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Radioprotection en cardiologie interventionnelle :

Garantir la sécurité des patients et des praticiens pour promouvoir l'innovation

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Résumé/Abstract

Résumé

Les innovations dans le domaine de la cardiologie ont conduit à la réalisation d'un nombre toujours croissant de procédures faisant appel aux rayons X. Ainsi, des effets déterministes de l'exposition aux rayonnements sont susceptibles de survenir chez les patients et les opérateurs, et une augmentation du risque de cancer radio-induit est suspectée dans ce contexte. Une connaissance précise du niveau d'exposition aux rayonnements ionisants et de ses déterminants est donc indispensable afin que le principe ALARA (As Low As Reasonably Achievable) puisse être appliqué. L'objectif de ce travail de thèse était donc d'étudier le niveau d'exposition aux rayonnement ionisants des patients et des opérateurs au cours des procédures de cardiologie interventionnelle faisant appel aux rayons X, ainsi que de préciser les déterminants de cette exposition.

Les travaux menés dans le cadre de cette thèse ont démontré que le niveau d'exposition aux rayonnements a diminué de façon importante au cours de la dernière décennie. Toutefois, des progrès peuvent encore être réalisés, notamment en modernisant les appareils à rayons X et en appliquant les règles de radioprotection. De même, nous avons identifié des procédures associées à un haut niveau d'exposition aux rayonnements pour lesquelles le développement de technologies de réduction de dose et de dispositifs de protection adaptés s'impose. Enfin, lorsqu'il est requis, le scanner cardiaque pré-procédural participe de façon prédominante à la dose globale de rayonnements reçue par les patients, et de nouvelles stratégies devront être mise en œuvre afin de réduire l'exposition des patients au moment de cet examen.

Mots-clés :

Radioprotection ; Cardiologie ; Innovation

Abstract

Innovations in cardiology have led to the performance of an ever-increasing number of procedures using X-rays. Thus, deterministic effects of radiation exposure can occur in both patients and operators, and an increased risk of radiation-induced neoplasm is suspected in this setting. An accurate knowledge of the level of exposure to ionizing radiation along with its determinants is critical to apply the ALARA (As Low As Reasonably Achievable) rule. Thus, we sought to determine the level of exposure to ionizing radiation of patients and operators during cardiology procedures using X-rays, and to investigate the determinants of this exposure.

The present research showed that the level of radiation exposure has decreased significantly over the last decade. However, further progress can be achieved by modernizing X-ray equipment and applying radiation protection rules. Similarly, we have identified procedures associated with high levels of radiation exposure for which the development of dose reduction technologies and suitable protective devices is required. When performed, the pre-procedural cardiac computed tomography is the main contributor to the overall radiation dose received by patients, and new strategies will have to be implemented to reduce the exposure of patients undergoing a pre-procedural computed tomography.

Keywords:

Radiation protection; Cardiology; Innovation

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Liste des abréviations

AK : air kerma

CHU : centre hospitalier universitaire

CTO : occlusion coronaire chronique

DAI : défibrillateur automatique implantable

FPS : frame per second

IMC : indice de masse corporelle

PDS : produit dose-surface

PM : pacemaker

PRI : point de référence interventionnelle

TAVI : remplacement valvulaire aortique percutané

TC : trans-carotide

TF : trans-fémoral

Introduction générale

Les procédures médicales constituent la première source d'exposition aux rayonnements ionisants dans la population générale (1), en rapport avec l'augmentation constante du recours à ce type d'examens, qu'ils soient à visée diagnostique ou thérapeutique. De même, de nombreux professionnels de santé sont exposés aux rayonnements ionisants, et l'existence d'un sur-risque de cataracte radio-induite dans cette population a été démontré (2). Enfin, alors que l'augmentation du risque de leucémie et de tumeur solide chez les travailleurs de l'industrie nucléaire est bien connue (3, 4), ce dernier reste sujet à controverse chez les professionnels de santé exposés aux rayonnements ionisants (5, 6).

Au cours des dernières décennies, des progrès importants ont été réalisés dans la prise en charge des patients présentant une pathologie cardiaque. En effet, depuis la première angioplastie coronaire réalisée en 1977 par Andreas Gruentzig (7), le nombre de procédures a augmenté de façon exponentielle. Secondairement, la rythmologie interventionnelle a connu un essor spectaculaire avec le développement de procédures d'ablation complexe (8) et l'apparition de la resynchronisation cardiaque (9). Enfin, de nombreuses procédures de cardiologie interventionnelle structurelle ont émergé, à l'instar du remplacement valvulaire aortique percutané (TAVI) (10). Ces procédures ont pour point commun d'être réalisées sous guidage fluoroscopique, et sont donc toutes associées à une irradiation du patient et de l'opérateur. Par conséquent, les cardiologues font partie des professionnels de santé les plus exposés aux rayonnements ionisants (11). Toutefois, les procédures de cardiologie faisant appel aux rayons X constituent un groupe hétérogène tant du point de vue des techniques d'intervention que de l'exposition aux rayonnements ionisants, et le niveau d'exposition ainsi que ses déterminants demeurent largement méconnus.

L'objectif de ce travail de thèse était donc d'étudier le niveau d'exposition aux rayonnements ionisants des patients et des opérateurs au cours des procédures de cardiologie faisant appel aux rayons X, ainsi que de préciser les déterminants de cette exposition.

Rappels biophysiques

En rencontrant de la matière organique, les rayonnements ionisants peuvent induire deux types d'effet. Tout d'abord, les *effets déterministes* sont prédictibles et directement liés à la dose. Il existe une dose seuil à partir de laquelle ils apparaissent, et ce seuil dépend notamment du tissu exposé. La sévérité des effets déterministes va augmenter avec la dose. En cardiologie interventionnelle, les patients peuvent présenter une dépilation, un érythème voire une nécrose cutanée de la zone d'entrée des rayons X (le dos du patient le plus souvent) (12), alors que les opérateurs peuvent présenter une cataracte radio-induite (2, 13-15). Ensuite, les *effets stochastiques* sont imprévisibles, leur probabilité d'apparition augmente avec la dose mais leur sévérité n'est pas liée à la dose. Il n'a jamais été identifié de valeur seuil à partir de laquelle ils apparaissent. De plus, la plupart des données dont nous disposons proviennent des catastrophes nucléaires (Hiroshima, Nagasaki, Tchernobyl) et l'effet de l'exposition répétée à de faibles doses demeure mal connu. En cardiologie interventionnelle, il est possible que les patients et les opérateurs soient exposés à une augmentation du risque de cancer radio-induit, notamment hématologique et cérébral (5, 6, 16). Compte tenu de l'absence de seuil d'apparition des effets stochastiques, l'attitude ALARA (As Low As Reasonably Achievable) est recommandée pour toutes les procédures médicales faisant appel aux rayonnements ionisants.

Il existe plusieurs façons d'appréhender la dose de rayonnements reçue par un être vivant (12). La *dose absorbée*, exprimée en gray (Gy), correspond à la quantité d'énergie déposée localement par unité de masse de tissu (J/kg). Elle permet d'estimer le risque déterministe local. L'*Air Kerma*, exprimé également en gray (Gy), correspond à la quantité d'énergie déposée localement en un point précis de l'espace (potentiellement virtuel). La *dose efficace*, exprimée en sievert (Sv), correspond à la conversion des doses absorbées de chaque partie du corps en une dose corps entier. Elle permet d'estimer le risque stochastique en tenant compte de la radiosensibilité des différents tissus du corps humain. La *dose équivalente*, exprimée en sievert (Sv), correspond à une dose relative tenant compte de la radiosensibilité du tissu étudié, et rend ainsi compte de la probabilité d'effet stochastique selon la nature du rayonnement et du tissu exposé.

Le *produit dose-surface (PDS)* et l'*Air Kerma (AK) au point de référence interventionnel (PRI)* (défini comme un point imaginaire localisé 15 cm sous l'isocentre du système de rayons X) sont les estimateurs de la dose de rayonnements reçue par le patient les plus fréquemment utilisés en cardiologie interventionnelle. Dans les deux cas, il ne s'agit pas de mesure réelle de la dose reçue mais d'une estimation produite à partir d'une mesure effectuée par une chambre d'ionisation à la sortie du tube à rayons X. Par commodité et conformément à

l'usage, « AK au PRI » sera dénommé « AK » dans la suite de ce travail. L'AK, exprimé en Gy, est un indicateur de dose caricatural correspondant à la dose délivrée en chaque point du champ irradié, en considérant toutes les incidences radiographiques comme étant superposées. Ainsi, l'AK est un bon estimateur de la dose à la peau dans une configuration spatiale stable, et donc du risque d'effet déterministe pour le patient. Toutefois, il faut noter que l'AK estime la dose en un point virtuel (IRP) ne correspondant pas nécessairement à la position du patient (et de son dos), qui est sous l'influence de l'opérateur. Enfin, l'AK n'est pas influencé par la collimation. Le PDS, exprimé en Gy.cm², est un indicateur de dose synthétique exprimant la quantité totale d'énergie délivrée au patient. Le PDS, estimant la dose reçue par le corps entier du patient, est ainsi liée au risque de présenter un effet stochastique. Il existe une relation linéaire entre le PDS et la dose efficace. Le PDS est indépendant de la hauteur de la table. Enfin, le PDS correspondant au produit de l'AK et de la surface du champ, il est influencé par la collimation.

Les cardiologues interventionnels sont exposés à de faibles doses de rayonnements ionisants de façon répétée tout au long de leur carrière. La principale source d'exposition aux rayonnements des cardiologues étant le rayonnement diffusé provenant du patient (effet Compton), il est vraisemblable que toute action sur l'irradiation des patients s'accompagnera d'une modification de la dose de rayonnements reçue par les opérateurs. En France, la dosimétrie des cardiologues interventionnels se fait à l'aide d'un dosimètre passif (dosimétrie par radio-photoluminescence) et d'un dosimètre actif (électronique), positionnés sous le tablier plombé, ainsi que d'une bague (dosimétrie par radio-thermoluminescence) qui doit idéalement être portée sur un doigt de la main gauche. Ces dispositifs permettent de mesurer la dose efficace (corps entier), correspondant à la dose reçue 10 mm sous le site du dosimètre (HP10), ainsi que la dose équivalente cutanée, correspondant à la dose reçue 0,07 mm sous la peau (HP0.07). Enfin, certaines équipes de radioprotection ajoutent un dosimètre passif positionné sur la tempe, permettant de mesurer la dose équivalente au cristallin (HP3). La loi Française impose aux travailleurs de ne pas dépasser une dose efficace de 20 mSv par an, une dose équivalente cutanée aux extrémités de 500 mSv par an et une dose équivalente au cristallin de 20 mSv par an et 100 mSv sur 5 ans. En ce qui concerne les femmes enceintes, la dose équivalente à l'enfant à naître ne doit pas excéder 1 mSv par an, alors qu'il est interdit de maintenir ou affecter une femme allaitante à un poste à risque d'exposition interne (17). Compte tenu des faibles doses auxquelles sont exposés les cardiologues interventionnels à l'échelle d'une procédure isolée, la plupart des études s'intéressant à l'irradiation des opérateurs ajoutent un dosimètre actif

positionné à l'extérieur du tablier afin de mesurer la dose à laquelle le praticien et son tablier sont exposés (toute diminution de cette dose s'accompagnera naturellement d'une diminution de la dose sous le tablier).

Partie I : Cardiologie interventionnelle coronaire

Dans cette première partie, nous aborderons l'exposition des patients et des médecins aux rayonnements ionisants au cours des procédures de cardiologie interventionnelle coronaire. L'évolution de l'exposition aux rayons X au cours de la dernière décennie, ainsi que l'impact d'une technologie moderne de réduction de dose seront abordés. Les différents déterminants du niveau de dose, qui sont pour la plupart sous le contrôle de l'opérateur, seront présentés. L'impact de la hauteur de la table du patient sur la dose de rayons X, qui restait jusqu'ici indéterminé, sera étudié.

1. Évolution de l'exposition aux rayons X au cours de la dernière décennie

Depuis les années 2000, de nombreux progrès ont été réalisés dans le domaine de la cardiologie interventionnelle. Les systèmes de rayons X, qui étaient initialement des amplificateurs de brillance, ont progressivement été remplacés par des systèmes plus sophistiqués (capteurs plans) dédiés à l'angiographie coronarienne. Les cathéters, les endoprothèses ainsi que les techniques d'imagerie endocoronaire et d'athérectomie rotationnelle sont apparus ou se sont améliorés, ce qui a permis de simplifier les procédures d'angioplastie coronaire. Enfin, l'optimisation des pratiques liées à une meilleure connaissance des principes radiophysiques régissant l'utilisation des rayons X par les cardiologues interventionnels ont pu permettre une amélioration des pratiques. D'un autre côté, à l'instar des procédures de désobstruction d'occlusion coronaire chronique (CTO), ces progrès techniques ont permis de réaliser des procédures complexes (donc potentiellement longues et très irradiantes) qui relevaient autrefois d'un traitement médical ou de pontages aorto-coronariens (18). Ainsi, le gain en termes de radioprotection obtenu grâce aux améliorations techniques et des pratiques pourrait être contrebalancé par la réalisation de procédures longues et irradiantes. Finalement, l'évolution de l'exposition aux rayonnements ionisants des patients et des opérateurs était inconnue.

a. Exposition des patients

Dans le cadre d'un travail préliminaire à cette thèse, nous avons donc comparé la dose de rayonnements reçue par les patients bénéficiant d'une procédure de cardiologie interventionnelle coronaire (diagnostique et/ou thérapeutique) à 10 années d'intervalle (2006 versus 2016). Cela était possible car un recueil de dose avait été effectué en 2006 dans le cadre d'un autre projet de recherche (19). Tous les patients qui avaient bénéficié d'une procédure de cardiologie interventionnelle coronaire au Centre Hospitalier Universitaire (CHU) de Reims au

cours de la période 1 (d'octobre 2005 à mars 2006) ou de la période 2 (de novembre 2015 à octobre 2016) étaient inclus. Le critère de jugement principal était la dose de rayonnements reçue par le patient, estimée à partir du PDS. En 2016, la dose de rayonnements reçue par les patients qui bénéficiaient d'une procédure de cardiologie interventionnelle coronaire était en moyenne 78% inférieure à celle reçue en 2006 ($p < 0,001$), alors que le temps de rayons X avait augmenté de 54% pendant la même période ($p < 0,001$) (**Figure 1**). En analyse multivariée incluant l'âge, l'approche artérielle (radiale ou fémorale), l'indice de masse corporelle (IMC), le temps de fluoroscopie et la réalisation d'au moins une angioplastie coronaire, la réduction de dose entre 2006 et 2016 restait significative ($p < 0,001$). L'approche radiale était quant à elle indépendamment associée à une augmentation de la dose de rayonnements reçue par les patients ($p < 0,001$). Ce travail avait fait l'objet d'une publication dans l'*American Journal of Cardiology* (20).

