ปริมาณรังสีที่ผิวหนังของผู้ป่วย จากการวัดโดยเรดิโอโครมิคฟิล์มและแดพมิเตอร์ ในผู้ป่วยที่รับการตรวจสวนหัวใจและรังสีร่วมรักษา

นายชูชีพ คำเครือ

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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THE PATIENT SKIN DOSE DETERMINED BY RADIOCHROMIC FILM AND DAP METER METHOD IN CARDIAC CATHETERIZATION AND INTERVENTIONAL RADIOLOGY

Mr. Choocheep Kumkrua

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Medical Imaging Department of Radiology Faculty of Medicine Chulalongkorn University Academic Year 2004

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Title	The Patient Skin Dose Determined by Radiochromic Film and DAP Meter Method in Cardiac Catheterization and Interventional Radiology
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การวัดปริมาณรังสีในการศึกษานี้ ได้จากการวัดโดยเรดิโอโครมิคฟิล์มและแดพมิเตอร์ ในผู้ป่วย 64 ราย ซึ่งได้รับการตรวจทางรังสีร่วมรักษา ได้แก่ Transarterial Oily Chemo Embolization (TOCE), Percutaneous Transhepatic Biliary Drainage (PTBD), Neurovascular Intervention/Angiography และ Percutaneous Transluminal Coronary Angioplasty/Stent (PTCA) ณ โรงพยาบาลจุฬาลงกรณ์ ปริมาณรังสีสูงสุดที่ได้จากวัดโดยเรดิโอโครมิคฟิล์มจะถูกเทียบผลกับการวัดโดยแดพมิเตอร์ซึ่งแสดงผลไปในทางเดียวกัน แต่เรดิโอโครมิคฟิล์มแสดงผลของปริมาณรังสีที่สูงกว่า ทั้งนี้เพราะปริมาณรังสีที่วัดจากฟิล์มเป็นปริมาณรังสีสูงสุดที่จุดบนผิวหนังแต่ปริมาณรังสีที่คำนวณจากแดพมิเตอร์เป็นปริมาณของอาณาบริเวณ

การคำนวณปริมาณรังสีจากแดพมิเตอร์นั้น ได้จากการรวมปริมาณรังสีจากหลายๆพื้นที่บนผิวหนังผู้ป่วย ดังนั้นปริมาณรังสีที่คำนวณได้จึงไม่ได้แสดงถึงจุดสูงสุดที่รังสีเข้าสู่ผู้ป่วย และเมื่อนำพื้นที่มาคำนวณด้วยแล้วจึงมีค่าไม่สูงเท่าปริมาณรังสีที่วัดโดยเรดิโอโครมิคฟิล์ม ซึ่งทำได้โดยการสแกนฟิล์มที่บริเวณที่สีของฟิล์มเปลี่ยนมากที่สุด และนำข้อมูลไปคำนวณด้วยโปรแกรมแมทแลบ (Matlab) ผลของการคำนวณแสดงปริมาณรังสีสูงสุดที่ผู้ป่วยได้รับการตรวจ Transarterial Oily Chemoembolization (TOCE) เท่ากับ 365 เซ็นติเกรย์, Percutaneous Transhepatic Biliary Drainage (PTBD) ปริมาณรังสีสูงสุดเท่ากับ 183 เซ็นติเกรย์, Percutaneous Transluminal Coronary Angioplasty/Stent (PTCA) ปริมาณรังสีสูงสุดเท่ากับ 294 เซ็นติเกรย์ และปริมาณรังสีสูงสุดในผู้ป่วยที่รับการตรวจ Neurovascular Intervention วัดได้ 180 เซ็นติเกรย์ ส่วนใน Neurovascular Angiography วัดได้ 110 เซ็นติเกรย์ ปริมาณรังสีที่ได้รับมากหรือน้อยขึ้นอยู่กับหลายปัจจัยแต่ที่มีอย่างมากผลต่อปริมาณรังสีคือเวลาที่ใช้ในการฟลู (fluoroscopy time) และในการศึกษานี้มีผู้ป่วย 1 รายที่ได้รับปริมาณรังสีสูงกว่าเกณฑ์ที่อาจทำให้เกิดบาดแผลบนผิวหนังในเวลาต่อมา ซึ่งมีค่า 300 เซ็นติเกรย์

ภาควิชา รังสีวิทยา ลายมือชื่อนิสิต.....

สาขาวิชา ฉายาเวชศาสตร์ ลายมือชื่ออาจารย์ที่ปรึกษา.....

ปีการศึกษา 2547 ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

4674819630 MAJOR MEDICAL IMAGING
KEYWORDS: DOSE AREA PRODUCT (DAP) METER, GAFCHROMIC FILM, PATIENT SKIN DOSE.
CHOOCHEEP KUMKRUA: THE PATIENT SKIN DOSE DETERMINED BY RADIOCHROMIC FILM AND DAP METER METHOD IN CARDIAC CATHETERIZATION AND INTERVENTIONAL RADIOLOGY

THESIS ADVISOR: ASSOCIATE PROFESSOR ANCHALI KRISANACHINDA, Ph.D.

The patient dosimetry in this study was determined by radiochromic film and Dose Area Product (DAP) methods. The dose measurement was carried out from 64 adult patients who underwent the interventional radiology examinations such as transarterial oily chemo embolization (TOCE), percutaneous transhepatic biliary drainage (PTBD), neurovascular intervention/angiography and percutaneous transluminal coronary angioplasty/stent (PTCA) at King Chulalongkorn Memorial Hospital. The maximum skin dose assessment from radiochromic film was compared with DAP calculation and showed the agreement, but radiochromic film showed higher radiation dose, because the calculated dose from DAP was the accumulated skin dose at different area and it was not the point entrance area of the patient. The maximum entrance skin dose from each case was determined by scanning radiochromic film to get the maximum density area on the film; this area represented the maximum entrance dose. However, the comparison of the radiochromic film and DAP were made to assess the patient skin dose and the maximum radiation dose from each procedure. The result shows the maximum skin dose from transarterial oily chemo embolization (TOCE) was 365 cGy, percutaneous transhepatic biliary drainage (PTBD) was 183 cGy, percutaneous transluminal coronary angioplasty/stent (PTCA) was 294 cGy, neurovascular intervention was 180 cGy and neurovascular angiography was 110 cGy The patient skin dose in this study depends on the length of fluoroscopy time and only one patient who reached the threshold dose of skin injury of 300 cGy.

Department Radiology Student's signature……

Field of study Medical Imaging Advisor's signature……

Academic year 2004 Co-advisor's signature……...

ACKNOWLEDGEMENT

It is my pleasure to acknowledge all those who had given me tremendous help and support in completing this study especially my advisor, Associate Professor Dr.Anchali Krisanachinda for her guidance and assistance throughout the whole project and Associate Professor Dr.Somjai Wangsuphachart for her guidance and valuable comments. I also like to thank all the staff of the cardiac catheterization unit and interventional radiology section for their assistances.

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CHAPTER I

BACKGROUND AND RATIONALE

An increasing number of invasive procedures, primarily therapeutic in nature and involving use of devices under fluoroscopic guidance, are becoming accepted medical practice. Examples of such procedures in this study are Percutaneous Transluminal Coronary Angioplasty / Stent (PTCA), neurointerventional radiology and catheter-based hepatobiliary interventional procedures include Transarterial Oily Chemoembolization (TOCE) and Percutaneous Transhepatic Biliary Drainage (PTBD). These procedures are performed by variety of medical specialists and may provide significant advantages over alternative therapies in terms of improved clinical outcome and reduced overall patient risk. However, physicians performed these procedures should be aware of the potential for serious radiation-induced skin injury caused by long periods of fluoroscopy occurring with some of these procedures. Such injuries have recently been reported as a result of radiation exposure during some of these procedures due to long fluoroscopic exposure times, high dose rates or both.

The radiochromic film known as Gafchromic film in this study was long widely used as a patient radiation dose detector [1]. It was applied to determine the dose in radiation therapy for many regions of the body i.e. breast [2]. The Gafchromic film was used in some study to measure the dose distribution in water in comparison to a solid phantom [3]. Some study showed the sensitivity of the Gafchromic film [4]. They showed how to apply the gafchromic film in many ways but mostly used in radiation therapy. The Gafchromic film used in this study was the new type that developed for low dose detection for diagnostic purpose. There were very few reports in this field; therefore this study was the first one for patient dose measurement in cardiac catheterization and interventional procedures at King Chulalongkorn Memorial Hospital.

In September 1994, the Food and Drug Administration (FDA) of the United States issued a public health advisory entitled *Avoidance of Serious X-Ray Induced Skin Injuries to Patients during Fluoroscopy-Guided Procedures* [5]. The advisory recommended, among several items, that information be recorded in the patient's record which permits estimation of absorbed dose to the skin. In September 1995, the FDA issued a follow-up advisory entitled *Recording Information in the Patients Record that Identify the Potential of Serious X-ray Induced Skin Injuries Following Fluoroscopically Guided Procedures* [6] which clarified some of the earlier recommendations. As stated in the September 1995 advisory, the purpose of the recommendation (the 1994 advisory) 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 [7].

The typical table top exposure rate measurements in the cardiac catheterization lab is vary between $1.29 \times 10^{-4} Ckg^{-1}\ min^{-1}$ to $2.58 \times 10^{-3} Ckg^{-1}\ min^{-1}$ ($0.5\ Rmin^{-1}$-$10\ Rmin^{-1}$)[6]. Also, many of the current imaging systems produce a high dose rate mode of operation. The exposure rate may be as high as $5.16 \times 10^{-3}\ C\ kg^{-1}\ min^{-1}$ ($20\ Rmin^{-1}$) for the equipment manufactured after 1995 and even higher for older equipments. Also, the output during cineradiography (cine) may be 10-30 times higher than the

standard fluoroscopy output. Some complicated cases may have a fluoroscopy "beam on-time" from 1-3 hours, including several minutes of cine.

Although the FDA encourages identification of those areas of the skin which are irradiated above a threshold dose, currently there is no practical system which would allow a physician or medical physicist to accurately determine the exposure dose to a specific area of the patient's skin [6]. Determination of the localized skin dose from a fluoroscopically guided interventional cardiac procedure is a significant challenge. It is a dynamic process that involves varying beam orientations and changing x-ray tube operating parameters throughout the procedure. The McMahon Medical Skin Dose Monitor is one device that allows for the measurement of dose on various parts of the body, but there are a finite number of detectors that can be taped to a patient's body surface. There are systems, such as the Patient Exposure Management Network (PEMNET), which measure the total exposure, exposure rate, and/or total radiation "on-time", but it doses not track beam orientations and thus not permit mapping of the spatial dose distribution. Multiple thermoluminescent dosimeters (TLDs) may be positioned on a patient, but much like the Medical Skin Dose Monitor, there are a finite number of TLDs which can be taped on a patient's body surface, but the readout and dose mapping are tedious.

Various silver halide photographic films had been tested as dosimetric devices. Single sheet of film can be easily positioned in the areas exposed to radiation in comparison to the tedious task of positioning multiple TLDs. Films are often used in the radiation therapy environment where the photon energies are higher than diagnostic x-ray energy. Most silver halide films are too sensitive at diagnostic x-ray energies for the dose range of interest in this work. Also, silver halide films are very sensitive to room light and require wet chemical processing [8]. In addition to problems with energy response in the 10 keV to 200 keV energy range, the film has a limited dose range. The sensitivity of the film allows for the measurement of dose up to approximately 2.0 Gy [9] which is not high enough for doses encountered in some interventional procedures.

