่อปริมาณรังสีจากการตรวจสวนหัวใจ โดยใช้แดพมิเตอร์และพอร์ทอลฟิล์ม ก่อนที่ท่านจะตกลงเข้าร่วมการศึกษาดังกล่าว ขอเรียนให้ท่านทราบถึงเหตุผลและรายละเอียดของการศึกษาวิจัยในครั้งนี้

ผู้ป่วยที่เข้ารับการตรวจสวนหัวใจโดยใช้การฉายรังสีแบบต่อเนื่อง เป็นเครื่องมือในการนำตรวจจะมีความเสี่ยงที่จะได้รับปริมาณรังสีสูงกว่าการตรวจวินิจฉัยทั่วไป และปริมาณรังสีที่ได้รับจะมีระดับอยู่ในเกณฑ์ที่สามารถยอมรับได้หรือไม่นั้นเป็นสิ่งที่น่าศึกษาอย่างยิ่ง

ดังนั้นการศึกษาวิจัยในครั้งนี้ มีวัตถุประสงค์เพื่อ วัดปริมาณรังสีที่ผิวหนังของผู้ป่วยต่อการตรวจหรือการรักษาแต่ละครั้งว่าเป็นปริมาณเท่าไร เพื่อไม่ให้เกินปริมาณรังสีสูงสุดที่ผู้ป่วยสามารถรับได้ และยังเป็นการศึกษาหาปัจจัยที่มีผลต่อการได้รับปริมาณรังสีที่ผิวหนังของผู้ป่วยด้วย

ในการวัดปริมาณรังสี จะใช้ พอร์ทอลฟิล์ม (Portal film) ซึ่งมีลักษณะเป็นแผ่นฟิล์มเอกซเรย์โดยมีซองสีเหลืองหุ้มอยู่ ขนาด 10 X 12 นิ้ว และแดพมิเตอร์ (DAP meter) ซึ่งเป็นเครื่องมือที่ใช้วัดปริมาณรังสีที่ออกมาจากหลอดเอกซเรย์โดยตรงในการวัดจะวางพอร์ทอลฟิล์มใต้ตัวผู้ป่วย บนเตียงเอกซรย์บริเวณหลังตรงช่วงอกซึ่งมีรังสีผ่านตัวผู้ป่วยขณะรับการตรวจ สำหรับแดพมิเตอร์ส่วนหัววัดจะติดที่หลอดเอกซเรย์โดยเครื่องอ่านจะแยกออกมาต่างหาก ซึ่งอุปกรณ์ทั้งสองชนิดนี้จะไม่รบกวนหรือเป็นอุปสรรคทั้งตัวผู้ป่วยและเจ้าหน้าที่ในขณะปฏิบัติงาน

หากท่านตกลงที่จะเข้าร่วมการศึกษาวิจัยนี้จะมีข้อปฏิบัติร่วมกันดังต่อไปนี้

1. ท่านไม่ต้องเสียค่าใช้จ่ายใดๆเพื่อการวัดปริมาณรังสีดังกล่าว

2. ก่อนเริ่มการตรวจแต่ละครั้ง ผู้วิจัยจะติดเครื่องมือคือ แดพมิเตอร์ที่หลอดเอกซเรย์และพอร์ทอลฟิล์มวางบนเตียงเอกซเรย์และใต้ตัวผู้ป่วยบริเวณหลังตรงกับช่วงหน้าอก โดยจะไม่ทำให้เกิดการระคายเคืองใดๆต่อผู้ป่วย

3. หลังจากที่แพทย์และเจ้าหน้าที่ทำการตรวจหรือรักษาเสร็จในแต่ละการตรวจ ผู้วิจัยจะทำการเก็บพอร์ทอลฟิล์มและนำค่าที่ได้จากแดพมิเตอร์ไปคำนวณหาปริมาณรังสีที่ผู้ป่วยได้รับในการตรวจครั้งนั้นๆ

การเข้าร่วมศึกษาวิจัยนี้ เป็นไปโดยสมัครใจท่านอาจจะปฏิเสธที่จะเข้าร่วม หรือถอนตัวจากการศึกษาวิจัยนี้ได้ทุกเมื่อ