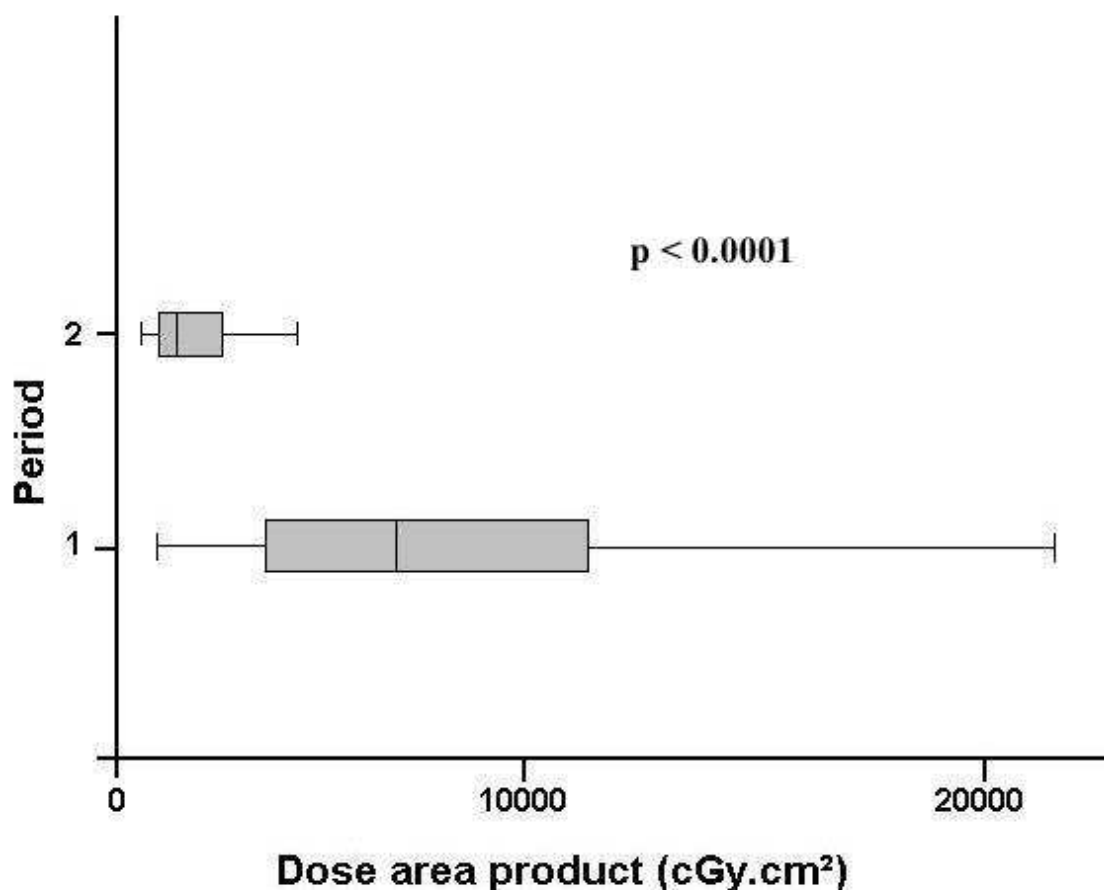


Figure 1 : Comparaison de l'exposition aux rayonnements des patients (estimée par le PDS) entre la période 1 (2006) et la période 2 (2016)

b. Exposition des opérateurs

Nous avons ensuite comparé l'exposition des cardiologues à 11 années d'intervalle. Pour ce faire, un recueil de dose avait été réalisé de façon prospective en 2017, à l'aide de dosimètres électroniques portés par les cardiologues, au bras gauche et à l'extérieur de tout dispositif de protection individuel, face au thorax du patient afin d'optimiser la réponse angulaire des dosimètres. Les données d'une étude précédente de 2006 (19), qui avaient été recueillies avec la même méthodologie et les mêmes dosimètres, avaient servi de comparateurs. Toutes les procédures de cardiologie interventionnelle coronaire réalisées par un opérateur unique au cours de la période 1 (d'octobre 2005 à mars 2006) et de la période 2 (de mars 2017 à juin 2017) étaient incluses. Le critère de jugement principal était la dose de rayonnements reçue par les opérateurs. En 2017, la dose de rayonnements reçue par les opérateurs était en moyenne 95% inférieure à celle reçue en 2006 ($p < 0,001$), en dépit d'une augmentation du temps de rayons X de 73% au cours de la même période ($p < 0,001$) (**Figure 2**). En analyse multivariée incluant l'IMC, le temps de rayons X et la réalisation d'au moins une angioplastie coronaire, la réduction de dose de rayonnements entre 2006 et 2017 restait significative ($p < 0,001$). Ce travail avait fait l'objet d'une publication dans l'*International Journal of Cardiology* (21).

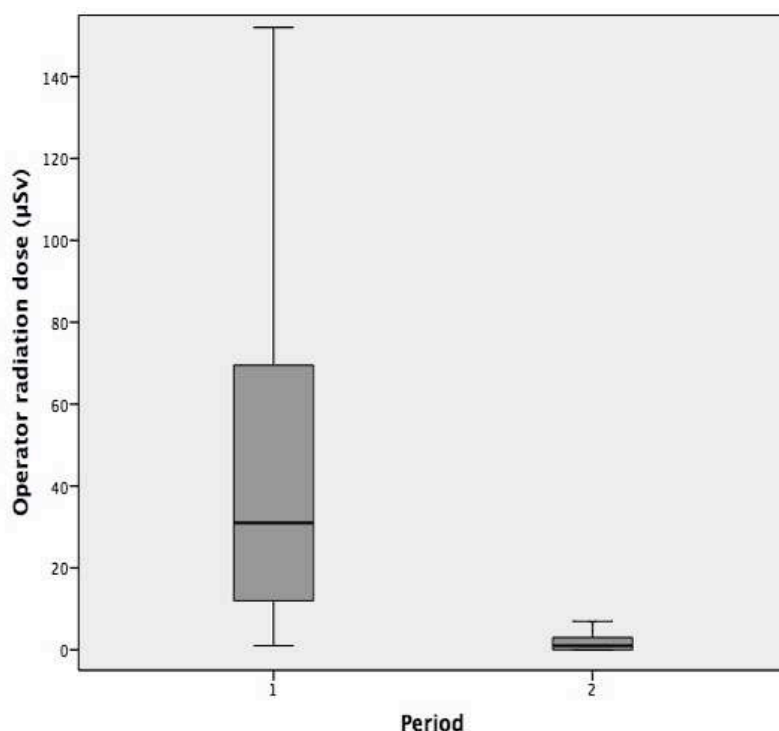


Figure 2 : Comparaison de l'exposition des opérateurs aux rayonnements entre la période 1 (2006) et la période 2 (2017)

2. Évaluation de l'efficacité d'une technologie de réduction de dose

a. La technologie ClarityIQ

La compagnie Philips (Philips Healthcare, Pays Bas) a développé la technologie de réduction de dose ClarityIQ. Cette technologie fait appel à un traitement algorithmique de l'image en temps réel (pseudo-collimation) combiné à une optimisation de la chaîne d'acquisition de l'image (déplacement de pixel en temps réel et algorithme de mouvement permettant de réduire les artefacts et le flou cinétique des zones anatomiques en mouvement rapide). Elle permet ainsi de diminuer la dose de rayonnement délivrée tout en obtenant des images d'une qualité suffisante. La littérature fait état d'une réduction spectaculaire de la dose reçue par le patient imputable à cette technologie (22-25). Cependant, ces études présentaient plusieurs limites (angioplastie coronarienne exclues, comparaison à un système de rayons X d'une autre firme) qui limitaient leur extrapolation et compromettaient leur validité. De plus, l'impact de cette technologie sur la dose reçue par les opérateurs n'avait jamais été étudiée.

b. Impact sur l'exposition des patients

Dans le cadre d'un travail préliminaire à cette thèse, nous avons donc souhaité mesurer la réduction de la dose de rayonnements reçue par les patients directement imputable à la technologie ClarityIQ parmi l'ensemble des patients bénéficiant d'une procédure de cardiologie interventionnelle coronaire (diagnostique et/ou thérapeutique). Tous les patients (sans aucun critère d'exclusion) qui avaient bénéficié d'une procédure de cardiologie interventionnelle coronaire dans notre centre pendant une période d'un an étaient inclus. Notre centre était équipé de deux salles de coronarographies. Les deux salles (A et B) étaient équipées d'un système de rayons X Allura Xper FD10 (Philips Healthcare, Pays Bas), mais seule la salle B était équipée de la technologie ClarityIQ. Le critère de jugement principal était la dose de rayonnements reçue par le patient, estimée par l'AK et le PDS. Au total, 2095 procédures de cardiologie interventionnelle coronaire ont été analysées. Les patients qui bénéficiaient de leur procédure dans la salle B recevaient en moyenne une dose de rayonnement inférieure de 23% (AK) et de 43% (PDS) à celle reçue par les patients qui bénéficiaient d'une procédure dans la salle A ($p < 0.001$) (**Figure 3**). La réduction de dose restait significative en analyse multivariée ajustée sur le temps de rayons X, l'IMC, l'approche artérielle, la réalisation d'au moins une angioplastie coronaire, le sexe et l'âge du patient. Ce travail avait fait l'objet d'une publication dans *Catheterization and Cardiovascular Interventions* (26).

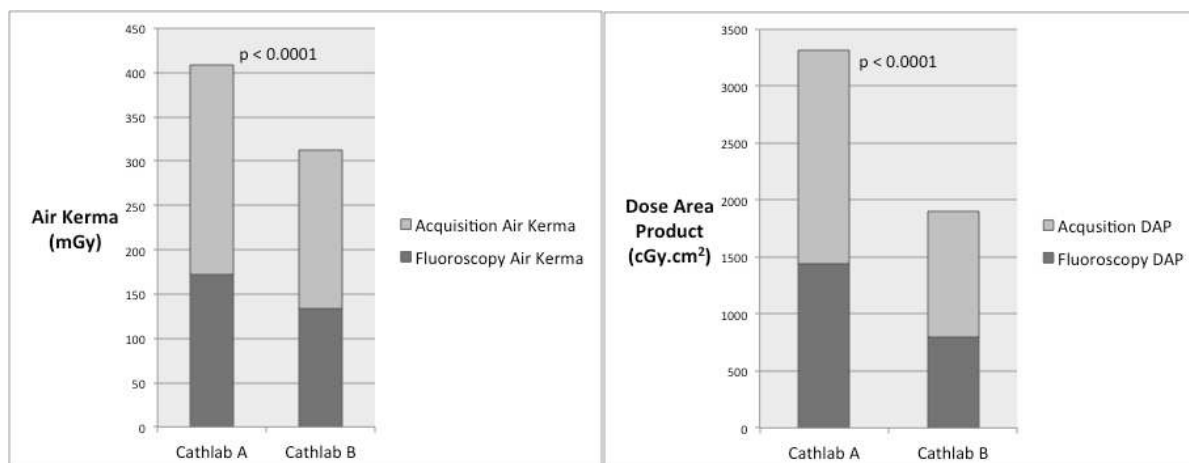


Figure 3 : Comparaison de l'exposition aux rayonnements des patients (estimée par l'AK [gauche] et le PDS [droite]) entre la salle A (sans ClarityIQ) et la salle B (avec ClarityIQ)

c. Impact sur l'exposition des opérateurs

Nous avons également souhaité déterminer le pourcentage de réduction de la dose de rayonnements reçue par les cardiologues interventionnels obtenue grâce au système de réduction de dose ClarityIQ. Nous avons donc inclus prospectivement tous les patients bénéficiant d'une procédure de cardiologie interventionnelle coronaire dans l'une des deux salles de coronarographie de notre centre. Les deux salles (A et B) étaient équipées d'un système de rayons X AlluraXper FD10 (Philips Healthcare, Pays Bas), mais seule la salle B était équipée de la technologie de réduction de dose ClarityIQ. Le critère de jugement était la dose de rayonnements reçue par l'opérateur, mesurée par un dosimètre électronique supplémentaire positionné au niveau du bras gauche de l'opérateur, à l'extérieur de tout équipement de protection individuel. Au total, 577 procédures de cardiologie interventionnelles coronaires étaient analysées. Lorsqu'ils travaillaient dans la salle B, les opérateurs recevaient en moyenne une dose inférieure de 71% par rapport à celle reçue lorsqu'ils travaillaient dans la salle A ($p < 0.001$) (**Figure 4**). La réduction restait significative en analyse multivariée ajustée sur le temps de rayons X, l'IMC, l'approche artérielle et la réalisation d'au moins une angioplastie coronaire. Ce travail avait fait l'objet d'une publication dans *JACC Cardiovascular Interventions* (27).

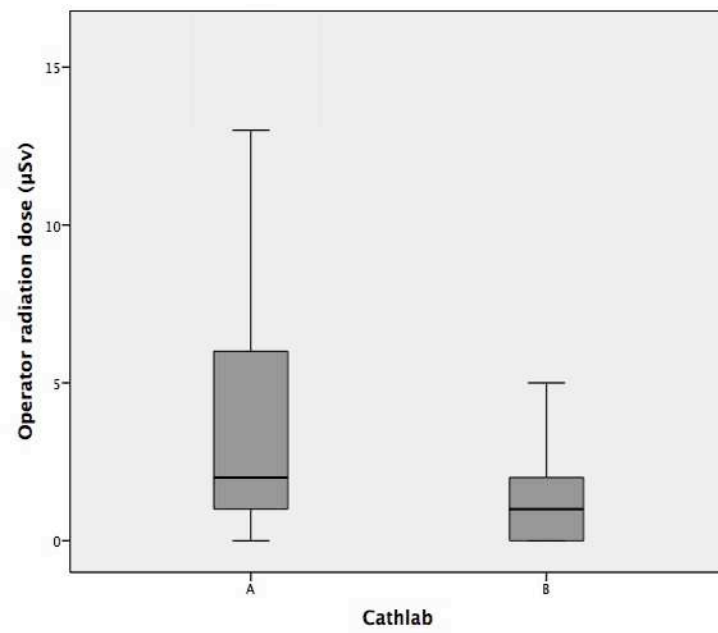


Figure 3 : Comparaison de l'exposition aux rayonnements des opérateurs entre la salle A (sans ClarityIQ) et la salle B (avec ClarityIQ)

3. Impact de la hauteur de table sur l'exposition aux rayonnements ionisants

a. Principaux déterminants de la dose de rayonnements

Les procédures d'angioplastie de *lésions coronaires complexes*, qui sont généralement longues avec un temps de rayons X important, sont associées à une exposition aux rayonnements ionisants plus importante. De même, l'*IMC* est étroitement lié à la dose de rayonnements reçue (28). Cela provient du fait que les systèmes de rayons X ajustent automatiquement la tension appliquée au tube (qui est directement liée au débit de photons et à la dose de rayons X) afin de maintenir une qualité d'image aussi constante possible. Les patients obèses, de par leur épaisseur importante, atténuent de façon plus importante les rayons X. Le système augmente alors le débit de photons afin de maintenir une qualité d'image satisfaisante. Plourde et al. (29) ont rapporté en 2015 une méta-analyse incluant des études comparant les *voies radiale et fémorale*, menées de 1996 à 2014. Les auteurs retrouvaient une augmentation faible mais significative du PDS au cours des procédures réalisées par voie radiale. Ces résultats sont toutefois à prendre avec prudence car cette méta-analyse regroupait des études publiées sur un intervalle de 18 ans, période au cours de laquelle l'utilisation de la voie radiale s'est développée puis généralisée. De plus, il est probable que le bénéfice en termes de morbi-mortalité apporté par l'utilisation de la voie radiale compense cette surexposition aux rayonnements (30). Enfin, la dose de rayonnements reçue est inversement corrélée à l'*expérience de l'opérateur* (28).