A new radiochromic film, gafchromic XR type R "Interventional" X-ray Dosimetry Film, was tested to determine its potential for patient skin dose monitoring in the cardiac catheterization laboratory. The film has been designed to measure doses up to 10 Gy or more for diagnostic x-ray energies that range from approximately 20 keV to 150 keV.

The other method for patient dose assessment is the use of a Dose Area Product (DAP) meter, where the detector will be placed on the housing of the x-ray tube. The read out data from DAP meter in $cGy.cm^2$ and the radiation area in cm^2 from the verification film placed on the couch under the patient, were calculated to determine the patient’s skin dose (cGy). The clinical research will be conducted at cardiac center and the section of vascular & interventional radiology at King Chulalongkorn Memorial Hospital where the clinical service on cardiac catheterization such as Percutaneous Transluminal Coronary Angioplasty / Stent (PTCA), neurointerventional radiology and catheter-based hepatobiliary interventional procedures include transarterial oily chemoembolization (TOCE) and percutaneous transhepatic biliary drainage (PTBD) are routinely performed employing fluoroscopy.

In this study both Gafchromic film and DAP meter, were used to determine the radiation dose in different procedures.

1. Gafchromic film was used to determine the maximum entrance dose.
2. DAP method was used to determine the total radiation dose of each procedure.

CHAPTER II

RESEARCH QUESTION AND RESEARCH OBJECTIVE

2.1 Research Objective

2.1.1 To determine the maximum patient skin dose using the Gafchromic film for various interventional radiology procedures.

2.1.2 To compare the results on maximum skin dose using Gafchromic film with radiation dose measurements by the DAP method.

2.1.3 To correlate the maximum patient skin dose with fluoroscopic time.

2.1.4 To report and establish the patient skin dose in order to protect the patient from the skin injury and increase the operational awareness.

2.2 Research Question

2.2.1 Primary Research Question

What is the maximum patient skin dose measured by Gafchromic film in various interventional procedures?

2.2.2 Secondary Research Question

What is the relationship between the measured patient skin dose by Gafchromic film and the calculated skin dose from dose area product (DAP) method?

2.3 Hypothesis

2.3.1 The maximum patient skin dose measured from Gafchromic film is 3 Gy and not exceed this limit threshold dose for skin injury.(see index I)

2.3.2 The agreement on measured skin dose by Gafchromic film and DAP meter method.

CHAPTER III

RESEARCH METHODOLOGY

3.1 Research Design

This study is a descriptive prospective cross sectional study.

3.2 Research Design Model

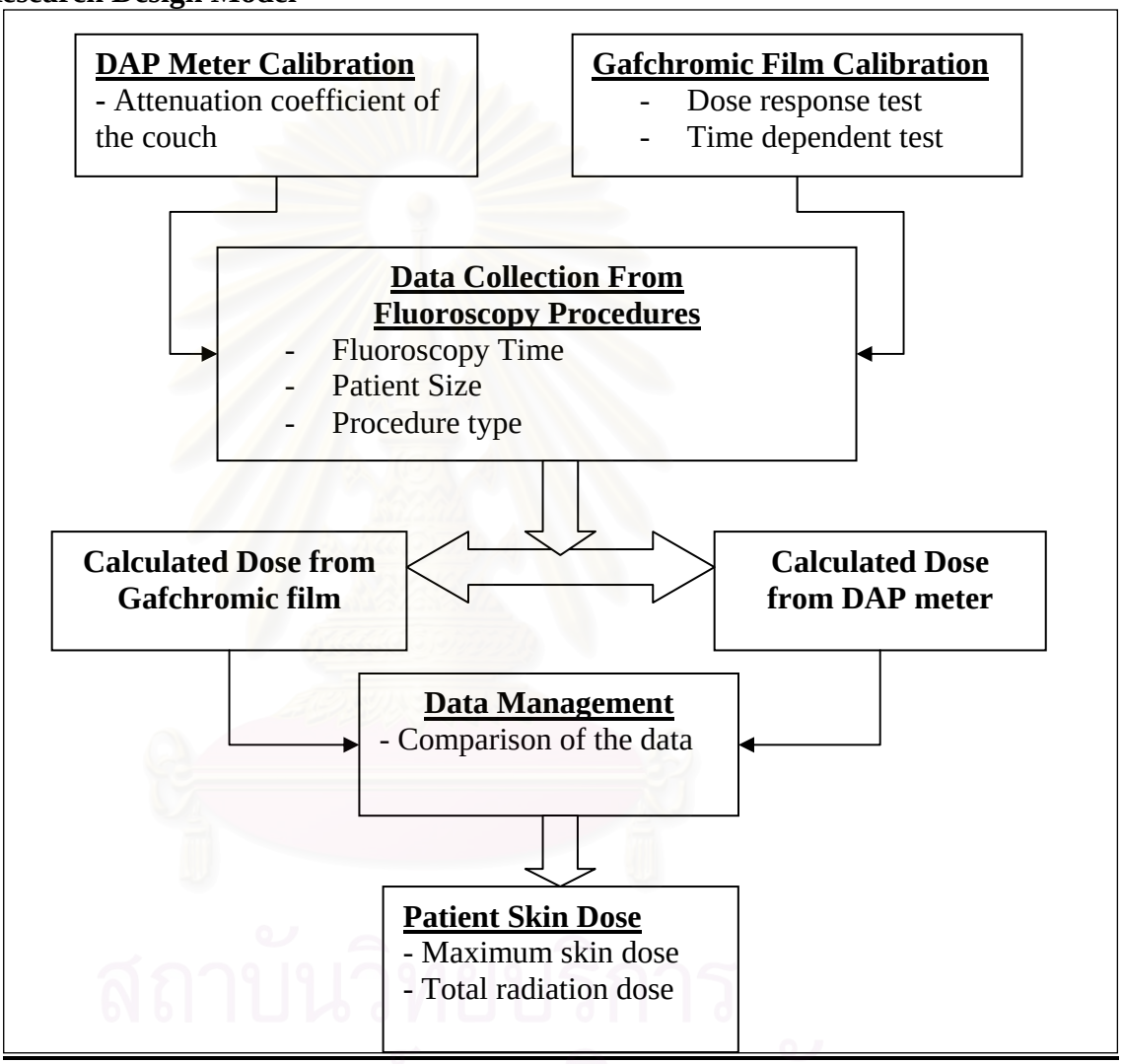


Figure 1**:** The research design model

3.3 Keywords

Dose Area Product (DAP) Meter, Gafchromic Film, Patient Skin Dose

3.4 Sample

3.4.1 Target Population

The patients who underwent interventional radiology and cardiac catheterization procedures at King Chulalongkorn Memorial hospital.

3.4.2 Consent Form

Informed consent from every patient was obtained before the procedure. (see appendix V)

3.4.3 Sample

The data was recorded on 64 patients who underwent the interventional radiology procedures , 21 cases for transarterial oily chemoembolization (TOCE), 5 cases for percutaneous transhepatic biliary drainage (PTBD), 22 cases for neurovascular interventional radiology procedure and 16 cases for percutaneous transluminal coronary angioplasty / stent (PTCA) at King Chulalongkorn Memorial hospital.

CHAPTER IV

MATHERIALS AND METHOD

4.1 Equipment and Accessories

4.1.1 Gafchromic XR Type R Film (Model 37-046)

Gafchromic XR Type R is a self-developing radiochromic film. The film has white opaque at one side and yellow on the other side. The color of the yellow side will be change to a green color and darker proportional to the amount of radiation dose ranged of 0.2 - 15 Gy. The film is energy independent between 60 keV - 120 keV, outstanding uniformity, dose rate and fractionation independent. This film type is designed and can be used to improve fluoroscopic technique and patient safety.

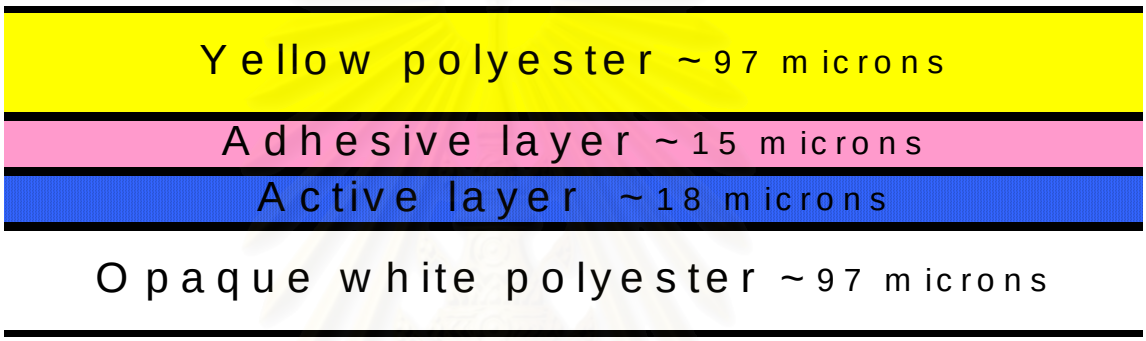


Figure 2: Configuration of Gafchromic XR Type R film

4.1.2 Dose Area Product (DAP) Meter (MODEL PTW-Diamentor E)

Dose-Area-Product (DAP) meter is large-area, transmission ionization chambers and associated electronics. In use, the ionization chamber is placed perpendicular to the beam central axis and in a location to completely intercept the entire area of the x-ray beam. The DAP, in combination with information on x-ray field size (FOV) can be used to determine the average dose produced by the x-ray beam at any distance downstream in the x-ray beam from the location of the ionization chamber.

DAP meter is used to measure the absorbed dose (cGy), 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^2 (R-cm^2) and DAP is expressed in gray-cm^2 (Gy-cm^2, usually read in cGy-cm^2).

A DAP ionization chamber which size is larger than the area of the x-ray beam is placed over the x-ray collimator. The chamber must intercept the entire x-ray field for an accurate reading, one proportional to the EAP. The reading from a DAP meter is affected by the exposure factors (kVp, mA, or time), the area of the field (FOV), or both. The chamber area must be larger than the maximum collimation, as the collimation blades are opened or closed the charge collected will also increase or decrease in proportion to the area of the field.

For example, a 5 x 5 cm^2 x-ray field with an entrance dose of 1 mGy will yield a 25 mGy-cm^2 DAP value. If the field is increased to 10 x 10 cm^2, with the same entrance dose of 1 mGy the DAP value increases to 100 mGy-cm^2, which is 4 times the DAP value for the 5 x 5 cm^2 field.

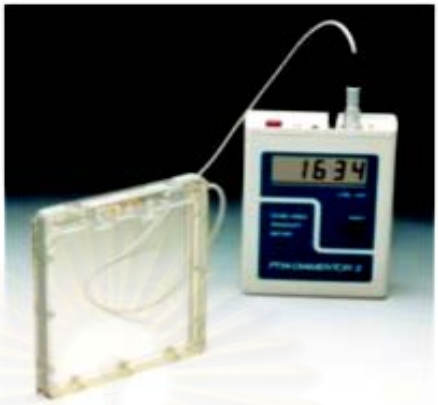


Figure 3: DAP meter and the Chamber

4.1.3 Digital Ionization Chamber

The digital ionization chamber (Victoreen model 4000M$^+$) was used for the x-ray system half value layer (HVL) and the table attenuation coefficient (k) measurements.

