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Evaluation of radiation dose during the percutaneous angioplasty for arteriovenous shunt assembling

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ABSTRACT

Percutaneous angioplasty (PTA) for dysfunctional hemodialysis is usually performed by radiologists, but not cardiologists, in Taiwan, so that the radiation dose in patients and physicians are usually unknown and related studies are rare. In this study, we are pioneering an investigation into the radiation dose in percutaneous angioplasty for arteriovenous shunt assembling and the effect of RADPAD device, a lead-free surgical drape containing Bi and Ba, on the decrease of a radiation dose in the non-targeted organs of the patient and also the operator. The radiation dose in a typical digital subtraction angiography (DSA) by the PTA protocol under a fixed field of view (FOV), was measured with optically simulated luminescent dosimeters arranged in a PIXY RS-102 anthropomorphic phantom.

The results indicate that there is a significant dose reduction at the hands (0.022 ± 0.002 mGy before treatment vs. 0.014 ± 0.001 mGy after treatment; P=0.021), but not at the lens (0.027 ± 0.003 mGy before treatment vs. 0.018 ± 0.001 mGy after treatment; P=0.058), and the gonads (0.026 ± 0.003 mGy before treatment vs. 0.020 ± 0.001 mGy after treatment; P=0.058), of the cardiologist/operator after treatment with the RADPAD drape. At the patient's abdomen, the dose significantly decreased from 1.597 ± 0.104 mGy to 0.031 ± 0.002 mGy (P < 0.001) after treated with the RADPAD shield. For the chest, lens and thyroid in the patient, the doses were respectively 0.154 ± 0.100 mGy (compared to 0.049 ± 0.001 mGy after treated with the RADPAD drape; P=0.0002), 0.066 ± 0.001 mGy (compared to 0.021 ± 0.001 mGy after the RADPAD treatment; P=0.009), and 0.208 ± 0.002 mGy (compared to 0.042 ± 0.003 mGy after shielded with the RADPAD drape; P < 0.0001), which represents an apparent reduction in dose. However, no significant difference was found in the dose-area product between before (179.9 ± 0.1mGy.cm^2) and after (177.4 ± 2.6 mGy.cm^2) the treatment (P=0.38).

In conclusion, the RADPAD drape significantly reduced radiation exposure to the patient during the PTA for the arteriovenous shunt assembling, which is suggested should be applied to the current cardiac catheterization.

1. Introduction

Nearly 400,000 patients are currently treated with hemodialysis in the United States, with Medicare spending $90,000 per patient for care in 2011. Although mortality rates are improving, they remain several fold higher than that of the age matched individuals in the general population (Hemodialysis Adequacy Work Group, 2006). The preferred type of access in patients undergoing hemodialysis is an arteriovenous fistula (AVF) (The National Kidney Foundation Kidney Disease Outcomes Quality Initiative, 1997).

The Kidney Disease Outcomes Quality Initiative provides evidence-based clinical practice guidelines for all stages of ESRD and reports autogenous AVF as the standard reference for primary vascular access, due to their longevity and low infection rates (Kalman et al., 1999). Sands et al. (1999) and Schwab et al. (2001) demonstrated a 10-fold increase in the thrombosis rate of synthetic polytetrafluoroethylene (PTFE) access when compared to the AVFs (Turmel-Rodrigues et al., 2000). Significant stenosis causing access dysfunction is a frequent complication in hemodialysis and requires repeated percutaneous transluminal balloon angioplasty (PTA) to maintain the patency (Falk, 2006). Many factors influencing the patency rate have been studied in previously reported series (Clark et al., 2002; Rajan et al.,

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2004). Interventions that can improve outcomes in dialysis are urgently needed. The standard of care for those patients who require chronic hemofiltration-based therapy is the arteriovenous (AV) fistula or graft. Unfortunately, more than half of these vital portals for dialysis access may fail within two years (Kalman et al., 1999 ; Pioni et al.,2002; Biuckians et al., 2008).