La *scopie* permet d'obtenir une imagerie en temps réel lorsqu'il n'est pas nécessaire de l'enregistrer. La diminution de la dose de rayonnements utilisée pour générer une image s'accompagne d'une diminution de la qualité de l'image et d'une augmentation du bruit. La *scopie* doit correspondre à la plus petite dose permettant de produire une image utilisable. La *graphie* génère des images d'une résolution supérieure permettant une interprétation diagnostique et un archivage. Elle fait appel à une dose de rayonnements supérieure, ce qui permet d'améliorer la qualité de l'image et de diminuer le bruit. La différence entre *scopie* et *graphie* réside dans la tension (kV) et le signal (mA) appliqué au tube, selon les réglages du constructeur. La génération d'une image en *graphie* fait appel à une dose de 10 à 15 fois supérieure à celle utilisée pour générer une image en *scopie* (12, 20). Les cardiologues interventionnels ont la possibilité de choisir la cadence image, exprimée en frame per seconde (FPS), de 7,5 à 50 FPS. Sur les systèmes de rayons X modernes, une cadence image de 7,5 FPS est suffisante aussi bien en *scopie* qu'en *graphie*, à l'exception probablement des incidences

caudales chez les patients obèses. Plus la cadence image augmente, plus la résolution temporelle augmente, et plus la dose de rayonnements reçue par le patient et l'opérateur augmente.

La *taille du champ* est déterminée par la taille physique du détecteur. L'utilisation d'un champ de plus petite taille permet d'agrandir l'image et d'améliorer la résolution spatiale, au prix d'une augmentation de la dose absorbée. La *collimation* du faisceau primaire, effectuée par des lamelles plombées motorisées, permet d'adapter la taille du faisceau primaire à la zone d'intérêt. La collimation permet donc de réduire la surface exposée et d'améliorer la qualité de l'image en augmentant le contraste visuel (réduction du niveau de bruit) tout en diminuant la dose absorbée. Les *filtres de contours* sont des lamelles atténuatrices placées à la sortie du tube de rayons X dont l'épaisseur diminue vers le centre de l'image. Ils provoquent une réduction partielle du faisceau primaire, et sont mobilisés en temps réel par l'opérateur. Ils permettent à la fois de diminuer la dose de rayonnements reçue par les patients, et d'améliorer le contraste par la réduction de l'intensité du rayonnement diffusé. Kuon et al. (31) ont démontré que les *incidences cranio-caudales* étaient responsables d'une augmentation de la dose de rayonnements reçue par le patient par rapport à l'incidence antéro-postérieure. De même, les incidences obliques, et en particulier les incidences obliques antérieures gauches occasionnent une augmentation de la dose de rayonnements reçue par le patient, en rapport avec l'atténuation importante des rayons X occasionnée le rachis (**Tableau 1**).

Tableau 1 : Principaux déterminants de la dose de rayonnements reçue par les patients et les cardiologues

Déterminants de la dose de rayonnements	Techniques pour diminuer la dose
	Utiliser toutes les techniques possibles au cours des :
Déterminants cliniques	- Procédures chez un patient obèse - CTO-PCI - Cathétérisations du sinus coronaire
Taille de champ	Limiter l'utilisation de petits champs
Mode de rayonnements	Préférer le mode scopie au mode graphie autant que possible
Cadence image	Choisir une cadence image de 7.5 fps aussi bien en scopie qu'en graphie
Angulation du faisceau	Limiter les incidences cranio-caudales et obliques autant que possible
Collimation	Collimater l'image dès que possible
Filtres de contour	Toujours utiliser les filtres de contour
Hauteur de table	Positionner la table du patient aussi haut que possible
Équipements de protection	Toujours utiliser les équipements de protection individuelle et collective

CTO-PCI: angioplastie percutanée d'une occlusion coronaire chronique; fps: frame-per-second

b. Rôle de la hauteur de table du patient

L'impact de la *hauteur de la table* du patient sur l'exposition des opérateurs aux rayonnements ionisants a été étudié, et ce travail a fait l'objet d'une publication dans *Radiation Protection Dosimetry* (32).

RÉSUMÉ

De par la relation quadratique inverse entre la dose et la distance par rapport à la source, il est conseillé de rapprocher le patient du capteur pour l'éloigner au maximum de la source (33). En parallèle, afin d'améliorer la qualité de l'image en sélectionnant les photons par la grille anti-diffusante (diminution du bruit), il est recommandé de fixer la distance foyer-image (DFI) à 1000 mm en Europe et à 1100 mm aux USA. Lorsque la table du patient est positionnée le plus haut possible (donc le plus loin possible de la source), la distance foyer-image (DFI) ne peut être à 1000 mm que sur les incidences de face et lorsque le patient est peu corpulent. En laissant la table en position haute, la DFI augmente lorsque l'épaisseur du patient augmente, ainsi que pour les incidences crânielles, caudales et obliques. La diminution de l'exposition aux rayonnements par un positionnement au plus haut de la table du patient n'est donc pas compatible avec le réglage de la DFI à 1000 mm.

Nous avons donc souhaité étudier l'impact de la hauteur de la table du patient sur le niveau de radiations reçue par les cardiologues interventionnels. La population d'analyse incluait toutes les procédures de cardiologie interventionnelle coronaire réalisées dans notre centre de mars à juin 2017. Les coronarographies diagnostiques et les procédures avec angioplastie coronaire étaient incluses. Afin d'harmoniser la population d'étude, les procédures réalisées en urgence et celles réalisées par 2 opérateurs étaient exclues. Un total de 4 cardiologues interventionnels étaient en activité dans notre institution pendant la période d'étude. Les mesures de protection habituelles telles que s'éloigner au maximum de la source de rayonnements et diminuer la taille du champ étaient systématiquement appliquées. Les opérateurs plaçaient la table du patient à la hauteur de leur choix et minimisaient systématiquement la DFI pour être le plus proche possible de 1000 mm.

La hauteur de la table du patient correspondait à la distance entre le sol et la table, et pouvait être réglée par les opérateurs entre 890 mm et 1160 mm. La hauteur de table moyenne était calculée pour chaque procédure en sommant la hauteur de table pendant chaque séquence de scopie et de graphie, et en divisant par le nombre total de séquences. La DFI pouvait être réglée par les opérateurs entre 870 mm et 1210 mm. La DFI moyenne était calculée de la même façon que la hauteur de table moyenne. Le critère de jugement principal était la dose de rayonnements reçue par l'opérateur, évaluée par un dosimètre électronique positionné au niveau du bras gauche de l'opérateur, à l'extérieur de tout dispositif de protection individuelle. Une analyse additionnelle de l'impact de la hauteur de la table a été effectuée « in-vitro » à l'aide d'un fantôme anthropomorphique, et en faisant varier graduellement la hauteur de table.

Au total, 225 procédures de cardiologie interventionnelle coronaire ont été incluses pour analyse. Lorsque la hauteur moyenne de la table était supérieure ou égale à 1126 mm (médiane), les opérateurs recevaient une dose de rayonnement en moyenne 53% inférieure à celle reçue lorsque la hauteur moyenne de la table était inférieure à 1126 mm ($p < 0.001$). Par ailleurs, la hauteur de table était significativement liée à la taille de l'opérateur. Une analyse multivariée a été effectuée, et l'exposition des opérateurs aux rayonnements ionisants restait significativement liée à la hauteur de table du patient ($p < 0.001$), indépendamment de l'opérateur, de l'approche artérielle et du temps de fluoroscopie. Les résultats de l'étude « in-vitro » retrouvaient une diminution progressive de l'intensité appliquée au tube, et par conséquent du débit de dose à la sortie du fantôme, à mesure que la hauteur de table augmentait (sans modification de la tension appliquée au tube).

Nos résultats démontrent donc qu'augmenter la hauteur de table du patient permet de diminuer significativement l'exposition des opérateurs aux rayonnements, indépendamment de l'opérateur (et donc de sa taille). Toutefois, la hauteur de table était fortement corrélée à la taille de l'opérateur, et il est possible que seuls les plus grands opérateurs puissent systématiquement placer la table en position haute. Enfin, placer la table en position haute n'est pas compatible avec une DFI de 1000 mm, et le choix de la position de la table apparaît donc être un compromis entre radioprotection de l'opérateur et optimisation de l'acquisition de l'image.

Publication 1 :

“Impact of the table height and the operator’s height on the level of radiation delivered to interventional cardiologists”

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IMPACT OF THE TABLE HEIGHT AND THE OPERATOR'S HEIGHT ON THE LEVEL OF RADIATION DELIVERED TO INTERVENTIONAL CARDIOLOGISTS

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Interventional cardiologists count among the health professionals that are most exposed to ionising radiation. To minimise exposure, it is recommended that the patient be placed at the maximum distance possible from the X-ray source, but this recommendation has not been clinically validated. We aimed to investigate the impact of the average table height on the level of radiation delivered to cardiologists performing coronary interventions. The population for analysis included all invasive coronary procedures performed in our centre from March to June 2017. The primary endpoint was operator radiation exposure, as assessed using personal electronic dosimeters located on the operator's left arm. In total, 225 invasive coronary procedures were analysed. When the average table height was 1126 mm or more, the operators received a radiation dose that was, on average, 53% lower than when the table was lower than 1126 mm. This reduction remained significant by multivariate analysis adjusted for the operator.

INTRODUCTION

Interventional cardiologists count among the health professionals that are most exposed to ionising radiation in the course of their work^(1, 2). Recent publications have reported that exposure to radiation is associated with an increased incidence of radiation-induced cataract (deterministic effects)^(3–6). In addition, controversy remains about an increased risk of brain tumours and a trend towards more frequent left-hemisphere localisation (stochastic effect) in this population^(6–10).

In addition to individual (lead apron and thyroid shield) and group protective (lead screen and table drape) measures, there are numerous factors amenable to the operator's control, which contribute to determining the patient's exposure to radiation^(11–14). Since the primary source of exposure to ionising radiation for the operator is the scatter of radiation from the patient^(15, 16), then it follows that modifying the patient's position may reduce the operator's exposure to radiation. The arterial access, the size of the image field, image acquisition speed, beam angle, collimation and the use of contour filters are all factors known to affect the patient's exposure to radiation, and thus, are also likely to affect the operator's exposure during invasive procedures^(11, 15, 16).

Similarly, given the inverse square relationship between the dose received by the patient and the distance from the X-ray tube, it is currently recommended that the patient be placed as near as possible to the flat panel detector which at the same time

maximises to distance away from the X-ray tube^(8, 16). In parallel, in order to improve image quality by selecting photons using a 'scatter-reducing grid' (noise reduction), it is recommended that the source-to-image receptor distance (SID) be positioned at 1000 mm in Europe, while in the USA, the recommended distance is 1100 mm^(8, 16). However, to the best of our knowledge, there are no clinical data (in vivo) validating these radio-physics recommendations for reducing operator exposure.

The aim of this study was therefore to study the impact of average table height on the exposure of operators to ionising radiation during invasive coronary procedures.

MATERIAL AND METHODS

Study design

This was a prospective, analytical, single-centre cohort study carried out in a large university hospital in France. The population for analysis included all invasive coronary procedures performed in a single catheterisation laboratory (cathlab) of our centre from March to June 2017. Both diagnostic and therapeutic procedures were considered. In order to harmonise the study population, we decided to exclude procedures performed in an emergency, those performed by two operators and emergent procedures of interventional cardiology (transcatheter aortic valve replacement, left atrial appendage closure...).

Four experienced interventional cardiologists (practicing for 25, 18, 10 and 3 years) are permanent practitioners at our institution. The cathlab used in the study was equipped with the AlluraXper FD10 system (Philips Healthcare, The Netherlands) using R7.2.9 Philips software, in service since January 2011, equipped with flat panel detectors (frame rate of 7.5 fps for coronary angiography and 15 fps for ventricular angiography, 20×20 cm size of field, 1024×1024 matrix). The equipment undergoes half-yearly control by the manufacturer, and annual external quality control. The delivered dose and the quality of the image are checked. Tubes are replaced if their performance is less than 90% of the standard. The cathlab is equipped with lead screens and table drapes with 0.5 mm Pb equivalent, positioned respectively above and below the table. All operators wear a leaded apron and a thyroid shield with 0.5 mm Pb equivalent. They also have a passive dosimeter with quarterly statements (Landauer, Glenwood, IL, USA) and an active dosimeter (APVL, Saint-Cyr-sur-Loire, France). Standard protective measures, such as keeping a maximum distance between the patient's thorax (X-ray source) and the operator and minimisation of the field of view, were equally applied in all cases. Diagnostic coronary angiography included five incidences for the left coronary and three incidences for the right coronary for all operators. They all used five French catheters for diagnostic angiographies and five or six French catheters for angioplasties regardless of the arterial access. Contrast medium was injected using the ACIST system (ACIST Europe B.V., Heerlen, The Netherlands). Operators positioned the patient table as high as comfortable, and systematically minimised the SID for a given table height so that the SID was as close as possible to 1000 mm. A radiology technician and a nurse were present in the cathlab for all procedures.