Figure 4: Digital ionization chamber (Victoreen model 4000M$^+$)

4.1.4 Portal Film (Verification Film) Kodak X-OmatV

The non screen ready packed film was used to verify the radiation area.

4.1.5 Radiographic/Fluoroscopic System

The following x-ray machines were used for each interventional radiology and cardiac catheterization procedures.

Table 1: the x-ray machines used for each procedure.

Procedures	Manufacturer	Model
Abdominal Interventional Radiology		
1. Transarterial Oily Chemoembolization (TOCE)	Siemens	Polystar
2. Percutaneous Transhepatic Biliary Drainage (PTBD)		
Neurovascular Interventional Radiology	Siemens	Neurostar
Percutaneous Transluminal Coronary Angioplasty / Stent (PTCA)	Siemens	Coroskop
	Siemens	Axiom

4.1.6 Flatbed Scanner

The flatbed scanner (EPSON STYLUS CX 5300) was used for scanning the Gafchromic film.

Figure 5: Flatbed scanner

4.2 Methods

The study was carried on as the following steps.

1. The evaluation of radiographic-fluoroscopic equipment performance.
2. The calibration of Gafchromic film and DAP meter.
3. The patient data collection using Gafchromic film and DAP meter methods.
4. The analysis of the data.
5. The evaluation of the patient skin dose.

4.3 The evaluation of radiographic-fluoroscopic equipment performance.

The performance of the radiographic-fluoroscopic equipment performance was evaluated prior the test of the Gafchromic-XR type R "Interventional" x-ray dosimetry Film. Those evaluations include the radiation output, x-ray field size, beam quality (HVL), and peak kilovoltage (kVp). The measured values should fall within the limits recommendated by AAPM standard.

4.4 Calibration of Gafchromic Film and DAP Meter

4.4.1 Gafchromic Film Calibration

Gafchromic film was calibrated at different exposure values. An electronic dosimeter Victoreen 4000M was firstly used to measure the exposure rate in air on the table, then Gafchromic film was later exposed at various exposure time and dose levels.

First, a dose response curve between color changed of the Gafchromic film and the radiation dose was generated. The Victoreen 4000M electronic dosimeter was placed on the tabletop (Source-to-Chamber Distance = 60 cm; Source-to-image Intensifier = 100 cm). The peak potential, current, and magnification mode were manually adjusted to 100 kVp and normal magnification mode respectively. The exposure rate at the tabletop is measured in five locations. The Gafchromic XR type R film was cut in to 5 cm x 5 cm sections sheets. The background density of each film was measured with a flatbed scanner and process with MatLab routine program. The cutting film was placed in the same location as the previously recorded exposure rates. From the measured exposure rates, an irradiation time were calculated for the dose to the film of 0.5, 0.7, 1.0, 1.2, 1.4, 1.6, 1.8, 2.0, 3.0, 4.0 and 5.0 Gy respectively. The film density was subsequently measured 24 hours after exposure. The dose response curve was created and the measured net density was compared to that specified by the film manufacturer.

The time dependence of density measurements was tested. All of the films from the previous section were monitored in one hour increment up to 8 hours. The color density changed on each film was also measured at time 12, 24, 96, 144 and 288 hours respectively.

4.4.2 DAP Meter Calibration

The purpose of the DAP meter calibration is to correct for

4.4.2.1 Energy Dependence of the Transmission Chamber.

In interventional radiology, the only important problem, deserving specific attention for DAP calibration, is the energy dependence of the transmission chamber, especially when the equipment includes copper filters, which substantially harden the X ray spectrum. This effect together with the kV variation can change the calibration factor by as much as 20 % or even more.

In certain radiological equipment and for some modes of operation, the copper filters are automatically inserted or changed. If a built-in DAP meter is available, the software in certain equipment design automatically corrects the values displayed by the built-in DAP meter for the energy dependence every time the filter is inserted or changed.

This automatic correction does not affect external DAP meters. Since filters are inserted or changed during the procedure, it is impracticable to keep track of these changes. For this reason, the only solution for external DAP meters is to choose a mid-

value for the calibration factor and give the range associated to it. For example, if the range is about 20%, a central value can be chosen and an uncertainty ± 10% can be associated to the DAP measurements on patients. The range can be obtained by measuring without copper filter and with the maximum copper filter. Once the range is known, the mean value of the two calibration factors can be chosen.

4.4.2.2 Calibration Procedure of DAP Meter

The following calibration procedure accounts for the energy dependence of the DAP meters. It is suggested to choose two modes of operation (which involve the maximum copper filter and no copper filter) and two different kV values representing the range of kV usually encountered in practice. If the x-ray system is not equipped with the copper filters, then the calibration procedure can be simplified accordingly.

The calibration factor or the attenuation factor by the couch is the ratio between the dose rate for the radiation which actually measured while the couch is against the x-ray beam and dose rate without the couch between the ionization chamber and the x-ray tube.

k = Dose Rate with the couch/Dose rate without the couch

k is the calibration factor to be applied to the transmission chamber to obtain the correct patient's DAP readout.

The setup is illustrated in the figure 6A, 6B. The copper absorber is needed to protect the image intensifier from direct irradiation and to drive the automatic exposure control to the kV values required. The distance from the tube to the tabletop should be similar to the one used in practice for an average patient size. The distance of the image intensifier to the reference chamber should be sufficient to minimize the backscatter from the copper absorber to the reference chamber.

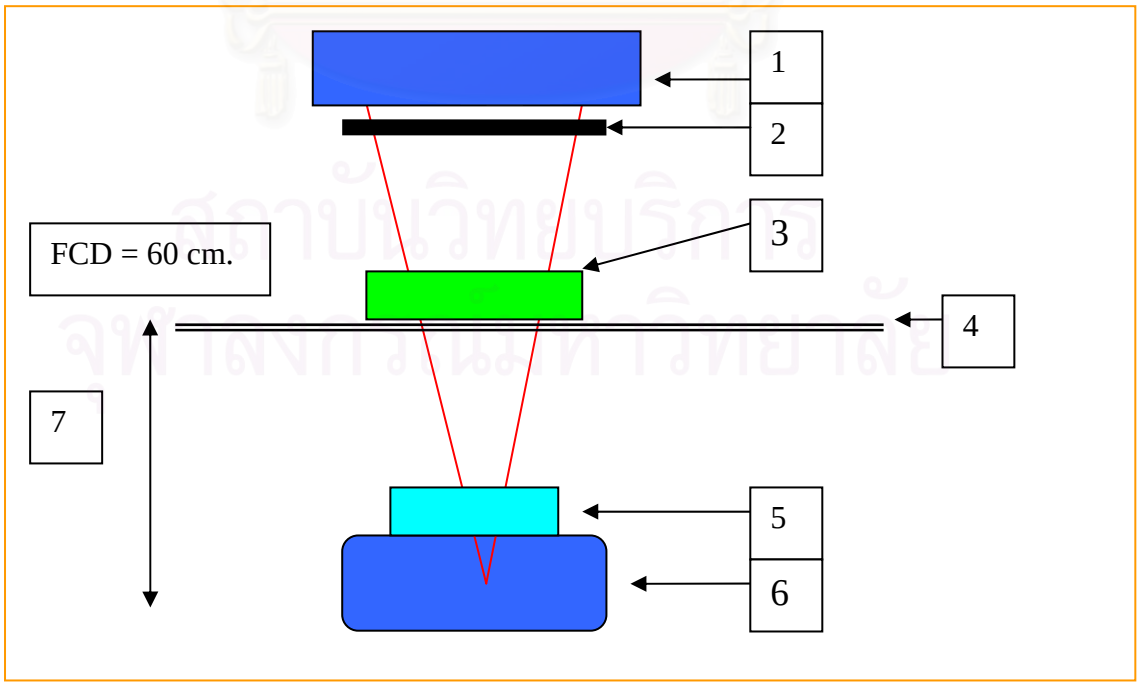


Figure 6A: The setting of the devices to calibrate DAP meter with attenuator.

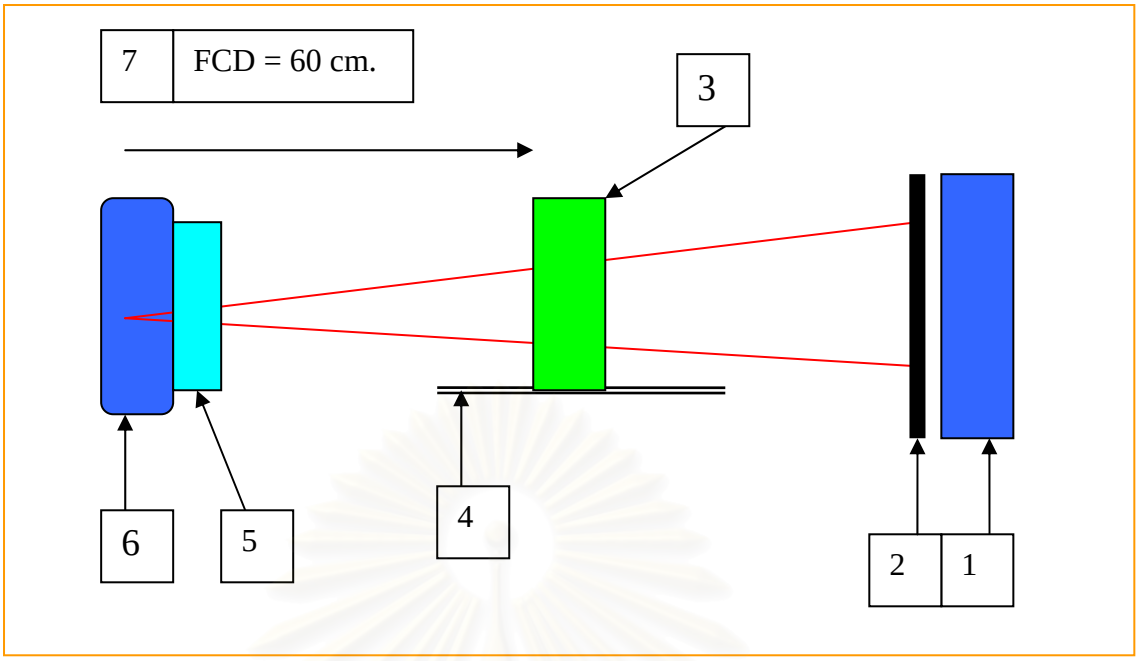


Figure 6B:The setting of the devices to calibrate DAP meter without attenuator.

1. Image intensifier
2. Copper absorber
3. Digital ionization chamber
4. Couch and mattress
5. Collimator
6. X-Ray tube
7. Distance from focal spot to chamber

Figure 6A and 6B show the settings of the devices to calibrate DAP meter, the dose rate is measured while the x-ray is and is not attenuated by the couch and without the couch.

The values of the measurements were recorded in a table. Every dose measurement was performed three times and the average was taken. See recommended table below:

Table 2: Determination of k factor for all radiographic/fluoroscopic systems.

Mode	Submode/ Image quality	Dose rate (mGy/min)	Table attenuation %	Absorber
C-arm at 0°				
C-arm at 90°				

4.5 Data Collection

Clinical measurements were performed on 64 patients undergoing interventional radiology and cardiac catheterization procedures using fluoroscopy at King Chulalongkorn Memorial hospital.