ประการสำคัญที่ท่านควรทราบคือ ผลของการศึกษาวิจัยนี้ จะใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น โดยข้อมูลต่างๆจะไม่มีการแพร่งพรายสู่สาธารณชน ขอรับรองว่าจะไม่มีการเปิดเผยชื่อของท่านตามกฎหมาย และท่านจะได้รับแจ้งปริมาณรังสีที่ท่านได้รับจากคณะผู้วิจัยในภายหลัง

หากท่านมีปัญหาหรือข้อสงสัยประการใดกรุณาติดต่อนายพัฒนพงษ์ แสนชนม์โทร01- 8735783ซึ่งยินดีให้คำตอบแก่ท่านทุกเมื่อ

ขอขอบคุณในความร่วมมือของท่านมา ณ ที่นี้

ใบยินยอมเข้าร่วมการวิจัย (Consent form)

การวิจัย เรื่อง ปริมาณรังสีเฉลี่ยที่ผิวหนังผู้ป่วยและปัจจัยที่มีผลต่อปริมาณรังสีจากการตรวจสวนหัวใจ

วันให้คำยินยอม วันที่.............เดือน................................ พ.ศ. ....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการทำการวิจัย วิธีการวิจัยอันตรายหรืออาการที่อาจเกิดขึ้นจากการทำการวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการทำวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิ์ที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลใดๆต่อข้าพเจ้า

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้องจะทำได้เฉพาะกรณีที่จำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม ....ผู้ยินยอม

( )

ลงนาม ....พยาน

( )

ลงนาม ....พยาน

( )

ลงนาม ....ผู้ทำวิจัย

( )

APPENDIX C
EQUIPMENT PERFORMANCE FOR FLUOROSCOPY EQUIPMENT

Hospital:	King Chulalongkorn Memorial Hospital	**Report Number:**	1
X-ray Unit:	**GE Advantx LC DC 1994**	**Date:**	April 25,2006
Room:	S.K. Building 4th Floor Room 1	**Test performed by:**	Phattanapong Saenchon

Antiscatter grid NOT removed.

DOSE ASSESSMENT

	SET	Measured
Focus-Intensifier d. (cm)	100	93
Patient dose measurement: Focus-Patient Dist	**51.5**	cm
Entrance II dose measurement: Focus-Ion ch. Dist	**42.5**	cm

Mode	Submode/ Image quality	Pulse rate (pulses/s)	Automatic added filtration (mm Cu)	Field size (cm)	kV	mA	(Patient entrance surface air kerma) Copper filter entrance air kerma (mGy/min)	Image Intensifier entrance air kerma (mGy/min)	Patient entrance surface air kerma at 60 cm (including backscatter (1.3) (mGy/min)	Phantom
Fluoro	A	6.3	0.0	9.0	75.0	3.8	48.6	14.9	46.5	2 mm Cu
Normal		8.3		9.0	75.0	3.9	48.4	14.8	46.4	
		12.5		9.0	76.0	3.7	51.0	15.6	48.8	
		25.0		9.0	76.0	3.7	49.2	15.1	47.1	
		6.3		6.0	76.0	5.1	49.3	15.0	47.2	
		8.3		6.0	76.0	5.2	65.8	20.2	63.0	
		12.5		6.0	76.0	5.6	63.6	19.5	60.9	
		25.0		6.0	76.0	5.2	63.8	19.6	61.1	
		6.3		4.5	76.0	6.3	54.1	16.6	51.8	
		8.3		4.5	74.0	6.6	74.0	22.7	70.9	
		12.5		4.5	81.0	6.3	74.0	22.7	70.9	
		25.0		4.5	91.0	6.2	75.2	23.0	72.0	

43

AUTOMATIC BRIGHTNESS CONTROL TEST

Mode	Submode/ Image quality	Pulse rate (pulses/s)	Automatic added filtration (mm Cu)	Field size (cm)	Pulse with (ms)	Automatic added filtration (mm Cu)	Dose rate (mGy/min)	kV	mA
Fluoro	Normal	low	1.5	9.0			26.9	75.0	2.2
			3.0	9.0			92.6	82.0	6.6
			4.5	9.0			100.4	101.0	4.0
			6.0	9.0			116.1	120.0	4.2

* only one mode and field size is checked (about 20 cm)