The fistulas and the venous outflow of the AV grafts are subjected to venous intimal hyperplasia and subsequent stenosis or thrombosis (Beathard, 1994, 1995; Besarab et al., 1995; Burger et al., 1990; Malik et al., 2005; McCarley et al., 2001; Safa et al., 1996; Schwab et al., 1989; Tessitore et al., 2003). The PTA is an established treatment for stenosis in AV grafts, native vein fistulas, and central outflow veins (Gray, 1997). There is a role for the PTA in the maintenance of access circuit patency on the basis of published technical success rates and clinical outcomes concluded by the Dialysis Outcomes Quality Initiative guidelines; however, the primary patency rate is less than 50% one year post intervention (The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI)/DOQI, 2001). Since the PTA procedure is performed with ionizing radiation, the operator and the staff are subjected to potential health risk due to radiation. Accordingly, minimizing radiation exposure is an important quality goal during fluoroscopy-guided procedure.

Over the past decade, the PTA has increasingly been performed for therapeutic and diagnostic purposes. Therapeutic procedures typically require longer fluoroscopy time. As a result, the operator and clinical staff are exposed to higher radiation doses (Kim et al., 2008). Many dysfunctional hemodialysis access interventions are performed by cardiologists every year in Taiwan, but unfortunately, the radiation doses to the patient and the physician are unknown.

In clinical practice, the operator has to approach the patient's body to perform percutaneous angioplasty. Therefore, the operator's hands and eyes may suffer from radiation exposure because no protective shield was applied at these regions during the catheterization procedure. So far, rare studies evaluated the radiation dose of target organs in patients and operators involved in the PTA. In addition, the pathological changes of eyes are imperative to be concerned as indicated by significantly higher incidences of radiation-associated cataracts noted in the interventional cardiologists (Clark et al.,2010;Vano et al., 2013; Ciraj-Bjela et al., 2010; Jacob et al., 2013).

Accordingly, in order to investigate the effect of radiation shield as well as to emphasize the importance of radiation protection during the PTA, we conducted a phantom study to assess the efficacy of a protective drape in reducing radiation exposure to the operator and patient.

2. Materials and methods

The radiation dose in patient was evaluated by using a PIXY RS-102 anthropomorphic phantom (Fig. 1) and optically simulated luminescent dosimeters (OSLD). A lead-free surgical drape containing a bismuth and barium was mounted around the flat detector. The results were recorded in a typical digital subtraction angiography (DSA) in a fixed field of view (FOV) for the PTA protocol. Therapeutic PTA procedures with one minute of an expected fluoroscopy time were included in this study. The investigated shielding drape, RADPAD, is a lead-free surgical drape containing Bi and Ba with a dimension of 11-in×34-in and weighed < 150 g (Worldwide Innovations & Technologies, Kansas City, US). This drape has been shown able to considerably reduce the scatter radiation during coronary angiography and percutaneous coronary intervention procedures (Politi et al., 2012; Murphy et al., 2011). A sham drape was used for the control group. In this study, we used a stationary floor-mounted under-couch C-arm system (Siemens Artis zee, Washington, DC). Before starting the PTA procedure, the drape was hung around the image intensifier with an adhesive strip.

There were three OSLDs positioned on the operator, including one pasted on the left collar of the procedure gown inside the lead apron, a second one attached to the left side of their eye goggles, and the third dosimeter placed on the procedure gown inside the left pocket. Four dosimeters were positioned on the phantom patient with each one on the left chest, abdomen, the left eye, and the thyroid. Each dosimeter was individually calibrated before the PTA procedure.

After the PTA procedure, the dosimeters were immediately collected and the data were read in the lab. The drape was placed around the flat panel and outside the primary X-ray beam (or FOV) as shown in Fig. 2a. Positioning of the operator and patient during the PTA was standardized as follows: the primary operator stood on the left side of the head at the end of the exam table as represented in Fig. 2b. The table was 25° rotated at to the right (for clinic simulation of right radiocephalic autogenous or brachio-prosthetic graft angioplasty). Following conditions were set for the procedure: table height=100 cm, source to image receptor distance (SID)=95 cm, FOV=32 cm and Cu filter=0.1 mm. The recorded parameters included X-ray tube voltage (kV), tube current (mA), absorbed dose (mGy), dose area product (DAP)mGy.cm^2) and equivalent dose (mSv).