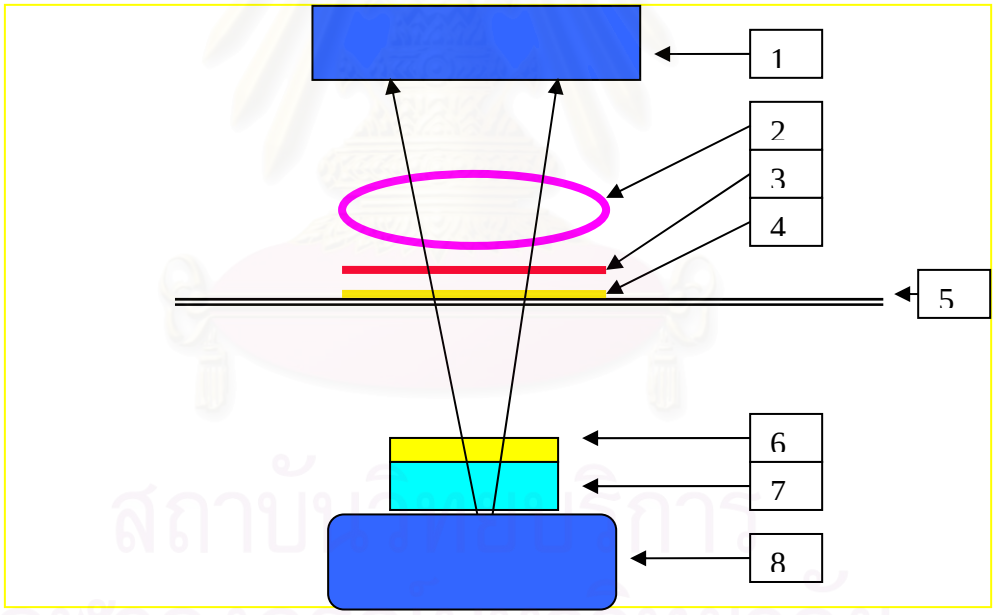
Those were undertaken on 21 cases of transarterial oily chemoembolization (TOCE) and 5 cases of percutaneous transhepatic biliary drainage (PTBD), 22 cases of neurovascular intervention and 16 cases of cardiac catheterization including both diagnostic and therapeutic procedures.

The setting of the device for data collection is shown by the followings.

1. DAP chamber was placed on the housing of the x-ray tube.

2. The portal film and Gafchromic film were placed on the couch under the patient, face the yellow side against the entrance x-ray beam, except the neurovascular intervention, the film was wrapped around the patient's head.

3. The data was recorded in the form shown in table 7 (see Appendix IV).



1. Image Intensifier
2. Object (Patient)
3. Verification Film (Portal Film)
4. Gafchromic Film(the yellow one)
5. Couch and Mattress
6. DAP Chamber
7. X-Ray Collimator
8. X-Ray tube

Figure 7: Setting of the devices for patient dose determination.

4.6 Measurement

Independent variables = Procedure types, kVp, mA, fluoroscopic time, size of patient.
Dependent variables = (patient skin dose) the reading from DAP meter, accumulation dose, the color changed on Gafchromic film.

4.7 Data Analysis

1. For Gafchromic film, once exposed, it was delayed for 24 hours to get accurate dose estimate. The density grew to the maximum by 24 hours which was generally less than 10% density growth between 1 to 24 hours after exposure.

2. Quantitative measurement on film was performed with a flatbed scanner, in reflection mode. An image of the film in 24 bit /pixel was acquired and scanned with 300 dpi in resolution. Images were saved in TIF format (attention to scan the relevant exposed area of the film only.)

3. The TIF image was processed with MatLab program:

    - Create a dose calibration curve which each color density changed was converted to dose.

4. Developed the portal film to determine the radiation area (cm^2) to calculate the absorbed dose (cGy) from the data from the DAP meter reading ($cGy.cm^2$).

5. The data from the DAP meter in $cGy.cm^2$ was divided by the area from portal film in cm^2 in order to determine the absorbed dose in cGy and corrected for attenuation factor (k).

CHAPTER V

RESULTS AND DISCUSSION

5.1 The Equipment Calibration

5.1.1 The Radiographic-Fluoroscopic (R-F) System Performance Test

The performance of the radiographic-fluoroscopic equipment performance was evaluated; those include the radiation output, x-ray field size, beam quality (HVL), and peak kilovoltage (kVp). The measured values are shown in table 3.

Table 3: The evaluation of the R-F system performance.

STUDIES	Neurostar	Polystar	AXIOM
Max Absorbed Dose Rate (mGy/min)	70.9	52.0	87.9
Pulse Rate (f/s)	30	Sub mode 3	30
FOV (cm)	14	16	16
Table Attenuation (%)	2.0	6.4	2.8
HVL (mm)	6.9	3.7	7.1
Fluoro- Image quality (lp/mm)	2.2	1.7	2.8

5.1.2 The Gafchromic Film Calibration

Figure 8 shows the result for measured color intensity on the film with different exposed radiation dose. The x-axis represents the absorbed dose in cGy, the y-axis shows the measured red color intensity recorded on the Gafchromic film detected by analyzing the scanned TIFF image from flatbed scanner with MATLAB program.

There is a general decrease in measured red color intensity with increased radiation dose. The curve shows the great changes in intensity of the red color at the dose less than 500 cGy. This calibration curve was used for the conversion of the red color intensity to the absorbed dose.

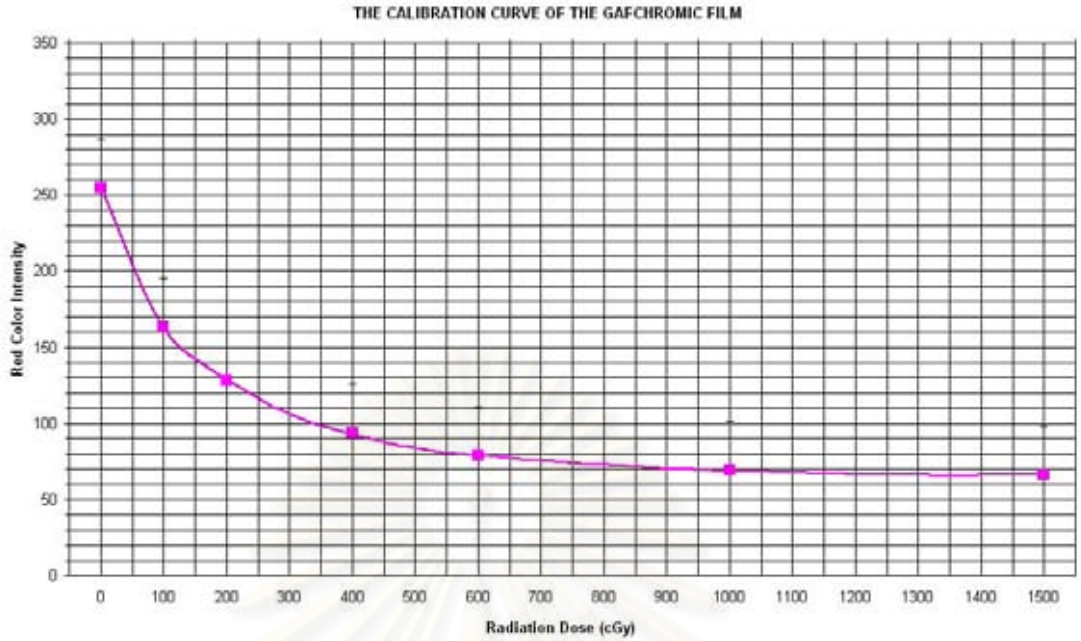


Figure 8: The calibration curve of Gafchromic film

Figure 9 shows the results of the time dependent calibration on Gafchromic film after exposure. The graph shows the post-exposure density changed on the Gafchromic XR type R radiochromic dosimetry film from 12 to 24 hours after exposure for various delivered doses and normalized to 1 (show in percentage on the graph) at 24 hours. This also reveals that post-exposure density changed, relative to the density at 24 hours, is essentially independent of the exposure dose and time. The density changes by about 8% between 12 hours and 24 hours after exposure, but the rate of the density change was less than 2% over the next 288 hours.

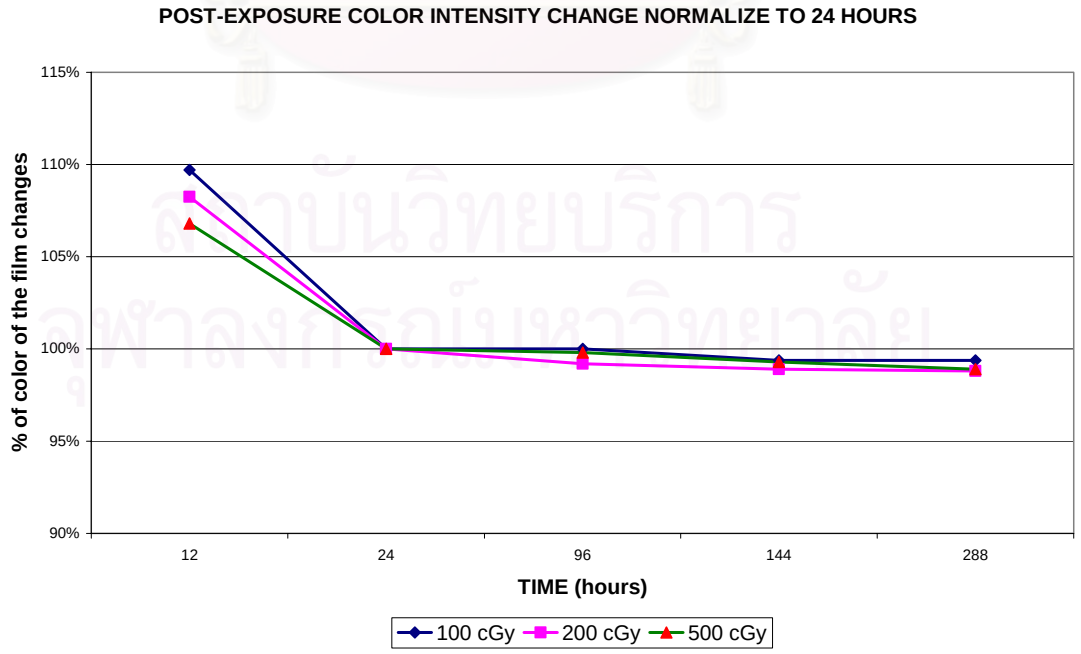


Figure 9: The time dependent curve of the Gafchromic film.

5.1.3 The Results of DAP Meter Calibration

Table 4 shows the result of the DAP calibration of the radiographic-fluoroscopic (R-F) system used for this study. The percentage of table attenuation shows in the last column represents the percent of radiation dose decreased when impinge on the patient couch. Siemens polystar couch absorbed largest radiation of 6.4 percent when compared to Siemens Neurostar of 2 percent and Siemens AXIOM of 2.8 percent.

Table 4: The table attenuation of each fluoroscopic machine.

Manufacture	Model	Submode/ Image quality	Dose rate C-arm at 0° (mGy/min)	Dose rate C-arm at 90° (mGy/min)	Absorber	Table attenuation (%)
Siemens	Axiom	Normal	17.2	17.7	2mm Cu	2.8
Siemens	Neurostar	Normal	4.4	4.5	2mm Cu	2.0
Siemens	Polystar	Normal	10.2	10.9	2mm Cu	6.4

As the table attenuation directly affects patient skin dose determination, the patient entrance dose decreases by this factor. The correction was applied to the readout from DAP meter in all cases.