MAXIMUM DOSERATE ASSESSMENT

Chamber to focus distance (cm) **48**

Mode	Submode/ Image quality	Field of view (cm)	Doserate (mGy/min)	
Fluoro	6.3	4.5	93.4	2mm
		6.0	110.9	2.0
		9.0	119.6	2.0
		4.5	120.5	2+
		6.0	117.8	2+
		9.0	117.8	2+

measure doserate for all modes and FOVs, dosimeter on the table and table at the lowest position
absorber: 2 mm of lead on the image intensifier (or equivalent attenuatin with a folded lead apron)

TABLE ATTENUATION

Mode	Submode/ Image quality	Doserate (mGy/min)	Table attenuation %	Absorber
C-arm at 0°	Normal	8.8	9..9	2mm Cu
C-arm at 90°	Normal	9.8		

Measurement of doserate in fluoro for the same mode and field size

IMAGE SIZE ASSESSMENT

Mode	Submode/ Image quality	Field of view (cm)	Horizontal size (cm)	Vertical size (cm)
Fluoro	Normal	15.0	13.0	13.3
	Mag I	12.0	11.3	11.3
	Mag II	11.0	9.8	10.0

* make measurements of field size for all the available magnifications with a lead ruler or coins

HALF VALUE LAYER ASSESSMENT

Al attenuator (mm)	Submode/ Image quality	Doserate (mGy/min)	HVL (mm)
0.0	Normal	7.4	
3.0		4.1	
6.0		2.8	
			3.2

make measurement in fluoro mode, add attenuator (copper sheets) on I.I. to drive kV to 80 kV

IMAGE QUALITY ASSESSMENT

Resolution should be assesed in the usual illumination conditions and from the operator's position. Leeds Test placed on Image Intensifier entrance surface with grid

High contrast resolution should have strip pattern at about 45° in respect to raster lines (no absorbers; kv: 40-60) All modes (fluoroscopy and image acquisition) and image qualities and FOVs

Monitor: | Focus-Intensifier d. (cm): 100

Mode	Submode/ Image quality	Focus(S/L)	Automatic added filtration (mm Cu)	Field size(cm)	kV	mA	Live image High contrast resolution,lp/mm
A	A	L	0.0	15.0	60.0	0.1	0.9
		L	0.0	12.0	60.0	0.1	1.0
		L	0.0	11.0	60.0	0.3	1.4
		S	0.0	15.0	60.0	0.1	0.9
		S	0.0	12.0	60.0	0.1	1.0
		S	0.0	11.0	60.0	0.3	1.4

COMMENTS

45

EQUIPMENT PERFORMANCE FOR FLUOROSCOPY EQUIPMENT

Hospital:	King Chulalongkorn Memorial Hospital	**Report Number:**	2
X-ray Unit:	**Siemens AXIOM Artis 2004**	**Date:**	April 25,2006
Room:	S.K. Building 5th Floor Room 1	**Test performed by:**	Phattanapong Saenchon

Antiscatter grid NOT removed.

DOSE ASSESSMENT

	SET	Measured
Focus-Intensifier d. (cm)	100	100
Patient dose measurement: Focus-Patient Dist	**60**	cm
Entrance II dose measurement: Focus-Ion ch. Dist	**40**	cm

Mode	Submode/ Image quality	Pulse rate (pulses/s)	Automatic added filtration (mm Cu)	Field size (cm)	kV	mA	(Patient entrance surface air kerma) Copper filter entrance air kerma (mGy/min)	Image Intensifier entrance air kerma (mGy/min)	Patient entrance surface air kerma at 60 cm (including backscatter (1.3) (mGy/min)	Phantom
Fluoro	A	30.0	0.2	25.0	75.5	100	42.1	15.1	54.7	
Normal				20.0	80.2	100	50.6	18.2	65.8	
				16.0	87.8	100	62.0	22.3	80.6	
		15.0	0.3	25.0	71.8	100	24.6	8.9	32.0	
				20.0	74.1	100	38.2	13.8	49.7	
				16.0	79.9	100	46.1	16.6	59.9	
		7.5	0.2	25.0	70.9	100	17.8	6.4	23.1	
				20.0	74.1	100	20.4	7.3	26.5	
				16.0	80.0	100	24.9	8.9	32.4	2 mm Cu