The anthropomorphic phantom was firstly placed supine without shielding protection to obtain baseline scattered radiation dose to the phantom patient and operator, which served as a control. Subsequently, the shielding drape was placed around the flat panel to determine the radiation doses in phantom patient and operator. The

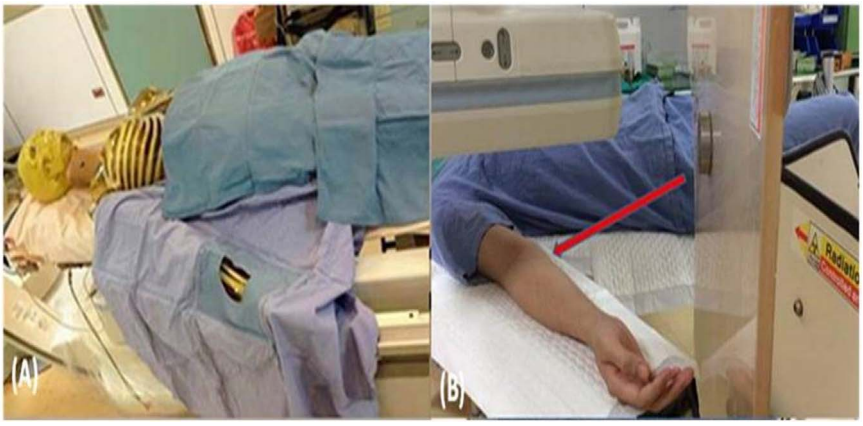

Fig. 1. Equipment arrangement for the comparison of radiation dose in patient between (A) shielded with a RADPAD drape and (B) without shielding drape in traditional procedure.

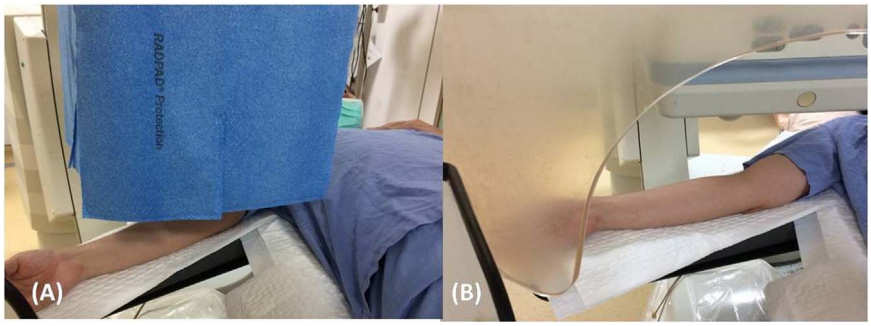

Fig. 2. Equipment arrangement for the comparison of radiation dose in operator when the flat panel was (A) shielded with a RADPAD drape to (B) that without shielding in traditional procedure.

flat panel was placed over the lower arm for the investigation during the hemodialysis access angiography and intervention procedures. Equivalent doses at each of the seven sites and the DAPs were the primary outcome. Equivalent doses at each of the seven dosimeter sites when using the radiation-attenuating drape were compared with that without the drape. Comparisons of the continuous variables were performed using the Student's *t*-test, and a two-tailed P-value < 0.05 was considered as significant for statistical analysis in this study.

3. Results and discussion

The energy range of the X-ray tube was 50–53 kV and the current was 647–669 mA. A significant dose reduction was found at the hands (0.022 ± 0.002 mGy before treatment vs. 0.014 ± 0.001 mGy after treatment; P=0.021) of the operator. No significant difference was found in equivalent dose at the lens (0.027 ± 0.003 mGy before treatment vs. 0.018 ± 0.001 mGy after treatment; P=0.058) and the gonads (0.026 ± 0.003 mGy before treatment vs. 0.020 ± 0.001 mGy after treatment; P=0.058) of the cardiologist/operator after treated with the RADPAD device (Fig. 3). The mean equivalent dose at each of the three sites (i.e., gonad, hands and lens) was significantly reduced in the radiation-attenuating drape group compared to the sham-drape group, with a reduction ≥90% in radiation exposure (and relative risk). The decreasing ratio of radiation dose is defined as the percentage of difference in radiation dose between before and after shielded to radiation dose before shielded [i.e., (radiation dose before shielded–radiation dose after shielded)/(radiation dose before shielded)×100%]. Since the operator has to remain close to their patient during the PTA, it is possible to reduce radiation exposure by minimizing the time required for PTA procedure or applying radiation shields. Considering practical requirement in the PTA, a radiation shield is relatively easier to achieve. In addition to personal protective gear (i.e., lead apron, thyroid neck shield and eye glasses) and under-couch lead skirts, mobile transparent protective shield ≥0.5 mm of lead-equivalent thickness positioned between the X-ray source and the patient or the operator can decrease their radiation exposure by up to ≥90% (Muniraj et al., 2015), which is similar to our results with the RADPAD drape.