5.2. The Results of the Clinical Trial

Table 5: The results of the study

Studies	x-ray tube	No.	Age (years)	Skin Dose from GF (cGy)	Radiation Area (cm^2)		Flu Time (min)		DAP ($cGy.cm^2$)	
				Max	Max	Min	Max	Min	Max	Min
TOCE		21	36-72	365	431	52	48	2.4	38,168	2,433
PTBD		5	17-87	183	186	82	15.03	1.51	5,972	520
Neuro	A			165	260	153	46	3.7	26,378	2,689
	B			165	285	153	21		16,825	1,176
	Total	22	17-61	180	285	153	46	3.7	36,221	3,865
PTCA		16	42-79	294	135	36	17.2	0.8	20,000	3,050
		64		365	431	36	48	0.8	38,168	520

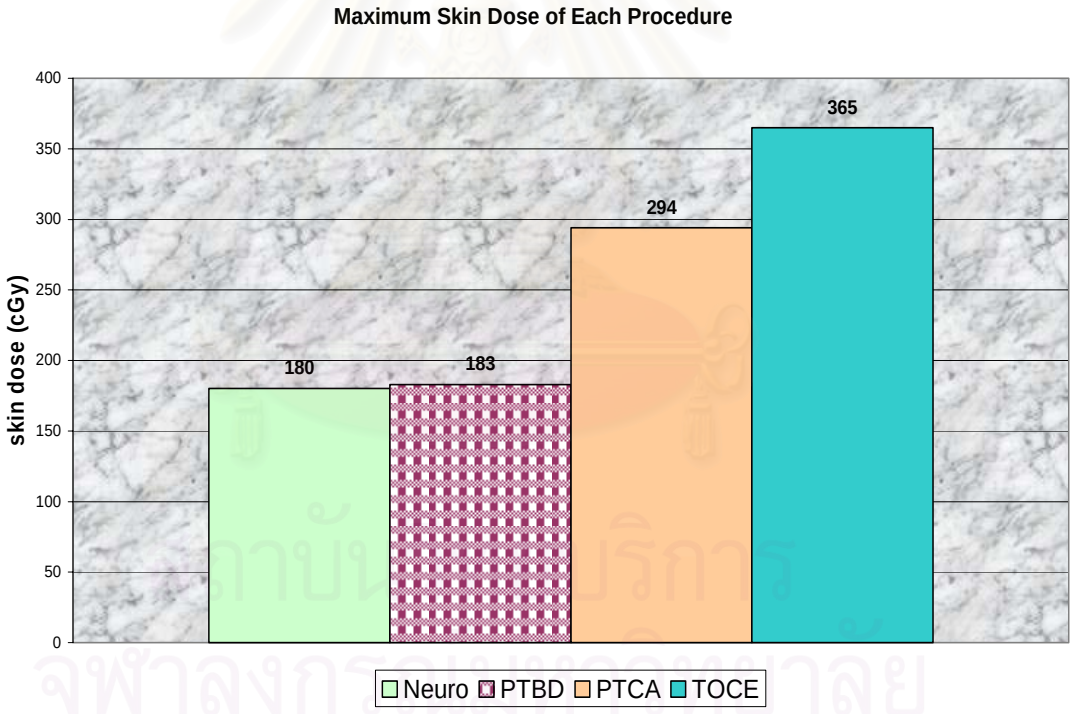


Figure 10: The maximum skin dose of each procedure.

The results of the study shows as the data in the table 5 and figure 10 performed on 64 patients, the maximum skin dose recorded from the TOCE procedure as 365 cGy. 294 cGy, quite high skin dose was measured from the PTCA procedure. The longest of fluoroscopic time, 48 minutes was recorded from the TOCE procedure also.

The results of each recorded procedure are shown in the following.

5.2.1 The Result from Neurovascular Interventional Radiology Procedure

Figure 11 shows the results for maximum skin dose measured on the film in radiation field A (x-ray tube A, PA axis tube). The x-axis represents the estimated dose from DAP in cGy. The y-axis shows the maximum dose measured from the Gafchromic film. A definite trend is seen where the measured peak dose increases as the estimated dose from DAP increases.

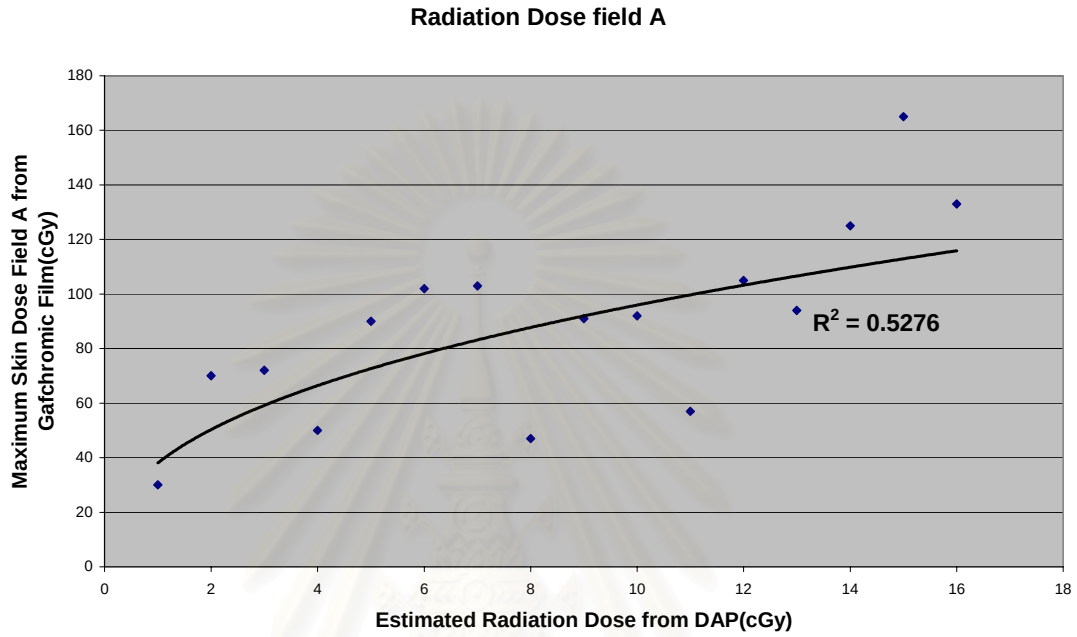


Figure 11: The maximum skin dose (cGy) in field A (PA axis) of neurovascular procedure measured by Gafchromic film compared to estimated dose from DAP meter (cGy).

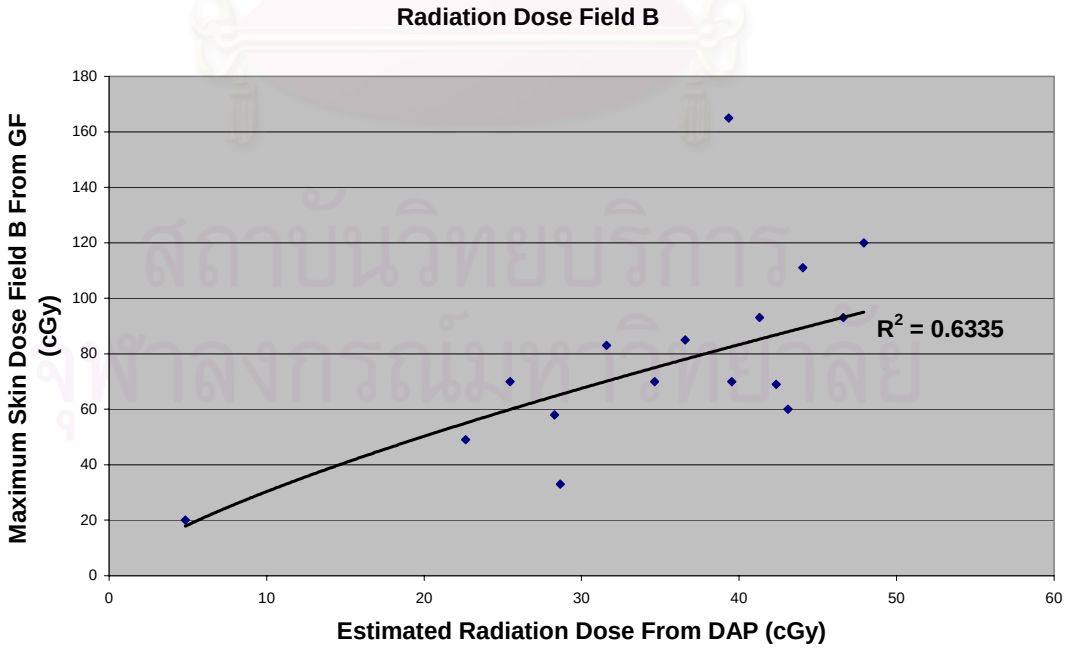


Figure 12: The maximum skin dose (cGy) in field B (lateral axis) of neurovascular procedure measured by Gafchromic film compared to estimated dose from DAP meter (cGy).

Figure 12 shows the results for maximum dose measured on the film in radiation field B (x-ray tube B, Lateral axis tube). The x-axis represents the estimated dose from DAP in cGy. The y-axis shows the maximum dose measured from the Gafchromic film. A definite trend is seen where the measured maximum dose increases as the estimated dose from DAP increases.

Figure 13 shows the results for the comparison of the maximum dose measured from Gafchromic film in cGy and fluoroscopic time in minute. The trend line is seen the maximum dose increase as the fluoroscopic time increase.

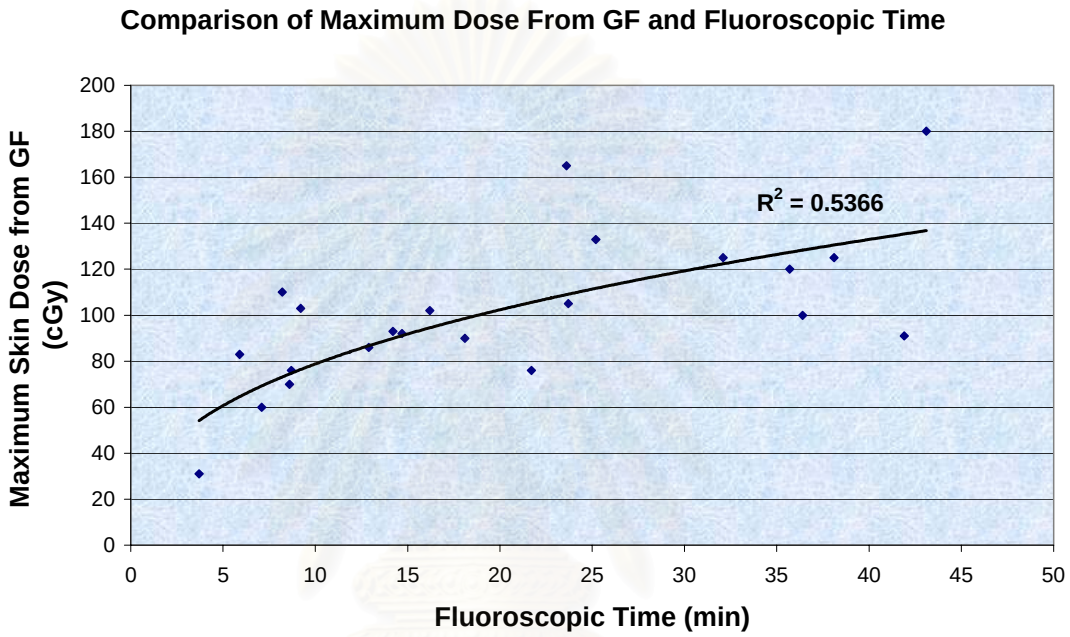


Figure 13: The relation of the maximum dose (cGy) and fluoroscopic time (minute) in neurovascular procedure.