Endpoints

The primary endpoint was operator radiation exposure, as assessed using personal electronic dosimeters EPD Mk2 (APVL, Saint-Cyr-sur-Loire, France) following IEC 61 526:2010 standards, with a silicon diode (μSv) located on the operator's left arm (Figure 1) in a standardised position, in order to optimise angular response with the ideal position placing the dosimeter at an angle of 0° in relation to the radiation source, namely, the patient's body in this instance⁽¹⁷⁾. Dosimeters undergo an annual calibration and functional state check by our radioprotection cell. The dosimeter has an energy response between 15 keV and 1.5 MeV (that means that it can measure beams of photons that have been created by electrons set in motion with a potential difference of 15 kV to 1.5 MV) and a dose range displayed from 0 to 9 999 mSv in increments of 0.1 μSv with a 20%



Figure 1. Assessment of operator radiation exposure using a personal electronic dosimeter positioned on the left arm.

uncertainty. Radiation doses were recorded at the end of each procedure.

The height of the patient table (measured from to table top), the source-to-image receptor distance (SID), the fluoroscopy and acquisition time, the patient's body mass index (BMI), the arterial approach used, the performance of angioplasty on at least one lesion, as well as the age and sex of the patient were obtained using the Dose Archiving and Communication System (DACS) Radiation Dose Monitor (Medsquare, Paris, France). The table height corresponded to the distance from the floor to the table, and could be adjusted by the operator to be between 890 mm and 1160 mm. The average table height was calculated for each procedure by summing the table height during each fluoroscopy and angiography sequence of the procedure, and then dividing by the total number of sequences. The SID could be adjusted by the operator to be between 870 mm and 1210 mm. The average SID was calculated identically to the average table height.

The radiation dose received by the patient was estimated by recording Air Kerma (AK) at the interventional reference point (defined as an imaginary point located 15 cm from the isocenter toward the source) and the Dose Area Product (DAP). However, these parameters were not investigated as secondary

endpoints as they are calculated on the basis of the ionisation chamber at the tube's exit, and thus, do not take account of the table height⁽¹¹⁾.

Additional in-vitro measurements were performed with a 12 cm thick by 30 × 30 cm poly(methyl-methacrylate) (PMMA) phantom, in a cathlab equipped with the AlluraXper FD10 Clarity system (Philips Healthcare, The Netherlands) using Philips R8.2.1.17 software, in service since March 2015, equipped with flat panel detectors (frame rate of 7.5 fps, 20 cm size of field, 1024 × 1024 matrix), with repeated 10 second cine acquisitions and source-to-image receptor distance of 1000 mm. We varied the table height from 920 mm to 1160 mm in increments of 40 mm. Voltage (kV) and intensity (mA) was obtained directly on the X-ray system. Dose rate (nGy/frame) on the top of the phantom was measured by an Unfors detector (RaySafe, Sweden) (Figure 2). The detector has a dose range displayed from 10 nGy to nine 999 Gy in increments of 0.01 nGy.

Statistical analysis

Quantitative variables are described as mean ± standard deviation and qualitative variables as number (percentage). Quantitative variables were compared using the Student *t* test or non-parametric Mann-Whitney test according to variable distribution (normality was assessed by the Kolmogorov-Smirnov test), or the Kruskal-Wallis test for more than two means. Qualitative



Figure 2. Assessment of dose rate at the exit of the PMMA phantom, using a dose detector.

variables were compared using Fisher's exact or the chi-square test as appropriate. Relations between quantitative variables were investigated using simple linear regression. The average height of the patient table was transformed into a binary categorical variable using the median of the average height of the table as the cut-off. Multivariate analysis was performed using generalised linear regression including all variables related to the primary endpoint with a *p*-value <0.20 by univariate analysis. The multivariate model was adjusted for the operator, and the inclusion of the average SID was forced. In view of the risk of collinearity between the table height effect and the estimated dose of radiation received by the patient, AK and DAP were not included in the multivariate model. Analyses were performed using SPSS version 21 (IBM SPSS Statistics). A *p*-value <0.05 was considered statistically significant; all tests were two-sided.

RESULTS AND DISCUSSION

Baseline patients characteristics and primary endpoint

During the study period, 225 invasive cardiology procedures were performed in the cathlab. The average table height during the procedure was 1118.3 ± 39.2 mm, with a median of 1126.7 mm. The main characteristics of the procedures according to table height are described in Table 1. When the average table height was greater than or equal to 1126 mm (cut-off point, corresponding to the median), the operator were exposed to a dose of radiation that was, on average, 53% lower than when the average table height was lower than the cut-off (*p* < 0.001) (Figure 3). The table height was significantly associated with the operator, with an average table height of 1079.3 ± 30.1 mm for operator 1 who measured 178 cm; 1122.9 ± 25 mm for operator 2, who measured 185 cm; 1151.2 ± 18.7 mm for operator 3 who measured 190 cm; and 1087.4 ± 39.2 for operator 4, who measured 171 cm (*p* < 0.001). Overall, 95% of all procedures with an average table height of 1126 mm or more were performed by operators 2 and 3, who measured 185 and 190 cm respectively.

In addition to being related to table height (*P* = 0.015), the dose of radiation received by the operator was also significantly associated by univariate analysis with the performance of at least one coronary angioplasty (*p* < 0.001), the arterial access (6.2 ± 17 μSv for the radial approach vs 17.5 ± 24.3 μSv for the femoral approach, *P* = 0.015), total fluoroscopy time (*p* < 0.001), and the operator (*p* < 0.001). Operator exposure was not related to the patient's sex (*P* = 0.98), the patient's BMI (*P* = 0.73), the patient's age (*P* = 0.33) or the average SID (*P* = 0.61) (these values are not shown in a table).

Table 1. Comparison of the characteristics of invasive coronary procedures according to the height of the patient table.

	Average table height < 1126 mm (n = 111)	Average table height ≥ 1126 mm (n = 114)	P-value
Patient age (years)	65.7 ± 12.9	66.7 ± 12.1	0.56
Patient sex (men/women)	78 (70%)/33 (30%)	72 (63%)/42 (37%)	0.32
Patient body mass index (kg/m ²)	27.9 ± 4.5	27 ± 4.5	0.15
Arterial access			0.85
Radial	94 (85%)	98 (86%)	
Femoral	17 (15%)	16 (14%)	
Angioplasty of at least one lesion	65 (59%)	57 (50%)	0.23
Total X-ray time (minutes)	8 ± 6.4	9.4 ± 7.4	0.14
Operator dose HP10 (μSv)	10.9 ± 23.2	5.1 ± 12	< 0.001
Air Kerma (mGy)	387.8 ± 307.6	401.7 ± 309.4	0.69
Dose Product Area (cGy.cm2)	2957.8 ± 2337.5	2955.2 ± 2414.2	0.71
Average source-to-image receptor distance (mm)	1097.8 ± 50.2	1160 ± 29.9	< 0.001
Operator (height)			< 0.001
Op 1 (178 cm)	46 (41%)	2 (2%)	
Op 2 (185 cm)	23 (21%)	33 (29%)	
Op 3 (190 cm)	8 (7%)	76 (66%)	
Op 4 (171 cm)	34 (31%)	3 (3%)	

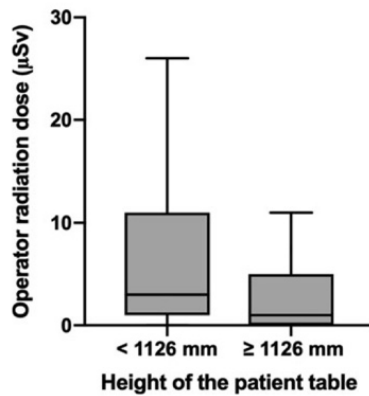


Figure 3. Box and whisker plots showing the distribution of operator radiation dose according to the height of the patient table. The boxes represent the median with the first and third quartiles, and the 'whiskers' represent the upper and lower limits excluding extreme values.

Multivariate analysis

By multivariate analysis adjusted for the operator (Table 2), the dose of radiation received by the operator was found to be significantly associated with the average table height ($P < 0.001$), the arterial approach ($P = 0.031$), the total X-ray time ($P < 0.001$), but not the performance of angioplasty on at least one lesion ($P = 0.53$) or the average SID ($P = 0.86$).

In-vitro measurements

In-vitro measurements showed a steady decrease of the current intensity (mA) applied to the tube and a decrease of the dose rate on the top of the phantom, when the table height increased, without modification of the voltage applied to the tube (Figure 4).

The position of the table at a height of 1126 mm or more makes it possible to reduce the operator's radiation exposure by 53% during invasive cardiology procedures, and in our study, this reduction was independent of the operator, the SID, the X-ray time, the arterial approach and the performance of angioplasty. This could be explained by the inverse square relationship between the dose of radiation received by the patient and the distance from the X-ray tube^(8, 16), given that the primary source of operator exposure is actually the radiation being scattered from the patient^(15, 16). In addition, our results are consistent with our in-vitro datas that showed a steady decrease of the intensity applied to the tube and therefore of the dose rate on the top of the phantom when the table height increases. The decrease in the tube current could be attributed to the increase in the amount of scattered radiation reaching the flat panel detector at higher table positions, thus decreasing the necessary mA to produce a constant dose rate at the input of the flat panel detector. The decrease to the dose rate on the top of the phantom when the table height increases, primarily due to the increase of the distance of the top of the phantom from the X-ray focus (law of the inverse square relationship with the distance) and secondary

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Table 2. Multivariate analysis of the factors associated with the radiation dose received by the operator (HP10), adjusted for the operator.

	Beta coefficient	Standard error	P-value
Average table height ≥ 1126 mm (vs <1126 mm)	-13.3	3	<0.001
Total X-ray time (per additional minute)	1.3	0.16	<0.001
Average source-to-image receptor distance (per additional mm)	0.005	0.027	0.86
Angioplasty performed on at least one lesion (vs no angioplasty)	-1.3	2.2	0.53
Radial approach (vs femoral)	-6.1	2.8	0.031

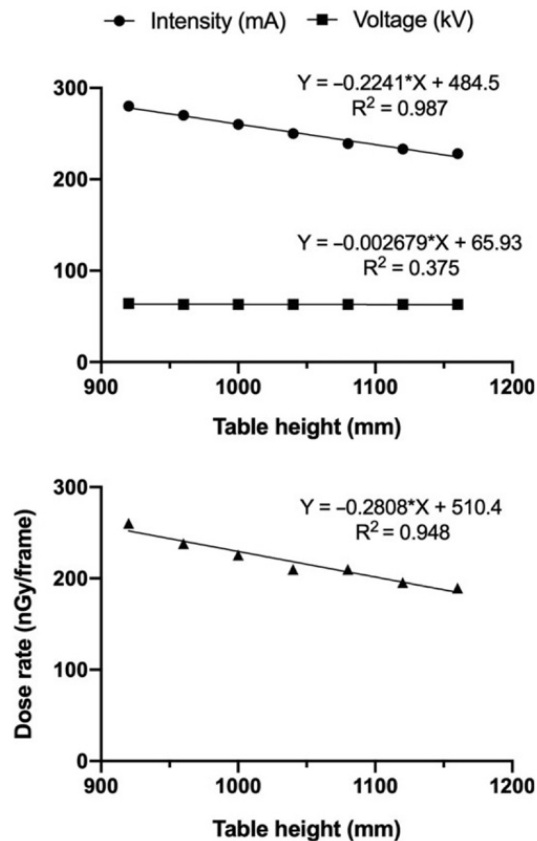


Figure 4. Measurements made with a 12 cm thick poly (methyl-methacrylate) (PMMA) phantom, with a field of 20 cm, cine acquisition and focus-image distance of 1000 mm. Table height is represented on the abscissa, voltage (kV), intensity (mA) and dose rate (nGy/frame) on the ordinate.

to the above-mentioned decrease in tube current. In contrast, average AK and DAP did not significantly differ between the two groups, which was expected because these parameters do not take account of the table height⁽¹¹⁾. The difference in dose received by patients in link with table height can be demonstrated

using a dosimeter positioned on the patient (i.e. dose measurement)^(11, 18).

Radiophysics recommendations in Europe advocate a source-to-detector distance of 1000 mm in order to improve image contrast by limiting noise using an anti-scatter grid^(8, 16). On the equipment in our cathlab (namely, the Allura Xper FD10 system, Philips Healthcare, The Netherlands), when the table is at 1160 mm (the highest possible position), the SID can only be 1000 mm on frontal projections, and when the patient is not obese. The SID increases as the patient's corpulence increases, as well as during cranial, caudal and oblique projections. The reduction of operator exposure to radiation by placing the table at a high position is thus incompatible with an SID of 1000 mm. However, SID was not related to the operator exposure in our study, and we did not observe here any perceptible change in the quality of the images when the table was in a high position. In addition, recorded SIDs represent best practice by placing the flat panel detector as close to the patient as possible.

The average height of the table during the procedure varied widely between operators in our study, and this is likely explained by the difference in height between operators. Indeed, the tallest operators most frequently placed the table higher than smaller operators (95% of the procedures with an average table height above the cut-off of 1126 mm were performed by operators 2 and 3, who were respectively 185 and 190 cm tall). The impact of the average table height on the radiation dose received by the operator remained significant after adjustment for the operator, meaning that placing the table in a higher position reduces the operator's exposure, regardless of the operator's height. However, even if it is likely that tall operators will have greater ease in placing patient's table in a high position, this should obviously not be allowed to compromise the performance of the coronary angioplasty or put its outcome in jeopardy.

Our findings could appear contradicting with d'Othée *et al.*⁽¹⁸⁾, who considered a virtual operator 178 cm tall whatever the table height and showed that when table height decreases, operator dose

decreases but patient dose increases. Conversely, in our study with four different operators from different heights, we showed that when table height decreased, operator (in-vivo results) and patients (in-vitro results) exposure increased. The explanation provides from the fact that, contrary to d'Othée *et al.*⁽¹⁸⁾, we think that it is likely that in real-life distance between patient and operators left arm only slightly vary, operators keeping the table as high as comfortable, and table height being significantly associated with the operator (so with the operator height) in our study. In addition, our results are in line with Sciahbasi *et al.* who described an inverse relationship between operators height and their thorax radiation dose⁽¹⁹⁾.

Limitations

Our study is limited by its single-centre and observational design, and by the relatively small number of cases and operators. Nevertheless, results of the in-vitro measurements provide an additional experimental argument for a causal relationship between table height and radiation exposure.

The electronic dosimeters EPD Mk2 has a relatively long integration time, so it is not optimal for the measurement of pulsed fluoroscopy. In addition, there is an 20% uncertainty on dose measurement, and the angulation between the patient's thorax and the dosimeter may have changed during procedure, that can affect the measure (due to angular response of the dosimeter). However, we chose this dosimeter because it is the reference device for hospitals, industry, research laboratories and civil security in France.

Distance between operator's dosimeter and patient has not been recorded. Nevertheless, as operators kept the table as high as comfortable, it is likely that this distance has only slightly varied. We do not have any information regarding the radiation dose to the lower half of the operator's body, and exposure of the lower extremities, including the feet, will also require increased attention⁽²⁰⁾.

Finally, the fact that two of the operators performed the majority of the procedures having table height above 1126 mm could represent a limitation. However, the impact of this imbalance is limited by the adjustment of the multivariate analysis for the operator.