AUTOMATIC BRIGHTNESS CONTROL TEST

Mode	Submode/ Image quality	Pulse rate (pulses/s)	Automatic added filtration (mm Cu)	Field size (cm)	Pulse with (ms)	Automatic added filtration (mm Cu)	Dose rate (mGy/min)	kV	mA
Fluoro	Normal	15.0		20			1.0	60.6	63.8
							2.0	69.3	100.0
							3.0	76.6	100.0
							4.0	78.6	100.0

* only one mode and field size is checked (about 20 cm)

MAXIMUM DOSERATE ASSESSMENT

Chamber to focus distance (cm)				**47.5**
Mode	Submode/ Image quality	Field of view (cm)	Doserate (mGy/min)	
Fluoro	Normal	25	36.1	
	3.0	20.0	36.4	
		16.0	29.9	
	7.5	25	28.4	
		20.0	27.0	
		16.0	13.9	
	15.0	25	38.7	
		20.0	36.7	
		16.0	30.2	
	30.0	25	38.8	
		20.0	36.4	
		16.0	29.9	

measure doserate for all modes and FOVs, dosimeter on the table and table at the lowest position
absorber: 2 mm of lead on the image intensifier (or equivalent attenuatin with a folded lead apron)

47

TABLE ATTENUATION

Mode	Submode/ Image quality	Doserate (mGy/min)	Table attenuation %	Absorber
C-arm at 0°	Normal	17.2	2.8	2mm Cu
C-arm at 90°	Normal	17.7		

Measurement of doserate in fluoro for the same mode and field size

IMAGE SIZE ASSESSMENT

Mode	Submode/ Image quality	Field of view (cm)	Horizontal size (cm)	Vertical size (cm)
Fluoro	Normal	25	17.0	16.8
		20.0	13.8	13.7
		16.0	11.0	10.9

* make measurements of field size for all the available magnifications with a lead ruler or coins

HALF VALUE LAYER ASSESSMENT

Al attenuator (mm)	Submode/ Image quality	Doserate (mGy/min)	HVL (mm)
0.0	Normal	50.6	
3.0		36.9	
5.0		29.9	
6.0		27.2	
7.0		25.5	7.1

make measurement in fluoro mode, add attenuator (copper sheets) on I.I. to drive kV to 80 kV

IMAGE QUALITY ASSESSMENT

Resolution should be assesed in the usual illumination conditions and from the operator's position. Leeds Test placed on Image Intensifier entrance surface with grid
High contrast resolution should have strip pattern at about 45° in respect to raster lines (no absorbers; kv: 40-60) All modes (fluoroscopy and image acquisition) and image qualities and FOVs

Monitor:

Focus-Intensifier d. (cm): 100

Mode	Submode/ Image quality	Focus(S/L)	Automatic added filtration (mm Cu)	Field size(cm)	kV	mA	Live image High contrast resolution,lp/mm
A	30.0	L	0.9	25	54.1		2.0
				20.0	55.3		2.5
				16.0	57.1		2.8
	15.0	L		25	53.4		2.5
				20.0	54.3		2.5
				16.0	55.5		2.5
	7.5	L		25	53.4		2.0
				20.0	54.3		2.0
				16.0	55.5		2.3
	3.0	L		25	53.4		2.0
				20.0	54.4		2.0
				16.0	55.5		2.0
	30.0	L		25	66.0		1.6
				20.0	68.0		1.6
				16.0	68.9		2.0
	15.0	L		25	63.5		1.4
				20.0	65.2		1.6
				16.0	68.0		1.6
DSA	30.0	L	2.0+0.9	25	64.5	447.7	2.8
DA				20.0	66.0	794.3	2.8
				16.0	66.6	799.8	3.0
	15.0	L	2.0+0.9	25	64.5	447.7	2.8
				20.0	66.0	794.3	2.8
				16.0	66.6	799.8	3.2

COMMENTS

VITAE

NAME	Mr.Phattanapong Saenchon
DATE OF BIRTH	June 26, 1974
PLACE OF BIRTH	Sakon Nakhon, Thailand
INSTITUTION ATTENDED	Mahidol University, Bachelor of Science (Radiological Technology) Year 2000
POSITION HELD & OFFICE	2000 to present Department of Radiology Sakon Nakhon Hospital, Sakon Nakhon Thailand Position: Radiological Technologist