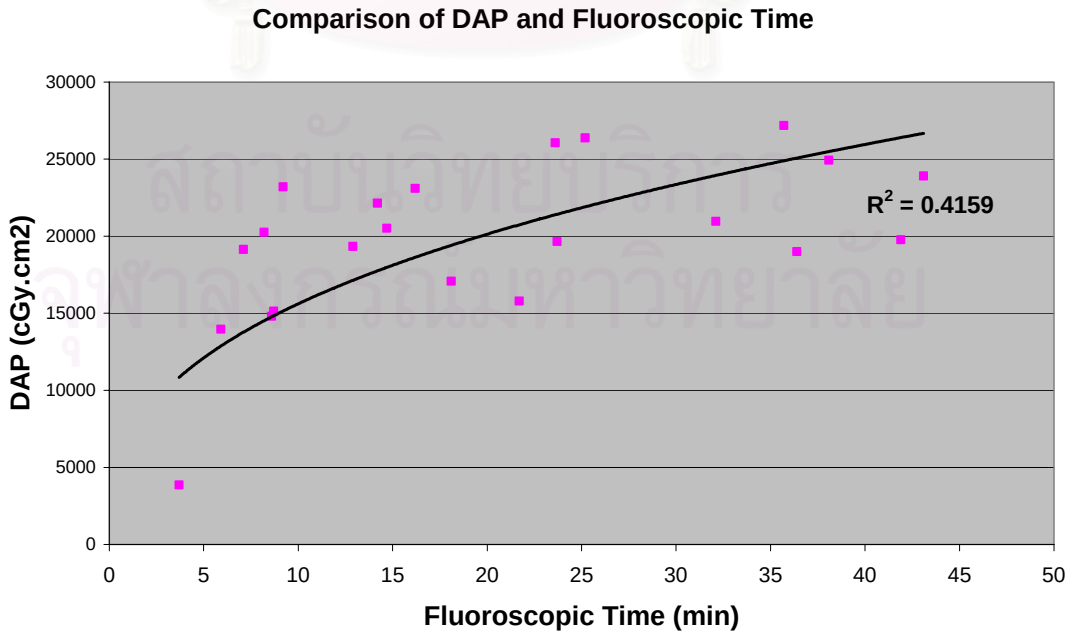


Figure 14: The relation between DAP (cGy.cm^2) and fluoroscopic time (minute).

Figure 14 shows the results for the relation between the DAP in cGy.cm^2 and fluoroscopic time in minute. The line shows the DAP increases as the fluoroscopic time increases but the data is scattered. DAP is the cumulative dose from all the path of the patient. In these case, the neurovascular interventional procedure used bi-plane fluoroscopic machine and DAP is the cumulative value from both of the x-ray tube. DAP's ability to estimate stochastic risk is degraded because of the lack of dose distribution information within the patient. The best way to assume an average weighting factor for all the tissues at risk. This may lead to an over or under estimate of risk in certain cases. As an example, it does not account for the differential risk of these neurovascular procedures from an AP or a lateral projection.

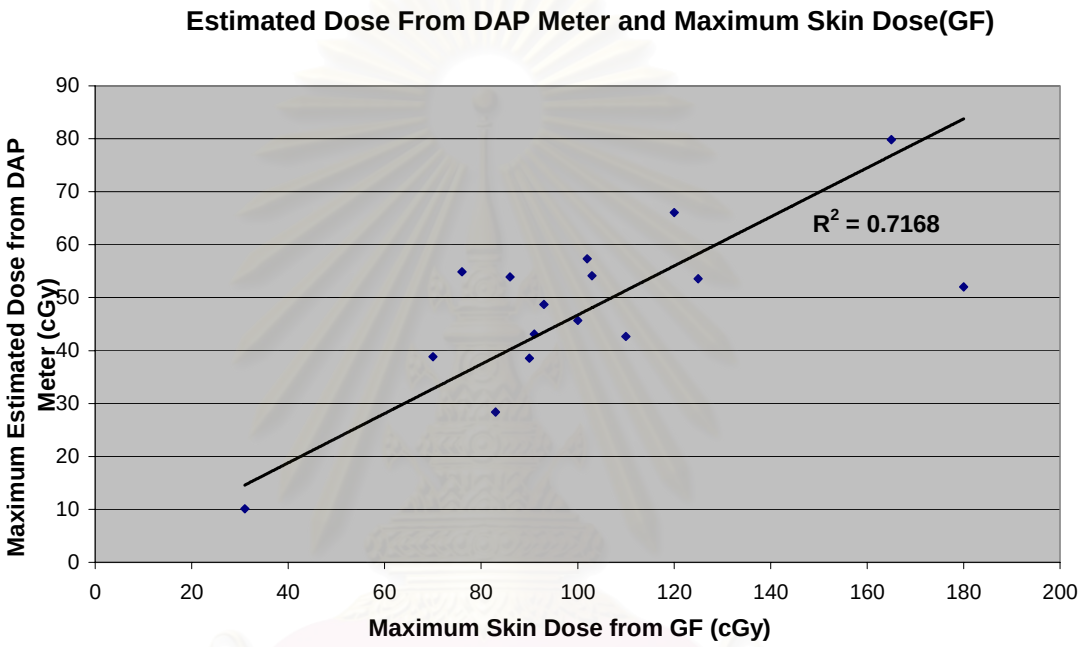


Figure 15: The relation between maximum skin dose from Gafchromic film (cGy) and estimated dose from DAP meter (cGy).

Figure 15 shows the results for the comparison of the maximum estimated dose from DAP meter and maximum dose from Gafchromic film. The x-axis shows the maximum dose measured from the Gafchromic film in cGy. The y-axis represents the dose from DAP meter in cGy. The maximum skin dose from Gafchromic film is 180 cGy and maximum estimated dose from DAP is 79 cGy. The curve shows the linear relation between maximum skin dose and estimated dose.

5.2.1 The Result from Percutaneous Transluminal Coronary Angioplasty/Stent (PTCA) Procedure

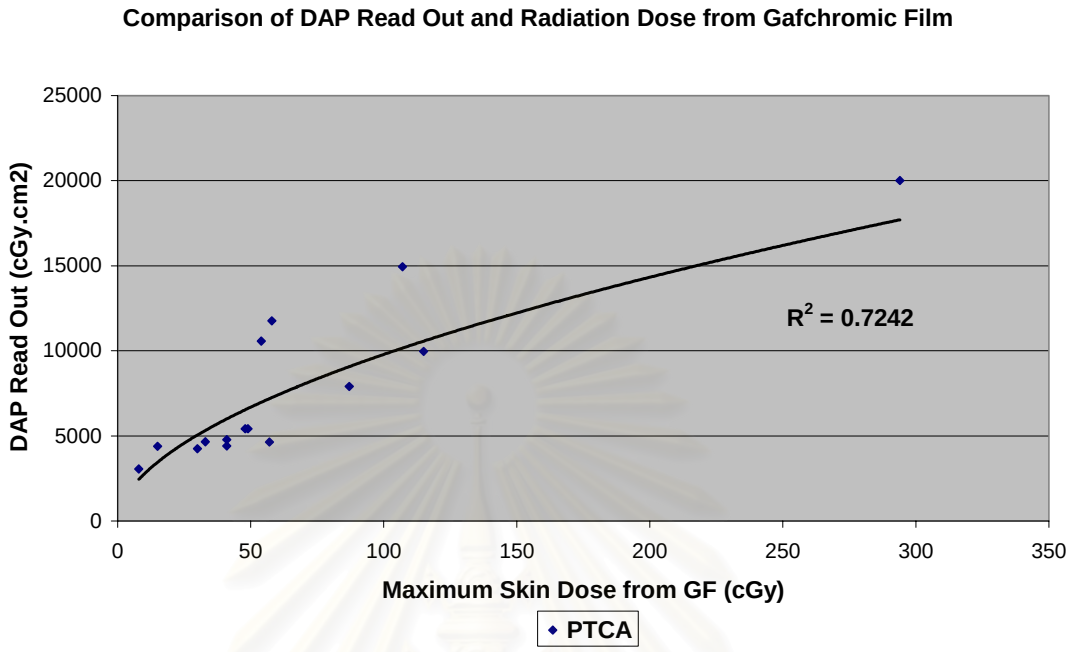


Figure 16: The relation between maximum skin dose measured by Gafchromic film and the DAP readout ($cGy.cm^2$)

Figure 16 shows the relation between the dose area product (DAP) and maximum dose from Gafchromic film. The x-axis shows the maximum dose measured from the Gafchromic film in cGy. The y-axis represents the DAP in $cGy.cm^2$. A trend line is seen where the maximum dose on Gafchromic film increase when the DAP readout increases.

5.2.3 The Result from Percutaneuos Transhepatic Biliary Drainage (PTBD) Procedure

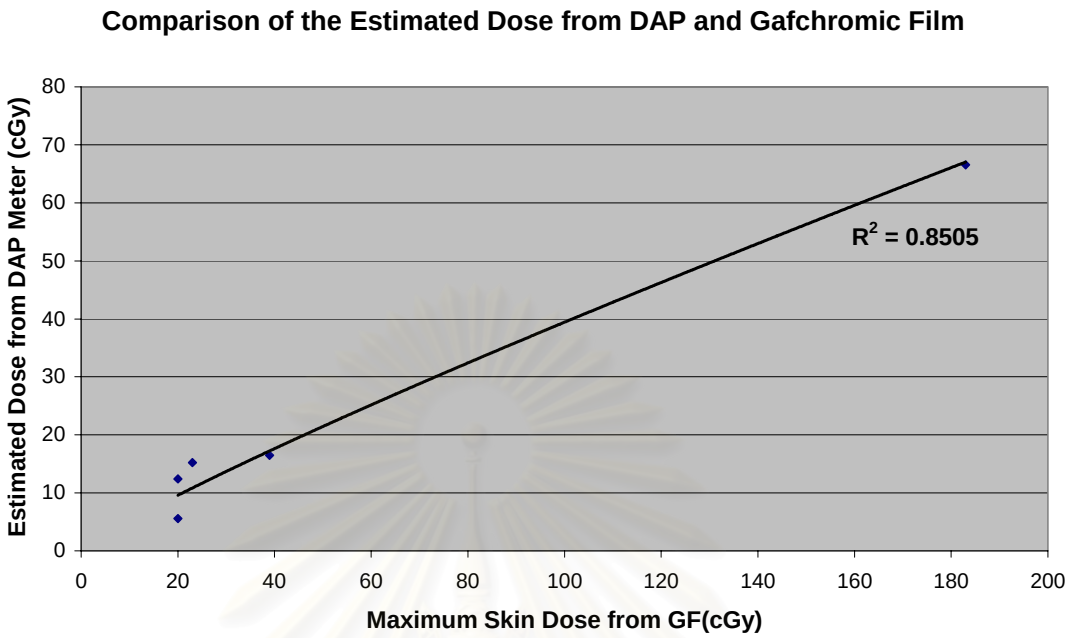


Figure 17: The relation between maximum skin dose (cGy) from Gafchromic film and estimated dose from DAP meter (cGy).