CONCLUSION

Our study suggests that increasing table height results in a significant reduction in operator's radiation exposure, with a 53% reduction during coronary invasive procedures when table height was 1126 mm or higher, regardless of the operator or the operator's height.

The height of the operator was strongly related to the position of the table during the procedure, with the tallest operators (respectively 185 and 190 cm) routinely placing the table in a higher position (above 1126 mm) than the operators who were less tall (171 and 178 cm).

Finally, although we found no relation between operator exposure and the SID, optimising image acquisition with the use of a scatter-reduction grid is not compatible with a high table position. The choice of table height during invasive coronary procedures remains a compromise between protection of the operator against ionising radiation and optimal image acquisition.

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Partie II : Rythmologie et électrophysiologie

Dans ce deuxième chapitre, nous étudierons l'exposition des patients et des médecins aux rayonnements ionisants au cours des procédures de rythmologie et d'électrophysiologie. L'impact de la resynchronisation ventriculaire sur l'exposition aux rayonnements ionisants des patients et des opérateurs sera étudié. De même, le niveau d'exposition des patients et des opérateurs au cours des procédures d'électrophysiologie sera mesuré. Enfin, la dose globale de rayonnements que reçoivent les patients bénéficiant d'une ablation de fibrillation atriale par radiofréquence ainsi que l'impact de l'obésité sur cette dose globale seront étudiés.

1. Impact de la resynchronisation ventriculaire sur l'exposition aux rayonnements

L'exposition aux rayonnements au cours des procédures d'implantation de stimulateur cardiaque et défibrillateurs automatiques implantables a été étudiée, et ce travail a fait l'objet d'une publication dans le *Journal of Radiological Protection* (35).

RÉSUMÉ

La resynchronisation ventriculaire est une des modalités thérapeutiques de l'insuffisance cardiaque avec dysfonction systolique du ventricule gauche (34). Elle repose sur l'implantation d'un stimulateur cardiaque bi-ventriculaire. Outre la sonde de stimulation positionnée dans le ventricule droit nécessaire pour tous les stimulateurs cardiaques (PM) et défibrillateurs implantables (DAI), une sonde de stimulation supplémentaire est placée dans le sinus veineux coronaire afin de pouvoir électro-entraîner le ventricule gauche. La mise en place de cette sonde supplémentaire peut être difficile et par conséquent augmenter le temps de rayons X par rapport aux implantations de PM et de DAI classiques (sans mise en place d'une sonde de stimulation dans le sinus coronaire). Cependant, le niveau de surexposition des patients et des praticiens associé à la resynchronisation ventriculaire (par rapport aux procédures sans resynchronisation) n'était pas connu. Nous avons donc souhaité mesurer et comparer la dose de rayonnements reçue par les patients et les opérateurs au cours des implantations de PM et de DAI avec ou sans resynchronisation ventriculaire.

La population d'étude se composait de toutes les implantations de PM et de DAI effectuées dans notre centre sur une période de 6 mois. Les procédures électives comme celles réalisées en urgence étaient incluses. Les patients ayant bénéficié de l'implantation d'un DAI sous-cutané ou d'un système de stimulation cardiaque transcathéter n'ont pas été inclus dans l'étude en raison du faible nombre de patients. Les critères de jugement étaient la dose de rayonnement reçue par l'opérateur, mesurée à l'aide d'un dosimètre électronique supplémentaire positionné sur le torse de l'opérateur, à l'extérieur de tout dispositif de protection individuel, et la dose de rayonnements reçue par le patient, estimée par le PDS.

Au total, 169 procédures ont été analysées (PM : 133 ; DAI : 36), dont 19 avec resynchronisation ventriculaire (PM : 10 ; DAI : 9). En comparaison des procédures « classiques » sans resynchronisation, les expositions des cardiologues et des patients étaient respectivement 9 fois et 14 fois supérieures au cours des procédures avec resynchronisation ventriculaire. La médiane du temps de fluoroscopie était de 28,6 minutes au cours des procédures avec resynchronisation cardiaque, contre 4,2 minutes durant les procédures sans resynchronisation. Il existait une forte corrélation entre l'exposition des opérateurs et celle des patients ($R^2 = 0,21$ au cours des procédures classiques, $R^2 = 0,57$ au cours des procédures de resynchronisation).

L'exposition des cardiologues au cours des procédures impliquant une resynchronisation cardiaque est donc particulièrement élevée, et il devient donc urgent de développer des mesures permettant d'améliorer la protection des opérateurs au cours de ce type de procédure.

Publication 2 :

“Impact of cardiac resynchronization therapy on cardiologists’ exposure to radiation during implantation of pacemakers and implantable cardioverter-defibrillators”

Charline Daval, Laurent Faroux, François Lesaffre, Thierry Blanpain, Jean-Pierre Chabert, Angeline Martin, Mathias Guinot, Nicolas Luconi, Madeline Espinosa, Pierre Nazeyrollas, Christophe Tourneux, Damien Metz

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Impact of cardiac resynchronisation therapy on cardiologists' exposure to radiation during implantation of pacemakers and implantable cardioverter-defibrillators

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Abstract

Cardiologists are among the health professionals that are most exposed to ionizing radiation, but there is no recent study quantifying overexposure of physicians during cardiac resynchronisation therapy (CRT) procedures compared to 'classical' implantation of pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs). We aimed to measure and compare operator exposure to radiation during implantation of PM and ICD with or without CRT. The study population comprised all PMs and ICDs implanted in a large referral centre over a six months period. The endpoint was operator radiation exposure, assessed using a personal electronic dosimeter located on operator's chest. In total, 169 PM/ICD implantations were analysed, 19 of which included CRT. Compared with 'classical' implantation, cardiologist radiation exposure was 9-fold greater during CRT procedures ($p < 0.001$). Physician exposure was related to dose-area product ($R^2 = 0.21$ during 'classical' implantations and $R^2 = 0.57$ during CRT procedures). Our study shows that cardiologists' exposure to radiation during CRT implantation was 9-fold greater than during procedures without CRT.

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Keywords: pacemaker, implantable cardioverter-defibrillator, cardiac resynchronisation, operator dosimetry

Introduction

Cardiology is one of the medical specialties that most exposes patients, physicians and nurses to ionizing radiation [1]. Biological effects of ionizing radiation can be stochastic or deterministic, respectively, carcinogenic or responsible for immediate tissue damage, such as burns. Several studies have shown that cardiologists have an increased risk of left-sided brain tumours, breast tumours or radiation-induced cataracts [2–6].

Cardiac resynchronisation therapy (CRT) is a proven adjuvant therapy option for patients with severe and drug refractory heart failure since it has been found to result in considerable symptomatic improvement and increased survival rates in this population [7]. However, the procedure is often technically challenging and may result in higher radiation exposure. Indeed, patient exposure to x-rays during implantation of a pacemaker (PM) or implantable cardioverter-defibrillator (ICD) has been studied in the past, with the detection of high doses during cardiac resynchronisation therapy (CRT) [8–11], but to the best of our knowledge there is no recent study quantifying the excess exposure of physicians during CRT procedures compared to ‘classical’ PM or ICD implantations.

The aim of our study was thus to measure and compare operator exposure to radiation during implantation of PM and ICDs, with versus without CRT.

Material and methods

Study population

This was a prospective, analytical, epidemiological, single-centre cohort study carried out in a large university hospital in France. The population for analysis included all endovascular PM and ICD implantations in a pectoral site with or without CRT performed in our centre from November 2017 to May 2018. PMs were implanted on a scheduled or emergency basis as indicated. ICD implantations were performed for primary or secondary prevention of ventricular arrhythmias in accordance with current recommendations [7]. Patients undergoing implantation of a subcutaneous ICD or a transcatheter pacing system (Micra[®], Medtronic, Minneapolis, USA) were excluded due to the small number of patients.

Procedures and electrophysiology laboratory

Procedures were performed in the electrophysiology laboratory under local anaesthesia. Devices included one or two leads in case of PM or ICD without CRT, and two or three leads (including a lead positioned in the coronary sinus for an epicardial endovascular stimulation of the left ventricle) in case of CRT. Devices were implanted on the right or left side, and via a cephalic and/or subclavian vein. The choice of the implanted device was left at the operator’s discretion, with a choice among devices from the following companies: Boston Scientific (Natick, USA), St Jude Medical Inc. (St Paul, USA), Biotronik (Berlin, Germany), Medtronic (Fridley, USA) or Sorin (Milan, Italie).

Three cardiologists with more than 8 years’ experience in electrophysiology and who were permanent practitioners during the study period, performed the procedures. They



Figure 1. Illustration of the personal electronic dosimeter located on operator's chest used to measure operator radiation exposure.

worked in a single electrophysiology laboratory, equipped with the Arcadis Avantic system (Siemens Healthcare, Erlangen, Germany), in service since January 2011, with image intensifier with a frame rate of 4 fps, 33 cm size of field. Only the fluoroscopy mode was used. The equipment undergoes half-yearly control by the manufacturer, and annual external quality control. The electrophysiology laboratory is equipped with table drapes with 0.5 mm Pb equivalent. All operators wear a leaded apron and a thyroid shield with 0.5 mm Pb equivalent. They also have a passive dosimeter with quarterly statements (Landauer, Glenwood, USA) and an active dosimeter (APVL, Saint-Cyr-sur-Loire, France). A nurse was present for all procedures.

Primary endpoint

The primary endpoint was cardiologist radiation exposure, as assessed using personal electronic dosimeters (APVL, Saint-Cyr-sur-Loire, France) with a silicon diode (μSv) located on the operator's chest outside of the apron (figure 1) in order to optimise angular response, with the ideal position placing the dosimeter at an angle of 0° in relation to the radiation source, namely, the patient's body in this instance [12]. The dosimeter has an energy response between 15 KeV and 1.5 MeV and a dose range displayed from 0 to 9 999 mSv in increments of $0.1 \mu\text{Sv}$. Radiation doses were recorded at the end of each procedure.

Patient radiation exposure was assessed by Dose area product (DAP), as measured by an ionisation chamber on the radiology apparatus. DAP is related to the overall patient body dose for standard patient geometry (stochastic risk) [13, 14]. Other variables recorded were: x-ray time, patient body mass index (BMI), as well as the age and sex of the patient. Data were obtained using the Dosimetric Archiving and Communication System (DACS) Radiation Dose Monitor (Medsquare, Paris, France—<https://medsquare.com/en>). All patients have

Table 1. Comparison of patient characteristics between procedures with or without cardiac resynchronisation therapy.

Variables	CRT (n = 19)	No-CRT (n = 150)	p-value
Patients:			
Female, n (%)	10 (53)	53 (31)	0.2
Age (years)	69 [63–77]	78 [68–84]	0.02
Weight (kg)	78 [65–99]	78 [63–89]	0.8
BMI (kg m^{−2})	25.8 [23.9–33.9]	26.7 [24–30.5]	0.8
Procedures (PM or ICD implantations):			
Device:			
PM, n (%)	9 (47)	124 (83)	0.001*
ICD, n (%)	10 (53)	26 (17)	
Side of implantation:			
Left, n (%)	17 (89)	40 (27)	<0.001*
Right, n (%)	2 (11)	110 (73)	
Venous access:			
Cephalic vein, n (%)	0 (0)	119 (79)	<0.001*
Subclavian vein, n (%)	19 (100)	31 (21)	
Cardiologist radiation dose (μSv)	56 [27–96]	6 [2–10]	<0.001
DAP (cGy.cm²)	3201.2 [1188.5–5463.5]	225.2 [136.6–346.4]	<0.001
X-ray time (min)	28.6 [16.8–39.5]	4.2 [2.9–6.1]	<0.001

CRT: Cardiac resynchronisation therapy; BMI: Body mass index; PM: Pacemaker; ICD: Implanted cardioverter-defibrillator; DAP: Dose-area product.

*p-value of the comparison of device (PM or ICD), side of implantation (left or right) and venous access (cephalic or subclavian)

given, at the time of their hospitalisation, their informed consent for an anonymous retrospective use of their medical data.

Statistical analysis

Quantitative variables are described as median and [interquartile range] and qualitative variables as number (percentage). Quantitative variables were compared using the Mann-Whitney test. Qualitative variables were compared using Fisher's exact or the chi-square test as appropriate. Relations between quantitative variables were investigated using simple linear regression. Analyses were performed using SPSS version 21 (IBM SPSS Statistics, Chicago, USA). A p-value <0.05 was considered statistically significant; all tests were bilateral.

Results

During the study period, 169 procedures were included with 133 PM and 36 ICD implantations of which 10 and 9 included CRT, respectively.

The characteristics of the study population are shown in table 1. Radiation exposure of operators and patients (as assessed by DAP) differed significantly between implantations with

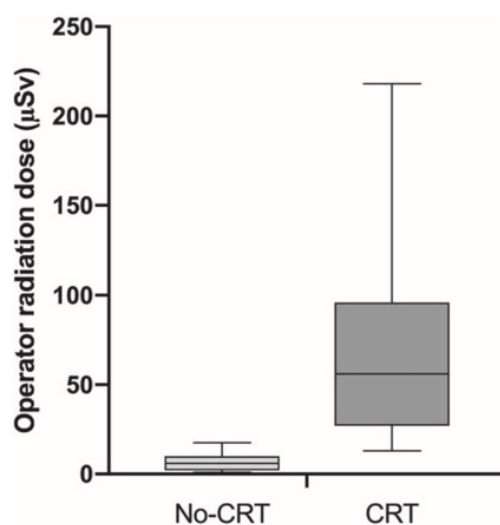


Figure 2. Box and whisker plots showing the distribution of operator radiation dose during procedures (PM and ICD implantations) with or without cardiac resynchronisation therapy. The boxes represent the median with the 1st and 3rd quartiles, and the 'whiskers' are drawn down to the 10th percentile and up to the 90th.

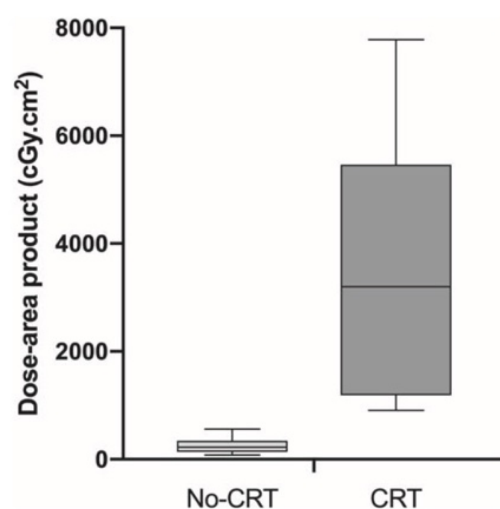


Figure 3. Box and whisker plots showing the distribution of patient radiation exposure during procedures (PM and ICD implantations) with or without cardiac resynchronisation therapy. The boxes represent the median with the 1st and 3rd quartiles, and the 'whiskers' are drawn down to the 10th percentile and up to the 90th.

versus without CRT ($p < 0.001$). Physicians exposure was 9-fold more radiation during CRT implantations, with a median operator dose at $56 \mu\text{Sv}$, versus $6 \mu\text{Sv}$ during procedures without CRT (figure 2), while median DAP was 14-fold greater during CRT implantations (figure 3).