Although several variables may affect radiation exposure (e.g., the experience level for the PTA, the complexity and need for additional interventions during the PTA, the involvement of a trainee, and the factors from the patient), applying a radiation-attenuating drape is a simple way to reduce annual radiation exposure to an acceptable level, even for an operator performing 100 therapeutic PTAs per year. The way to apply the radiation-attenuating drape around the flat panel during the PTA significantly decreases the radiation exposure to the operator and staff by about 30%. Accordingly, proper shields (e.g., the RADPAD drape) are helpful to the cardiologist/operator in reducing radiation dose, especially at the hands, during the PTA for arteriovenous shunt assembling.

At the abdomen of the patient, the dose significantly decreased from 1.597 ± 0.104 mGy to 0.031 ± 0.002 mGy ($P < 0.001$) when shielded with the RADPAD device. For the chest, lens and thyroid in the patient, the doses were respectively 0.049 ± 0.001 mGy (compared to 0.154 ± 0.100 mGy before treatment; P=0.0002), 0.021 ± 0.001 mGy (compared to 0.066 ± 0.001 mGy before treatment; P=0.009) and 0.042 ± 0.003 mGy (compared to 0.208 ± 0.002 mGy before treated with the RADPAD device; $P < 0.0001$), which represent an apparent reduction in dose (Fig. 4). However, no significant difference was found in the dose-area product (what the operator usually used to evaluate the dose) between the two groups (179.9 ± 0.1mGy.cm^2 before treatment compared to 177.4 ± 2.6 mGy.cm^2 after treatment; P=0.38). The radiation-attenuating drape was found effective in reducing radiation exposure to abdomen of the patient by about 98%, as compared to a sham drape. Accordingly, proper radiation shield is suggested for the patients to decrease health risk during the PTA.

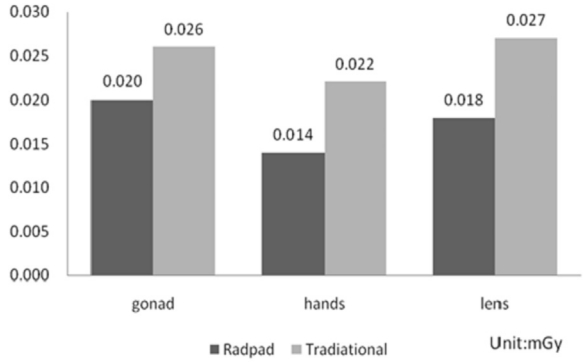

Fig. 3. Comparison of absorbed dose in organs of the operator protected with the RADPAD device to that without shielding in traditional procedure (unit: mGy). The decreasing ratios in dose at the gonad, hands and lens are 23%, 36% and 33%, respectively, after shielded with the RADPAD drape.

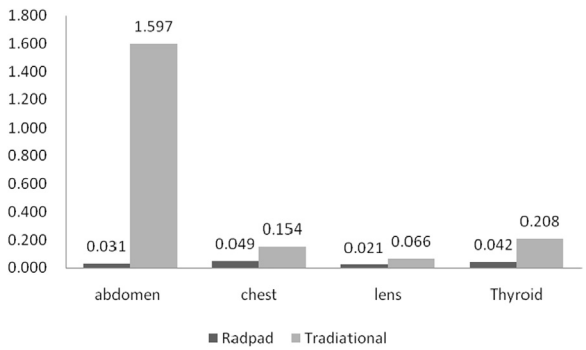

Fig. 4. Comparison of absorbed dose in organs of the patient protected with the RADPAD device to that without shielding in traditional procedure (unit: mGy). The ratios reduced in dose at the abdomen, chest, lens and thyroid are respectively 98%, 68%, 68% and 80%, after shielded with the RADPAD drape.

4. Conclusion

Using the RADPAD device during percutaneous intervention significantly decreased radiation dose at abdomen, chest, lens and thyroid of the patient during the PTA procedure for arteriovenous shunt assembling. The radiation dose in operator can be significantly reduced at the hands in cardiac catheterization when the flat-detector is shielded with the RADPAD device. Accordingly, applying the shielding drape in the PTA is helpful to decrease health risk in the patient and operator from radiation exposure. The way of radiation protection with the drape could be referable for clinical routines in PTA.

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