Figure 17 shows the results for the comparison of the estimated dose from DAP meter and maximum dose from Gafchromic film. The x-axis shows the maximum dose measured from the Gafchromic film in cGy. The y-axis represents the dose from DAP in cGy. A linear relation is seen where the maximum dose is 183 cGy on Gafchromic film and estimated dose from DAP is 66 cGy.

5.2.4 The Result from the Transarterial Oily Chemoembolization (TOCE) Procedure

Figure 18 shows the relation between the estimated dose from DAP meter and maximum dose from Gafchromic film. The x-axis shows the maximum dose measured from the Gafchromic film in cGy. The y-axis represents the dose from DAP in cGy. The maximum skin dose from Gafchromic film is 365 cGy and maximum estimated dose from DAP is 175 cGy. A trend line is seen where the maximum dose increases as the dose from DAP increases.

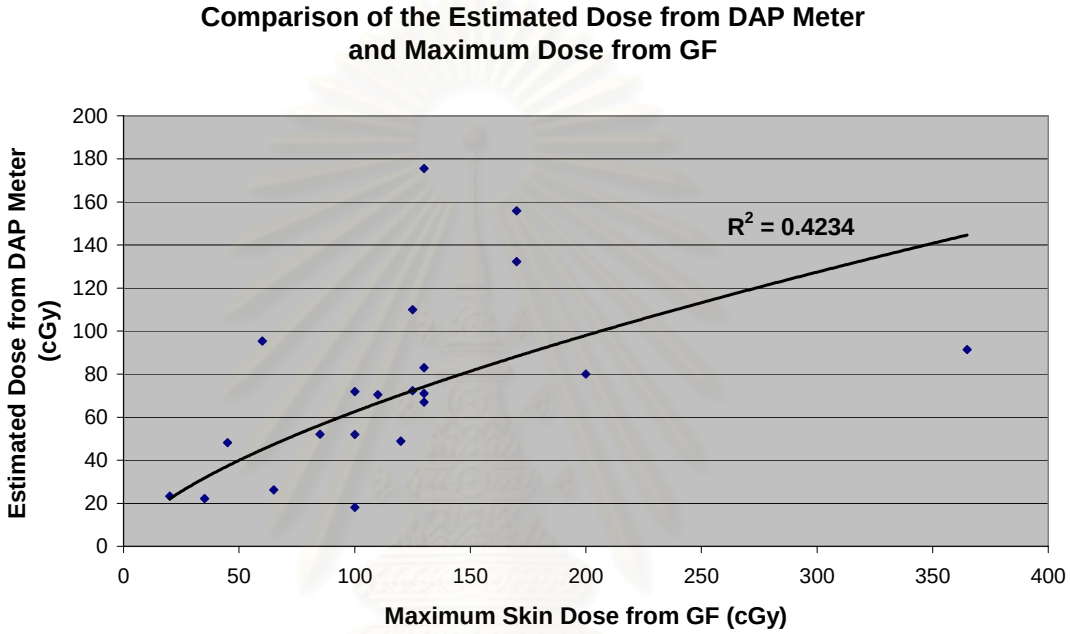


Figure 18: The relation between maximum skin dose (cGy) from Gafchromic film and estimated dose from DAP meter (cGy).

5.3 Discussion

The result shows the linear correlation between the estimated dose from DAP meter and the maximum skin dose from Gafchromic film. There are several factors affected the dose estimation by the DAP meter such as the variation of the radiation field, the angle of the x-ray tube, fluoroscopic mode, field sizes during fluoroscopy, those made uncertain area for dose estimation.

The maximum skin dose determined by Gafchromic film of each procedure is certainly higher than the estimated dose from DAP meter. Because the DAP is the cumulative dose from every exposures at many parts of the patient, so the dose could be estimated from the averaged radiation areas, while maximum dose measured at one point on exposed skin. Both results compliment to each other and benefit the patients except the maximum exceeds the threshold level of skin injury.

Interventional radiology and cardiac catheterization procedures described in this study may also increase the risk for late effects such as radiation-induced skin injuries. The potential for such late effects should not be disregarded in risk/benefit considerations, especially for individuals with many decades of expected life remaining, such as pediatric and young adult patients, or for procedures involving absorbed dose to radiosensitive tissues such as the breast and gonads. These interventional procedures can also result in increased occupational exposure to physicians and staff, and efforts to reduce the exposure to patients will result in reductions in the exposure to those conducting the procedures.

Complicating the assessment of the magnitude of the problem of injuries from fluoroscopy is the fact that the injuries are not immediately apparent. Typical times to onset or appearance of the effect are given in Table 6 (see appendix I). Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physician performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. For this reason, it is recommended that patient skin dose should be recorded in the patient's record. Consideration should be given to counseling such patients on the possible symptoms and risks from those procedures.

5.4 Conclusion

The Gafchromic film detector has adequately measured maximum skin dose during fluoroscopic procedure for interventional radiology procedures and cardiac catheterization. It can provide information for point dose assessment or profile measurements of dose if required. Even though the dose measurement is simple and accurate but the high cost of the film may prevent its regular use for monitoring skin dose directly.

The DAP meter is convenience for radiation dose estimation and it should be installed in every radiographic-fluoroscopic system for dose assessment. The readings can over or underestimate dose risk due to many factors, as e.g. the difficultly to correlate the exposure with skin area on the patient.

There was only one incident on TOCE procedure where maximum skin dose, 365 cGy exceeded the threshold dose for temporary epilation, 300 cGy [11] (see appendix I).

The determination of the radiation dose in interventional radiology and cardiac catheterization is a benefit for radiation injury prevention and also increase the awareness of the radiologist and cardiologist in using the radiation for interventional procedures.

The result can be used as a guideline for studying the dose range of each procedure (see table 5) in order to optimize exposure technique and the radiation dose for the benefit of the patient in interventional radiology and cardiac catheterization procedures.

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11. Food and Drug Administration, Recording Information in the Patient's Medical Record that Identifies the Potential for Serious X-Ray Induced Skin Injuries Following Fluoroscopically Guided Procedures. Important Information for Physicians and Other Health Care Professionals, September 9th, 1994.

APPENDICES

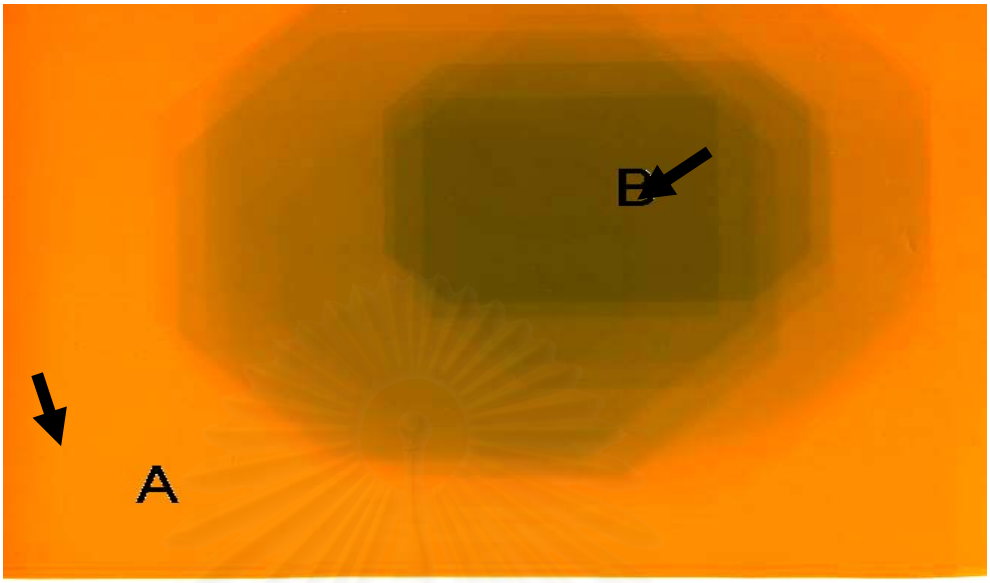
APPENDIX I

Table 6: Shows the radiation induced skin injuries

Radiation-Induced Skin Injuries				
Effect	**Typical Threshold Absorbed Dose (Gy)***	**Hours of Fluoroscopic "On Time" to Reach Threshold+ at:**		**Time to Onset of Effect++**
		Usual Fluoro. Dose Rate of 0.02 Gy/min (2 rad/min)	**High-Level Dose Rate of 0.2 Gy/min (20 rad/min)**	
Early transient erythema	2	1.7	0.17	Hours
Temporary epilation	3	2.5	0.25	3 wk
Main erythema	6	5.0	0.50	10 d
Permanent epilation	7	5.8	0.58	3 wk
Dry desquamation	10	8.3	0.83	4 wk
Invasive fibrosis	10	8.3	0.83	
Dermal atrophy	11	9.2	0.92	>14 wk
Telangiectasis	12	10.0	1.00	>52 wk
Moist desquamation	15	12.5	1.25	4 wk
Late erythema	15	12.5	1.25	6-10 wk
Dermal necrosis	18	15.0	1.50	>10 wk
Secondary ulceration	20	16.7	1.67	>6 wk

* The unit for absorbed dose is the gray (Gy) in the International System of units. One Gy is equivalent to 100 rad in the traditional system of radiation units.
+ Time required to deliver the typical threshold dose at the specified dose rate.
++ Time after single irradiation to observation of effect.

APPENDIX II



A = Unexposed area
B = Exposed area
Figure 19: Shown the exposed Gafchromic XR type R film