Median x-ray time was 28.6 min during CRT implantations versus 4.2 min during implantations without CRT ($p < 0.001$). Physician radiation exposure was related to DAP ($R^2 = 0.21$ during 'classical' implantations and $R^2 = 0.57$ during CRT procedures).

Discussion

Our study found that cardiologists were exposed to a radiation dose that was 9-fold greater during CRT implantations (PM and ICD) than during procedures without CRT, and this variability is mainly related to changes in DAP. In addition, coronary sinus catheterisation needed for the implantation of the left ventricular lead may represent a technical difficulty. This step frequently involves an increase in the x-ray time in left anterior oblique (LAO) incidence, known to be the most irradiating incidence [14].

In order to reduce x-ray exposure, operators have to minimise the number of LAO incidences, collimate the x-ray beam as much as possible, and optimise the table position by placing the patient as far as possible from the x-ray source (i.e. placing the table in a high position) that allows a reduction in both patient and operator exposure, although working out of the isocentre is likely to increase scattered radiation [14]. In addition, the sensor-based navigation system MediGuide® (St Jude Medical, St Paul, USA) allows three-dimensional reconstruction of anatomy from recorded fluoroscopy images, which would allow a dramatic reduction in the radiation dose during CRT implantations, without increasing the frequency of complications [15, 16]. Similarly, the use of an electro-anatomical mapping system, such as Ensite Velocity® (St Jude Medical, St Paul, USA) would allow a drastic reduction in ionizing radiation exposure, procedure time and contrast medium use [17, 18]. However, the use of these technologies is limited by their cost and accessibility and requires the use of a Siemens x-ray system (Siemens Healthcare, Erlangen, Germany).

The exposure of patients undergoing a PM or ICD implantation also varies significantly between procedures with versus without CRT, in the same manner as operator exposure. This is not surprising since the main source of operator exposure is the scattered radiation from the patient [13, 19].

With the same methodology, we showed that in the catheterisation laboratory, the average cardiologists' exposure to radiation ranged from 2 to 7 μSv for an average x-ray time of 8 min [20]. Here, physicians' exposure was higher with a median of 6 to 56 μSv , for a maximum of 614 μSv during a complex CRT procedure in an obese patient. In contrast, patients' exposure was comparable with mean DAP ranging from 1400 to 3000 $\text{cGy}\cdot\text{cm}^2$ in the catheterisation laboratory [20] and median DAP ranging from 225 to 3200 $\text{cGy}\cdot\text{cm}^2$ at the electrophysiology laboratory. This difference can be explained by the impossibility of using a lead screen during PM and ICD implantation (as cardiologists have to be close to the operative site, i.e. patient's shoulder, which is right next to the x-ray field, i.e. patient's thorax), by a greater sensitisation to the radiation protection rules in the catheterisation laboratory, as shown by the lower number of publications on x-ray exposure of operators during PM and ICD implantations compared to the catheterisation laboratory, and probably by an annual number of implantations of PM and ICD which remains clearly lower than the number of coronary angiography and angioplasty, despite a recent increase in the number of CRT implantations following the publications reporting the benefit of CRT on the prognosis [21, 22].

The dose collection was not computerised and required the intervention of the cardiologist wearing the dosimeter, so there was uncertainty as to the accuracy of the data. However, our medical team has been using these dosimeters for clinical research purposes for several years [12, 20, 23], and therefore has significant experience with dose collection.

Study limitations

Our study is limited by its single-centre design and by the relatively low number of procedures, which leads to a large dispersion of the results. However, these are original data since, to the best of our knowledge, there are no recent data on the exposure of operators to ionizing radiation in the electrophysiology laboratory, collected using a methodology that has previously been shown to be valid. In addition, our results are consistent with those of previous studies [11, 24].

Conclusions

Operator's radiation exposure is particularly high during cardiac resynchronisation procedures. Indeed, our study showed that cardiologists' exposure to radiation during CRT implantation was 9-fold greater than during procedures without CRT implantation.

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Disclosures

The authors declare that there is no conflict of interest.

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2. Variation de l'exposition aux rayons X en électrophysiologie

Nous avons ensuite souhaité mesurer et comparer l'exposition aux rayonnements des patients et des opérateurs au cours des procédures d'électrophysiologie, et ce travail a fait l'objet d'une publication dans le *Journal of Interventional Cardiac Electrophysiology* (36).

RÉSUMÉ

Peu d'études se sont intéressées à l'exposition des patients aux rayonnements ionisants au cours des procédures d'électrophysiologie, et à notre connaissance aucune étude n'avait comparé le niveau d'exposition aux rayons X des opérateurs au cours des différentes procédures d'électrophysiologie.

Nous avons donc inclus toutes les procédures d'électrophysiologie effectuées au CHU de Reims sur une période de 6 mois. Les explorations électrophysiologiques ainsi que les procédures d'ablation par radiofréquence (tachycardie jonctionnelle par ré-entrée intra-nodale ou voie accessoire, flutter atrial commun et fibrillation atriale) étaient incluses. Les procédures de modulation du nœud atrio-ventriculaire et les ablations de tachycardie ventriculaire n'étaient pas incluses en raison du faible nombre de procédure. Les critères de jugement étaient la dose de rayonnement reçue par l'opérateur, mesurée par un dosimètre électronique supplémentaire positionné sur le bras gauche de l'opérateur à l'extérieur de tout équipement de protection individuel, ainsi que la dose de rayonnements reçue par le patient, estimée par le PDS.

Au total, 150 procédures d'électrophysiologie ont été analysées (exploration électrophysiologique : 29 ; ablation de fibrillation atriale : 46 ; ablation de flutter commun : 47 ; ablation de tachycardie jonctionnelle par ré-entrée intra-nodale : 15 ; ablation de voie accessoire atrio-ventriculaire : 13). En comparaison avec les explorations électrophysiologiques diagnostiques (catégorie de référence), l'exposition des opérateurs était 3 fois supérieure au cours des ablations de fibrillation atriale, 9 fois supérieur au cours des ablations de tachycardie jonctionnelle (par ré-entrée intra-nodale ou voie accessoire), et 10 fois supérieure au cours des ablations de flutter atrial. En ce qui concerne l'exposition des patients, en comparaison avec les explorations électrophysiologiques diagnostiques, elle était 3 fois supérieure au cours des ablations de fibrillation atriale, 5 fois supérieure au cours des ablations de flutter atrial et 6 fois supérieure au cours des ablations de tachycardie jonctionnelle.

Notre étude a donc démontré qu'il existait d'importantes variations du niveau d'exposition aux rayonnements ionisants en fonction du type de procédure d'électrophysiologie. C'était au cours des procédures d'ablation de flutter atrial et de tachycardie jonctionnelle que l'opérateur était le plus exposé aux rayonnements ionisants. Bien que l'exposition des patients aux rayonnements en électrophysiologie semble être très nettement inférieure à celle au cours des procédures de coronarographie/angioplastie coronaire, l'exposition des opérateurs apparaît quant à elle être du même ordre de grandeur. Il conviendra

donc de diminuer cette exposition dans le futur, et cela passera par une meilleure mise en œuvre des mesures de radioprotection ainsi que par le développement de technologies de réduction de dose.

Publication 3 :

“Physicians’ exposure to radiation during electrophysiology procedures”

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Physicians' exposure to radiation during electrophysiology procedures

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Abstract

Purpose Cardiologists are among the health professionals that are most exposed to ionizing radiation, but there is no study comparing the level of exposure of physicians during different electrophysiology procedures. We aimed to measure and compare cardiologists' exposure to radiation during different electrophysiology procedures.

Methods The study population comprised all electrophysiology procedures performed over a 6-month period in a large referral centre. The endpoint was operator radiation exposure, assessed using a personal electronic dosimeter located on the operator's left arm.

Results In total, 150 electrophysiology procedures were analyzed. Compared with electrophysiology studies (reference category), physician radiation exposure was 3-fold greater during ablation of atrial fibrillation, 9-fold greater during ablation of atrioventricular nodal reentrant tachycardia (AVNRT)/atrioventricular reentrant tachycardia (AVNT), and 10-fold greater during ablation of atrial flutter ($p < 0.001$). Physician exposure was mainly related to X-ray time ($R^2 = 0.28$).

Conclusions Our study showed significant differences in cardiologists' exposure to ionizing radiation depending on the type of electrophysiology procedure. Atrial flutter and AVNRT/AVNT ablations are the procedures in which operators are most exposed to ionizing radiation.

Keywords Electrophysiology · Radiation risk · Radiation protection · Dosimetry

1 Introduction

Cardiologists are among the health professionals that are most exposed to ionizing radiation [1]. Recent publications have suggested that through deterministic effects,

there may be an increased risk of radiation-induced cataracts in personnel working in catheterisation laboratories (cathlabs) [2–5], while stochastic effects may contribute to an increased frequency of left-hemisphere brain tumours in this population [6].

Radiation exposure of physicians working in cathlabs has been studied in the past, with a reported mean dose per procedure of 2 to 7 μSv [7]. In the field of electrophysiology, patient exposure has previously been studied [8–11], but the only available data regarding operator exposure are either outdated [12–14], or *in vitro* data (anthropomorphic phantom) [15]. To the best of our knowledge, there is no study comparing the level of exposure of physicians during different electrophysiology procedures.

The aim of our study was thus to measure and compare operator exposure to radiation during different types of electrophysiology procedure.

Laurent Faroux and Charline Daval contributed equally to this work.

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2 Methods

2.1 Study population

This was a prospective, analytical, epidemiological single-centre cohort study carried out in a large university hospital in France. The population for analysis included all consecutive electrophysiology procedures performed in our centre from November 2017 to May 2018. Diagnostic electrophysiology studies and radiofrequency ablation procedures (atrioventricular nodal reentrant tachycardia (AVNRT), atrioventricular reentrant tachycardia (AVRT), common atrial flutter and atrial fibrillation) were included. Atrioventricular node and ventricular tachycardia ablations were not included because of the small number of procedures.

2.2 Electrophysiology procedures

During electrophysiology procedures, 1 to 3 venous femoral sheaths of 6 to 8.5 Fr were implanted. Electrophysiology studies, AVNRT, AVNT and flutter ablations were performed under local anaesthesia without electroanatomical mapping. Atrial fibrillation ablation procedures were preceded by a cardiac angio-CT to use the CARTO 3 software (Biosense Webster, Johnson & Johnson, Irvine, CA, USA). They were performed under general anaesthesia, and trans-septal puncture was performed under trans-oesophageal echocardiographic and fluoroscopic control.

Three cardiologists with 8 or more years' experience in electrophysiology and who were permanent, full-time practitioners in the Department during the study period performed the procedures in a single electrophysiology laboratory, equipped with the Arcadis Avantic system (Siemens Healthcare, Erlangen, Germany), in service since January 2011, with an image intensifier with a frame rate of 4 fps, and 33 cm size of field. The equipment undergoes half-yearly control by the manufacturer, and annual external quality control. The electrophysiology laboratory is equipped with lead screens and table drapes with 0.5-mm Pb equivalent used consistently. All operators wear a leaded apron and a thyroid shield with 0.5-mm Pb equivalent. They also have a passive dosimeter with quarterly statements (Landauer, Glenwood, USA) and an active dosimeter (APVL, Saint-Cyr-sur-Loire, France). A nurse was present for all procedures.

2.3 Endpoints

The primary endpoint was cardiologist radiation exposure, as assessed using personal electronic dosimeters (APVL, Saint-Cyr-sur-Loire, France) with a silicon diode (μSv) located on the operator's left arm outside the apron (Fig. 1) in order to optimise angular response, with the ideal position placing the dosimeter at an angle of 0° in relation to the radiation source,



Fig. 1 Illustration of the personal electronic dosimeter located on the operator's left arm used to measure operator radiation exposure

namely, the patient's body in this instance [16]. The dosimeter has an energy response between 15 keV and 1.5 MeV and a dose range displayed from 0 to 9999 mSv in increments of 0.1 μSv . Radiation doses were recorded at the end of each procedure. This measurement corresponds to the dose received at 10 mm under the site of the dosimeter (HP10), and represents the probability of stochastic health effects from radiation.

Patient radiation exposure was assessed by dose area product (DAP), as measured by an ionisation chamber on the radiology apparatus. DAP is related to the overall patient body dose for standard patient geometry (stochastic risk) [17, 18]. Other variables recorded were x-ray time, patient body mass index (BMI) and age and sex of the patient. Data were obtained using the Dosimetric Archiving and Communication System (DACS) Radiation Dose Monitor (Medsquare, Paris, France). All patients have given, at the time of their hospitalisation, their informed consent for an anonymous retrospective use of their medical data.

2.4 Statistical analyses

Quantitative variables are described as median and (interquartile range) and qualitative variables as number (percentage).

Table 1 Comparison of population characteristics between different electrophysiology procedures

Variables	Electrophysiology study (<i>n</i> = 29)	Atrial fibrillation ablation (<i>n</i> = 46)	Atrial flutter ablation (<i>n</i> = 47)	AVNRT/AVNT ablation (<i>n</i> = 28)	<i>p</i> value
Patients					
Male, <i>n</i> (%)	18 (64)	34 (74)	34 (72)	15 (54)	0.4
Age (years)	56 (39–72)	61 (56–67)	66 (59–76)	30 (18–48)	< 0.001
BMI (kg/m ²)	26.1 (23.4–30.5)	28.4 (26.4–31.2)	28.1 (24.4–31.2)	23.8 (21.2–25.5)	< 0.001
Procedures					
X-ray time (min)	4.2 (1.8–5.4)	6.6 (4–9.8)	13.6 (7.4–20.5)	21.3 (10.9–35.6)	< 0.001
DAP (cGy cm ²)	148.2 (97.2–231)	429.6 (269.1–845.1)	786.6 (341.4–2880.9)	884.4 (318.5–1872.6)	< 0.001
Operator radiation dose (μSv)	1 (0–3)	3 (1–4)	9 (4–22)	10 (5–19)	< 0.001

BMI body mass index, DAP dose area product, AVNRT atrioventricular nodal reentrant tachycardia; AVNT atrioventricular reentrant tachycardia

Quantitative variables were compared using the Kruskal–Wallis test. Qualitative variables were compared using Fisher's exact or the chi-square test as appropriate. Relations between quantitative variables were investigated using simple linear regression. Analyses were performed using SPSS version 21 (IBM SPSS Statistics, Chicago, USA). A *p* value < 0.05 was considered statistically significant; all tests were bilateral.