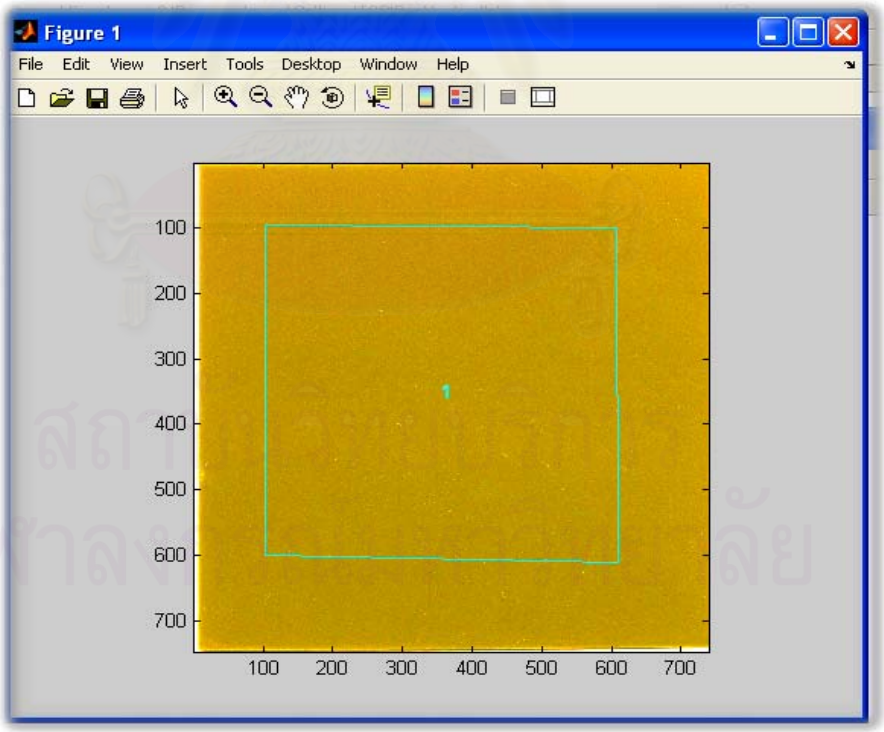


Figure 20: MatLab program, the analyzing window

APPENDIX III

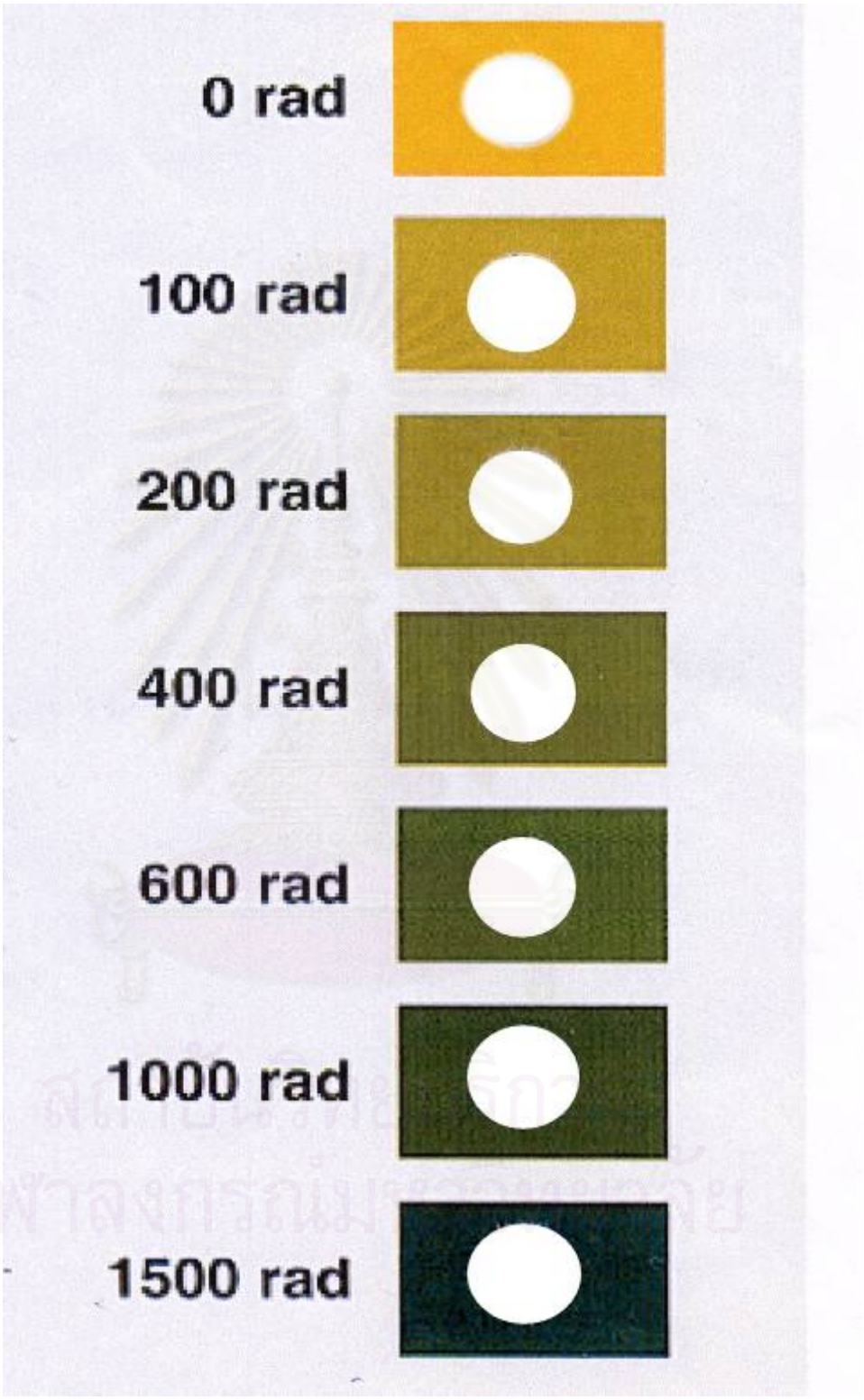


Figure 21: The Gafchromic dose reference strip.

APPENDIX IV

Table 7: CASE RECORD FORM

Clinical data collection sheet for interventional dose project		
Facility identification		
Equipment ID		
Plane for bi-plane system, if applicable		
Procedure		
Initial DAP setting		
Initial cumulative fluoroscopy time		
Patient name		
Patient ID		
Patient height		
Patient weight		
Patient gender		
Patient Age		
Portal or Gafchromic film in place?		
Superior position mark on film?		
Patient left marked on film		
Start time		
Fluoroscopy dose mode setting initially and at 10 minute intervals		
End time		
DAP readout at end		
Cumulative fluoroscopy time at end		
DA or digital fluorography frames		
DA or digital fluorography frame rate		
Dose mode setting for DA and fluorography		
Typical kV, mAs for DA and DF		
DSA frames(number)		
Dose mode setting for DSA		
Typical kV, mAs for DSA		
Cine frames rate		
Cine frames (number)		
Equipment setting for Cine		
Number of Cine runoffs		
Typical kV, mAs for Cine		
Gafchromic film ID		
Calculated patient skin dose		
Cardiologist / Radiologist		
Cardiologist / Radiologist exposure / case (Pocket Dosimeter)		
Data Collector		

APPENDIX V

PATIENT CONSENT FORM

ข้อมูลสำหรับผู้เข้าร่วมวิจัย

การศึกษา: ปริมาณรังสีที่ผิวหนังของผู้ป่วย จากการวัดโดยเรดิโอโครมิคฟิล์มและแดพมิเตอร์ ในผู้ป่วยที่ทำการตรวจสวนหัวใจและรังสีร่วมรักษา

เรียน ผู้เข้าร่วมวิจัยทุกท่าน

ท่านเป็นผู้ได้รับเชิญจากผู้วิจัยให้เข้าร่วมการศึกษาเพื่อวัดปริมาณรังสีที่ผิวหนังของผู้ป่วยในการตรวจสวนหัวใจและรังสีร่วมรักษา โดยใช้เรดิโอโครมิคฟิล์มและแดพมิเตอร์ ก่อนที่ท่านตกลงเข้าร่วมการศึกษาดังกล่าว ขอเรียนให้ท่านทราบถึงเหตุผลและรายละเอียดของการศึกษาวิจัย ในครั้งนี้

ผู้ป่วยที่เข้ารับการตรวจสวนหัวใจและรังสีร่วมรักษาโดยใช้การฉายรังสีแบบต่อเนื่อง(Fluoroscopy) เป็นเครื่องมือในการนำตรวจนั้น จะมีความเสี่ยงที่จะได้รับปริมาณรังสีสูงกว่าการตรวจวินิจฉัยทั่วไป และปริมาณที่ได้รับจะมีระดับอยู่ในเกณฑ์ที่สามารถยอมรับได้หรือไม่นั้นเป็นสิ่งที่น่าศึกษา

ดังนั้นการศึกษาวิจัยในครั้งนี้ มีวัตถุประสงค์เพื่อ วัดปริมาณรังสีที่ผิวหนังของผู้ป่วยต่อการตรวจหรือการรักษาแต่ละครั้งว่าเป็นปริมาณเท่าไร และมีวิธีการลดปริมาณรังสีที่ผู้ป่วยได้รับอย่างไร เพื่อไม่ให้เกินปริมาณรังสีสูงสุดที่ผู้ป่วยสามารถรับได้

ในการวัดปริมาณรังสีนั้น จะใช้เรดิโอโครมิคฟิล์ม(Radiochromic film) ซึ่งจะมีลักษณะเป็นแผ่นฟิล์มสีเหลืองด้านหนึ่งอีกด้านหนึ่งสีขาว ขนาด14 x17 นิ้ว และแดพมิเตอร์ (DAP meter) ซึ่งเป็นเครื่องมือที่ใช้วัดปริมาณรังสีที่ออกมาจากหลอดเอกซเรย์โดยตรง ในการวัดเรดิโอโครมิคฟิล์มนั้นจะวางอยู่ใต้ตัวผู้ป่วย บนเตียงเอกซเรย์ตรงบริเวณที่รังสีผ่านตัวผู้ป่วย และสำหรับแดพมิเตอร์นั้น ส่วนหัววัดจะติดอยู่ที่หลอดเอกซเรย์ โดยเครื่องอ่านค่าจะแยกออกมาต่างหาก ซึ่งอุปกรณ์ทั้งสองชนิดนี้จะไม่รบกวนหรือเป็นอุปสรรค ทั้งผู้ป่วยและเจ้าหน้าที่ในขณะปฏิบัติงาน

หากท่านตกลงที่จะเข้าร่วมการศึกษาวิจัยนี้ จะมีข้อปฏิบัติร่วมดังต่อไปนี้

1. ท่านไม่ต้องเสียค่าใช้จ่ายใดๆ เพื่อการวัดค่าปริมาณรังสีดังกล่าว
2. ก่อนเริ่มการตรวจในแต่ละครั้ง ผู้วิจัยจะติดเครื่องมือคือ แดพมิเตอร์ที่หลอดเอกซเรย์และเรดิโอโครมิคฟิล์มวางบนเตียงใต้ตัวผู้ป่วย สำหรับการตรวจ neurointerventional radiology ซึ่งเป็นการตรวจรักษาบริเวณศีรษะ เรดิโอโครมิคฟิล์มจะวางอยู่ด้านหลังและด้านข้างของศีรษะ โดยจะไม่ทำให้เกิดการระคายเคืองใดๆต่อผู้ป่วย

3. หลังจากที่แพทย์และเจ้าหน้าที่ทำการตรวจหรือการรักษาเสร็จในแต่ละการตรวจ ผู้วิจัยจะทำการเก็บเรดิโอโครมิคฟิล์มและนำค่าที่ได้จากแดพมิเตอร์ไปคำนวณหาปริมาณรังสีที่ผู้ป่วยได้รับในการตรวจครั้งนั้นๆ

การเข้าร่วมการศึกษาวิจัยนี้ เป็นไปโดยสมัครใจท่านอาจจะปฏิเสธที่จะเข้าร่วม หรือถอนตัวจากการศึกษาวิจัยนี้ได้ทุกเมื่อ

ประการสำคัญที่ท่านควรทราบ คือ ผลของการศึกษาวิจัยนี้ จะใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น โดยข้อมูลต่างๆ จะไม่มีการแพร่งพรายสู่สาธารณชน ขอรับรองว่าจะไม่มีการเปิดเผยชื่อของท่านตามกฎหมาย

หากท่านมีปัญหา หรือข้อสงสัยประการใด กรุณาติดต่อ นายชูชีพ คำเครือ โทร 063230956 - ซึ่งยินดีให้คำตอบแก่ท่านทุกเมื่อ

ขอขอบคุณในความร่วมมือของท่านมา ณ ที่นี้

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ใบยินยอมเข้าร่วมการวิจัย (Consent form)

การวิจัย เรื่อง ปริมาณรังสีที่ผิวหนังของผู้ป่วย จากการวัดโดยเรดิโอโครมิคฟิล์มและแคพมิเตอร์ ในผู้ป่วยที่ทำการตรวจสวนหัวใจและรังสีร่วมรักษา

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

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการทำวิจัย วิธีการวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการทำวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลใดๆ ต่อข้าพเจ้า

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีที่จำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....ผู้ยินยอม

(.....)

ลงนาม.....พยาน

(.....)

ลงนาม.....ผู้ทำวิจัย

(.....)

VITAE

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