3 Results

During the study period, 150 electrophysiology procedures were included, namely, 29 electrophysiology studies, 46 atrial fibrillation ablations, 47 common atrial flutter ablations, 15 AVNRT ablations and 13 AVRT ablations.

Characteristics of the procedures are shown in Table 1. Radiation exposure of operators and patients (as assessed by DAP) differed significantly according to the electrophysiology procedure (*p* < 0.001). Compared to electrophysiology studies, median physician radiation exposure was 3-fold greater during ablation of atrial fibrillation, 9-fold greater during ablation of AVNRT/AVNT and 10-fold greater during ablation of atrial flutter (Fig. 2). Median DAP was 3-fold higher during atrial fibrillation ablations, 5-fold higher during atrial flutter and 6-fold greater AVNRT and AVNT ablations (Fig. 3). Median X-ray time and BMI were on average 13.6 min and 28.1 kg/m² during atrial flutter ablations and 21.3 min and 23.8 kg/m² during AVNRT and AVNT ablations.

Both physician radiation exposure and dose area product were strongly related to X-ray time ($R^2 = 0.28$ and $R^2 = 0.55$ respectively).

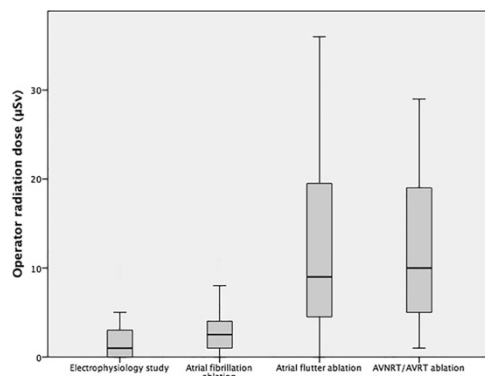


Fig. 2 Box and whisker plots showing the distribution of operator radiation dose according to the electrophysiology procedure (*p* < 0.001). The boxes represent the median with the 1st and 3rd quartiles, and the “whiskers” represent the upper and lower limits excluding the extreme values

4 Discussion

4.1 Operator radiation exposure

Our study found significant differences in cardiologists' exposure to ionizing radiation depending on the type of procedure, and this variability is directly related to changes in X-ray time. Operators are significantly more exposed during ablation procedures, with the exception of atrial fibrillation ablation procedures in which X-ray time is low thanks to mapping systems.

We recently demonstrated with the same methodology that the average exposure of cardiologists to radiation in the cathlab ranged from 2 to 7 μSv per procedure, for an average X-ray time of 8 min [7], whereas in the present study, median exposure of cardiologists working in the electrophysiology laboratory ranged from 1 to 10 μSv, depending on the type of procedure. Operator exposure therefore appears to be similar in electrophysiology than in the cathlab.

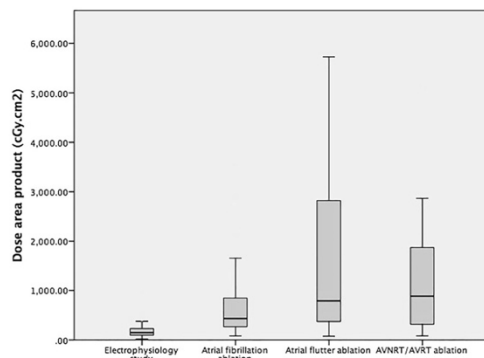


Fig. 3 Box and whisker plots showing the distribution of patient radiation exposure according to the electrophysiology procedure ($p < 0.001$). The boxes represent the median with the 1st and 3rd quartiles, and the “whiskers” represent the upper and lower limits excluding the extreme values

4.2 Patient radiation exposure

The exposure of patients undergoing an electrophysiology procedure also varies significantly depending on the type of procedure, in the same manner as operator exposure. This is unsurprising, since the main source of operator exposure is the scattered radiation from the patient [17, 19]. In the cathlab, patients are exposed to a radiation dose ranging from 1900 to 3300 cGy cm² [20], while in the present study, we found that patients were exposed to a median dose ranging from 148 to 884 cGy cm². Patient exposure to radiation therefore seems to be considerably lower in the electrophysiology laboratory than in the cathlab, although operator exposure is similar. This could be explained by greater awareness among interventional cardiologists as compared to rhythmologists about the rules for reduce the dose of radiation (increasing table height at maximum, optimizing source-to-image distance, use of low frame rate, use of collimation and contour filters) and protecting against scattered radiation from patient (optimizing the use of lead screens and table drapes) [18], as reflected by the low number of publications pertaining to X-ray exposure of operators in the electrophysiology laboratory compared to the catheterisation laboratory.

4.3 Atrial flutter and AVNRT/AVNT ablation procedures

Surprisingly, operator exposure was similar during AVNRT/AVNT ablations and atrial flutter ablations, whereas the median X-ray time was 57% higher during AVNRT/AVNT ablations. This could be explained by the fact that median BMI of patients with AVNRT/AVNT ablations was 23.8 kg/m² versus 28.1 kg/m² for patients with atrial flutter ablation. Indeed,

BMI is an important determinant of scattered radiation [18], and the main source of exposure for cardiologists is radiation scattered from the patient [17, 19]. In addition, the left anterior oblique (LAO) incidence is mostly used during atrial flutter ablation, and this incidence is known to be the most irradiating [18].

4.4 Study limitations

Our study has some limitations, namely, the single-centre design and the relatively low number of procedures. However, these findings are original and relevant since, to the best of our knowledge, there are no recent data on operator exposure to ionizing radiation in the electrophysiology laboratory, collected using a methodology that has already been proven to be valid.

Our study showed significant differences in cardiologists' exposure to ionizing radiation depending on the type of electrophysiology procedure, and this is during ablation of atrial flutter and AVNRT/AVNT that operators are the most exposed.

Despite a considerably lower patient exposure to radiation in the electrophysiology laboratory than in the cathlab, operator exposure appears to be similar. It will therefore be necessary to reduce operator exposure in the future, and to this end, to develop new technologies as well as optimizing radiation protection practices in the electrophysiology laboratory.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent All patients have given, at the time of their hospitalisation, their informed consent for an anonymous retrospective use of their medical data.

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3. Dose globale de rayonnements reçue par les patients au cours des ablations de fibrillation atriale par radiofréquence

Nous avons souhaité étudier la part relative du scanner pré-procédural et de la procédure elle-même sur l'exposition globale aux rayonnements ionisants des patients bénéficiant d'une procédure d'ablation de fibrillation atriale par radiofréquence, ainsi que l'impact de l'obésité du patient sur cette exposition globale. Ce travail a fait l'objet d'une publication dans l'*American Journal of Cardiology* (38).

RÉSUMÉ

Les patients bénéficiant d'une ablation de fibrillation atriale par radiofréquence sont exposés aux rayonnements ionisants non seulement au moment de la procédure, mais également au cours du scanner cardiaque pré-procédural. L'exposition globale aux rayons X, tenant compte à la fois du scanner pré-procédural et de la procédure d'ablation de fibrillation atriale n'a jamais été étudiée. Par ailleurs, il a été montré par le passé que, au cours des procédures d'ablation de fibrillation atriale par radiofréquence, les patients obèses recevaient une dose de rayonnements 3 fois supérieure à celle reçue par les patients de corpulence normale (37). Toutefois, cette étude avait été menée à une époque où les systèmes de cartographie tridimensionnelle n'étaient pas encore développés dans cette indication, et elle ne considérait par conséquent que la dose de rayons X reçue au moment de la procédure d'ablation. Nous avons donc souhaité mesurer la dose de rayonnements globale à laquelle sont exposés les patients bénéficiant d'une ablation de fibrillation atriale par radiofréquence. Nous avons également voulu étudier l'impact de l'obésité sur la dose globale de rayonnements.

Pour ce faire, nous avons inclus tous les patients qui ont bénéficié d'une procédure d'ablation de fibrillation atriale par radiofréquence au CHU de Reims sur une période de 21 mois. Le PDS (estimation de la dose reçue au cours de la procédure d'ablation) ainsi que le produit dose-longueur (PDL ; estimation de la dose reçue au cours du scanner pré-procédural) ont été convertis en une dose efficace (mSv). Un surpoids était défini comme un IMC compris entre 25 et 30 kg/m², alors qu'une obésité était définie comme un IMC supérieur ou égale à 30 kg/m².

Un total de 144 procédures d'ablation de fibrillation atriale par radiofréquence a été inclus. La dose globale moyenne était de 11,4 mSv, et 82% de cette dose provenait du scanner cardiaque pré-procédural. Les patients obèses recevaient une dose globale en moyenne 75% supérieure à celle reçue par les patients de corpulence normale, et cette augmentation restait significative en analyse multivariée ($p=0.009$) ajustée sur le temps de fluoroscopie, le sexe du patient, le volume de l'atrium gauche et le type d'ablation (isolation des veines seule ou associée à un autre geste d'ablation).

Publication 4 :

**“Impact of Obesity on Overall Radiation Exposure for Patients Who Underwent
Radiofrequency Ablation of Atrial Fibrillation”**

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Impact of Obesity on Overall Radiation Exposure for Patients Who Underwent Radiofrequency Ablation of Atrial Fibrillation



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Patients who underwent radiofrequency ablation of atrial fibrillation are exposed to X-rays not only during the procedure but also during the preprocedural computed tomography. No study has investigated the cumulative effective dose received by patients who underwent atrial fibrillation ablation and identified factors influencing this dose. We aimed to evaluate the overall exposure to ionizing radiation in patients who underwent radiofrequency ablation of atrial fibrillation. The secondary objective was to estimate the impact of obesity on this exposure. All patients who underwent a first attempt of radiofrequency ablation of atrial fibrillation in our center over a 21 months period were included. Dosimetric indicators from preprocedural computed tomography and the ablation procedure were collected and converted into an effective dose. A total of 144 radiofrequency ablation of atrial fibrillation were included. The mean cumulative effective dose was 11.4 mSv, and 82% of the dose was from the computed tomography. Obese patients received a dose that was 75% higher than normal-weight patients, and this increase remained significant by multivariate analysis. In conclusion, overall exposure to ionizing radiation for patients who underwent radiofrequency ablation of atrial fibrillation seems acceptable, and the majority of the overall effective dose comes from the computed tomography. Obese patients are exposed to a 75% higher dose than normal-weight patients. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:1213–1217)

Interventional cardiology, in constant evolution for several decades, now enables to manage a wide range of diseases minimally invasively but effectively. These interventions have in common to be performed under X-ray guidance, and sometimes to require, like transcatheter aortic valve replacement, the realization of one or more irradiating procedures during the preintervention work-up. Since the advent of 3D cardiac mapping systems, performing radiofrequency (RF) ablation of atrial fibrillation (AF) leads to perform an Electrocardiogram (ECG)-gated synchronized computed tomography (CT) scan upstream the procedure. Because patients who underwent AF ablation are generally young, they are likely to experience an increase in the radiation-induced cancer risk after RF ablation of AF.^{1,2} In this context, study of the overall exposure to ionizing radiation (including preprocedural CT and the procedure itself) is increasingly important, but existing study has only investigated the X-ray exposure during the ablation procedure.^{3–6} Moreover, studying obesity in the context of AF ablation is important as it affects the rate of procedural success,⁷ and it has been shown previously that obesity was a major determinant of X-ray exposure in patients who underwent AF ablation. However, this study was conducted at a time when

3D cardiac mapping systems was not developed for this indication, and therefore considered only the radiation exposure during the ablation procedure.⁴ The main objective of our study was therefore to evaluate the overall exposure to ionizing radiation of patients who underwent RF ablation of AF. The secondary objective was to estimate the impact of obesity on this exposure.

Methods

This was a retrospective cohort study, including all patients who underwent a first attempt of RF ablation of AF in our center from January 2017 to September 2018. Clinical, echocardiographic, biologic, and dosimetric data were retrospectively compiled using medical records and the Dosimetry Archiving and Communication System (DACS) of our center (Dosimetry Archiving and Communication System, Medsquare, Paris, France). All patients have given, at the time of their hospitalization, their informed consent for an anonymous retrospective use of their medical data.

RF ablation procedures were all performed with the same 3D cardiac mapping system (CARTO3 software, Biosense Webster, Johnson & Johnson, Irvine), under general anesthesia, with 3 venous femoral sheaths of 6Fr, 8Fr, and 9Fr, with respectively a reference decapolar diagnostic catheter positioned in the coronary sinus, a deflectable circular duodecapolar catheter with variable diameter for anatomical and electrical mapping of the left atrium and the pulmonary veins (PV; LASSO NAV, Biosense Webster, Johnson & Johnson, Irvine), and a 3.5 mm irrigated RF catheter (THERMOCOOL SMART TOUCH, Biosense

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See page 1216 for disclosure information.

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Webster, Johnson & Johnson, Irvine). Transseptal puncture was performed under transoesophageal echocardiography and fluoroscopy guidance. PV ostia were localized thanks to the CT scan and the intracardiac impedance. No PV angiograms were performed before the ablation. Electrical and anatomical mapping of the left atrium was supported by the FAM software (Fast Activation Mapping, Biosense Webster, Johnson & Johnson, Irvine). PV isolation was performed for all procedures, associated with an atrial electrical defragmentation for persistent AF not converted to sinus rhythm, atrial tachycardia, or atrial flutter after PV isolation. Focal atrial tachycardia and atrial flutter occurring during procedure were mapped and ablated. If a common right atrial flutter has been previously documented or was documented during ablation procedure, cavo-tricuspid isthmus was treated by RF ablation. Validation of the isolation of PV was performed by the demonstration of an entry and an exit block on each pulmonary vein, 30 minutes after the last RF application. Linear lesions were validating by differential pacing.

The same cardiologist, with an experience of more than 300 RF ablation of AF, performed all the ablation procedures in a single electrophysiology laboratory equipped with the Arcadis Avantic system (Siemens Healthcare, Erlangen, Germany) in service since January 2011 (image intensifier with a frame rate of 4 fps and 33 cm size of field). The equipment undergoes half-yearly control by the manufacturer, and annual external quality control. The electrophysiology laboratory is equipped with lead screens and table drapes with 0.5 mm Pb equivalent used consistently. All operators wear a leaded apron and a thyroid shield with 0.5 mm Pb equivalent. They also have a passive dosimeter with quarterly statements (Landauer, Glenwood) and an active dosimeter (APVL, Saint-Cyr-sur-Loire, France). A fellow and a nurse were present for all procedures. A retrospectively ECG-gated synchronized angiographic CT scan from the aortic arch to a few centimeters under the diaphragmatic cupolas and focused on the left atrium was systematically performed on a dual energy CT Discovery 750 HD scanner (General Electrics, Massachusetts, in service since April 2012).

Overweight was defined as a body mass index (BMI) from 25 to 30 kg/m² and obesity was defined as a BMI greater than or equal to 30 kg/m². "PVI alone" corresponded to the PV isolation (PVI) without ablation of complex fractionated electrograms or linear ablation, whereas "PVI+" corresponded to PVI with at least one other ablation (including cavo-tricuspid isthmus ablation). Left atrium volume was calculated basis on the three-dimensional CT reconstruction. In patients with paroxysmal AF or persistent AF in sinus rhythm at the time of ablation, success was defined as a successful PVI. In patients in spontaneous AF at the time of ablation, success was defined as a successful PVI associated with a restoration of sinus rhythm (without electrical cardioversion) or with a conversion in an organized atrial tachycardia.

Depending of the type of irradiating procedure, 2 dose estimators are provided by the apparatus. To homogenize doses and to enable calculation of a cumulative dose, we converted these estimators into an effective dose (ED). The dose area product (DAP), expressed in cGy.cm², used

in cardiology and interventional radiology, is a synthetic dose indicator expressing the total amount of energy delivered to the patient. A simplified formula makes it possible to estimate the ED from the DAP: ED (mSv) = DAP (cGy.cm²) × 0.002 (mSv/cGy.cm²).^{8,9} CT uses another estimator determined by the anatomical region studied, the dose length product (DLP), expressed in mGy.cm. A coefficient enables conversion of DLP to ED according to the anatomical region, and the following formula proposed by Christner et al directly converts DLP into ED: ED (mSv) = DLP (mGy.cm) × 0.021 (mSv/mGy.cm).⁸⁻¹⁰ The primary end point was the cumulative ED, calculated by summing ED received during the preprocedural CT and during the ablation procedure.

Quantitative variables are described as median and [interquartile range] or mean ± standard deviation and qualitative variables as number (percentage). Quantitative variables were compared using nonparametric Kruskal-Wallis test. Multiple comparisons between normal weight, overweight, and obese patients were performed using the Dwass, Steel, Critchlow-Fligner analysis. Qualitative variables were compared using Fisher's exact. Relations between quantitative variables were investigated using simple linear regression. Multivariate analysis was performed using a generalized linear regression including all variables related to the primary endpoint with a p value <0.10 by univariate analysis. In view of the risk of collinearity between the left atrial volume and the pattern of AF (paroxysmal or persistent), only the variable most significantly related to the overall ED by univariate analysis was introduced in the multivariate model. All analyses were performed using SPSS version 21 (IBM SPSS Statistics, Chicago). A p value <0.05 was considered statistically significant; all tests were 2-sided.

Results

A total of 144 patients who underwent a first attempt of RF ablation of AF in our center over the 21 months period were included. The overall ED ranged from 4 to 42.3 mSv, with an average of 11.4 mSv. Eighty two percent of the exposure was related to the preprocedural CT, with an ED of 9.4 ± 5.8 and 2 ± 2 mSv for the CT and the ablation procedure respectively.

Forty three percent of the patients were overweighted and 33% were obese. Table 1 presents the comparison of patients according to their BMI. Median overall ED of overweight and obese patients was respectively 23% (p=0.2) and 75% (p=0.007) higher than normal-weight patients (Figure 1). Besides BMI, overall ED was significantly associated with the patient sex (p=0.005), the X-ray time (p=0.001), the type of AF (paroxysmal or persistent) (p=0.01), the left atrial volume (p=0.001) but was not associated with PVI alone (p=0.09), hypertension (p=0.13), diabetes (p=0.4) or patient age (p=0.9). After adjustment, BMI (p=0.009) and X-ray time (p=0.004) remained significantly associated with the overall ED (Table 2).

Procedural success was strongly related to the type of AF, since the rate of successful ablation was of 100% of patients with paroxysmal AF or persistent AF in sinus

Table 1
Comparison of population characteristics between normal-weight (BMI <25 kg/m²), overweight (25 kg/m² ≤ BMI <30 kg/m²), and obese patients (BMI ≥30 kg/m²)

Variables	Overall population (n = 144)	Normal-weight (n = 34)	Overweight (n = 62)	Obese (n = 48)	Obese vs Normal- weight p value*	Overall p value [†]
Population:						
Age (years)	60 [53-66]	60 [48-67]	60 [54-65]	59 [52-66]	0.7	0.9
Women	30 (21%)	9 (26%)	9 (15%)	12 (25%)	1	0.2
Hypertension	60 (42%)	9 (26%)	27 (44%)	24 (50%)	0.04	0.1
Diabetes	12 (8%)	1 (3%)	6 (10%)	5 (10%)	0.4	0.5
Heart failure	15 (10%)	2 (6%)	6 (10%)	7 (14%)	0.3	0.5
CHA ₂ DS ₂ -VASC:						
0	40 (28%)	11 (32%)	17 (28%)	12 (25%)		
1	52 (36%)	11 (32%)	26 (42%)	15 (31%)	0.8	0.9
2	33 (23%)	8 (24%)	12 (19%)	13 (27%)		
>2	19 (13%)	4 (12%)	7 (11%)	8 (17%)		
Left atrial volume (ml)	110 [92-145]	103 [90-135]	110 [95-140]	120 [98-170]	0.1	0.09
Atrial fibrillation:						
Paroxysmal	73 (51%)	23 (68%)	35 (56%)	15 (31%)	0.002	
Persistent	71 (49%)	11 (32%)	27 (44%)	33 (69%)		0.003
Procedural data:						
PVI alone	77 (54%)	18 (53%)	41 (66%)	18 (38%)	0.2	0.01
Procedural time (min)	125.4 [105-150]	126.9 [105.9-139.5]	125.4 [99.3-150]	127.2 [111.2-165]	0.4	0.3
Dosimetric data:						
Overall ED (mSv)	9.7 [7.1-13.8]	6.9 [5.3-12.1]	8.5 [7.1-11.2]	12.1 [9.9-16]	<0.001	<0.001
CT:						
DLP (mGy.cm)	384.5 [278.7-531.6]	244.7 [202.7-502.5]	340.9 [287.6-456.9]	450.9 [388.3-616.7]	<0.001	<0.001
ED (mSv)	8.1 [5.9-11.2]	5.1 [4.3-10.6]	7.2 [6-9.6]	9.5 [8.2-13]	<0.001	<0.001
AF ablation:						
DAP (cGy.cm ²)	699.4 [393.7-1232.4]	671.3 [354.1-671.3]	496.6 [293.1-979.4]	859.3 [475.3-1968.7]	0.2	0.006
ED (mSv)	1.4 [0.7-2.5]	1.3 [0.7-2.2]	1 [0.6-2]	1.7 [1-3.9]	0.2	0.006
X-ray time (min)	6.8 [4.5-10.5]	8.3 [5.4-12.5]	5.8 [3.7-8.6]	9 [4.8-11.1]	0.9	0.005

CT = computed tomography; DAP = dose area product; DLP = dose length product; ED = effective dose; PVI = pulmonary-veins isolation.

* Dwass, Steel, Critchlow-Fligner analysis (quantitative variables), and Fisher's exact test (qualitative variables).

† Kruskal-Wallis test (quantitative variables) and Fisher's exact test (qualitative variables).

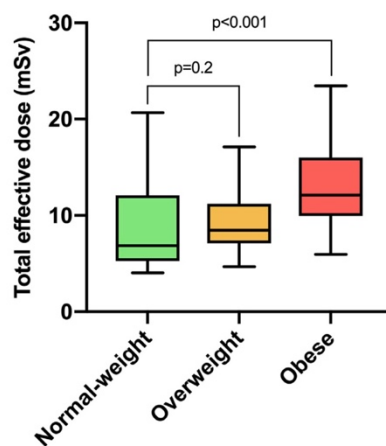


Figure 1. Box and whisker plots showing the distribution of the overall effective dose for normal-weight (BMI <25 kg/m²), overweight (25 kg/m² ≤ BMI <30 kg/m²) and obese patients (BMI ≥30 kg/m²). The boxes represent the median with the first and third quartiles, and the "whiskers" represent the upper and lower limits excluding the extreme values (Tukey's style).

rhythm at the time of ablation, whereas the success rate dropped to 49% in patients in spontaneous AF at the time of ablation ($p < 0.001$). In addition, success of ablation was related to BMI and left atrial volume ($p = 0.04$ and $p < 0.001$, respectively) but not to the DAP ($p = 0.7$) or the overall ED ($p = 0.8$).

Discussion

Our study, which is the first to consider the global exposure to ionizing radiation for patients who underwent a RF

Table 2
Multivariate analysis of the factors associated with the overall effective dose received by the patient

	Beta coefficient	Standard error	p value
X-ray time (per additional minute)	0.27	0.10	0.004
BMI (per additional kg/m ²)	0.27	0.11	0.009
Female (vs male)	-2.24	1.19	0.06
Left atrial volume (per additional ml)	0.03	0.01	0.06
PVI alone (vs PVI+)	0.15	1.01	0.9

AF = atrial fibrillation; PVI+ = pulmonary-veins isolation associated with one or several other ablations.

ablation of AF, found an overall ED of 11.4 mSv on average, which appears to be acceptable in relation to the reference standards of irradiating procedures performed in cardiology. Indeed, a standard ED of 22 mSv for a CRT implant and of 81 mSv for the angioplasty of a coronary chronic total occlusion have been reported.⁸ The advent of 3D cardiac mapping systems has significantly reduced the X-ray time during RF ablation of AF,¹¹ as evidenced by the small contribution of the ablation procedure itself to the overall ED (18% in average). However, X-ray time in our population seems to be smaller than what is usually described,¹² which may have an impact on our results.

Ector et al⁸ reported in 2007 the dosimetric characteristics of a cohort of 90 AF ablation procedures, at a time when 3D cardiac mapping systems were not developed for this indication. They reported an average ED of 22.4 mSv with an average X-ray time of 83 minutes. BMI was strongly associated with the ED, obese patients receiving more than 3 times the ED of normal-weight patients. The present study showed that the overall ED for obese patients was 75% higher than normal-weight patients, and therefore underlines that the impact of obesity on radiation exposure for patients who underwent a RF ablation of AF significantly decreased over the past decade.

Finally, our findings confirm that technology evolutions (such as 3D cardiac mapping systems and contact force sensing catheters) have dramatically reduced the radiation exposure and the X-ray time of patients who underwent RF ablation of AF^{5,11} (respectively 2 mSv and 8.2 minutes of X-ray in our study). It also highlights that it was obtained at the cost of an important radiation exposure at the time of the preprocedural CT (82% of the overall dose in our study). However, the global ED remains clearly lower than the ED of ablation procedures performed without mapping of the left atrium.^{4,6} In addition, preprocedural CT allows to describe PV anatomy (PV size, supernumerary, or accessory PV) and to identify a potential atrial thrombus, and thus improves procedural safety. The shift in the relative proportions of ionizing radiation received from preprocedure CT and the procedure itself over the years (previously, more derived during the procedure, now more derived from the CT scan), should encourage to replace preprocedural CT by gadolinium-enhanced cardiac magnetic resonance imaging¹³ or ultrasound (using the CartoSound feature integrated with electroanatomic mapping system) for determining left atrial anatomy, neither of which use any ionizing radiation.

Due to the single-center design of our study, some factors may affect generalizability of our results, including the use of transoesophageal echocardiography for transseptal puncture. Some labs use only fluoroscopy for transseptal puncture, thus changing the ratio of CT to ablation ration. The use of higher frame rates than 4 fps would change the ratio also. The fact that fluoroscopy time was lowest in overweight patients compared with the other 2 cohorts was likely due to small sample size rather than a biologically feasible explanation and constitutes a limitation of our study. However, we present complete dosimetric data from a homogeneous cohort of patients who underwent RF ablation of AF. We thus provide an estimation of the overall ED received by the

patients, which has never previously been reported, to the best of our knowledge.

Patients who underwent RF ablation of AF are exposed to an average overall ED of 11.4 mSv and 82% of the exposure is related to the preprocedural CT, highlighting the shift in the relative proportions of ionizing radiation received from preprocedure CT and the procedure itself over the years. Impact of obesity on overall exposure to ionizing radiation, which was previously considered to be major with a dose increase of more than 300% for obese patients, seems finally revealed to be moderate. Indeed, the overall ED for obese patients was only 75% higher than normal-weight patients.

Disclosures

The authors have no conflicts of interest to disclose.

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Partie III : Cardiologie interventionnelle structurelle

Dans cette troisième partie, nous étudierons l'exposition globale aux rayonnements ionisants des patients bénéficiant d'un TAVI. L'impact de l'approche artérielle et du type de valve sur l'exposition des patients et des opérateurs au cours des TAVI sera également étudié.

1. Exposition globale aux rayonnements ionisants des patients bénéficiant d'un remplacement valvulaire aortique percutané

Nous avons souhaité étudier la part relative du TAVI et des différents examens pré- et post-procéduraux sur l'exposition globale aux rayonnements ionisants des patients bénéficiant d'un TAVI, ainsi que les déterminants de cette exposition globale. Ce travail a fait l'objet d'une publication dans l'*American Journal of Cardiology* (47).

RÉSUMÉ

Le TAVI est actuellement indiqué chez les patients présentant un risque chirurgical intermédiaire à élevé (44), et est appelé à devenir le traitement de première intention de la maladie aortique chez les patients à bas risque chirurgical (45, 46), une population susceptible de présenter une augmentation du risque de cancer radio-induit suite au TAVI. Nous avons donc souhaité évaluer l'exposition globale aux rayonnements ionisants des patients bénéficiant d'un TAVI par voie trans-fémorale, tenant compte non seulement de la procédure de TAVI, mais également des examens faisant appel aux rayons X réalisés au moment du bilan pré-TAVI ainsi qu'en post-procédure.

Pour ce faire, tous les patients qui ont bénéficié d'un TAVI par voie trans-fémorale pour une sténose aortique sévère dans notre centre sur une période de 26 mois ont été inclus. Les indicateurs dosimétriques de la coronarographie (PDS) et du scanner cardio-vasculaire (PDL) pré-TAVI, de la procédure de TAVI (PDS) et des éventuelles investigations post-procédurales (exploration électrophysiologique, implantation d'un PM ; PDS) ont été converties en dose efficace (mSv).

Un total de 119 TAVI ont été inclus pour analyse. La dose efficace cumulée moyenne était de 37,3 mSv. Trois examens irradiants ont été nécessaires pour 84 patients (71% de la population, i.e. une coronarographie, un scanner et la procédure de TAVI), alors que 30 patients (25%) ont eu besoin de 4 procédures irradiantes, et 5 patients ont eu besoin d'une cinquième procédure (4%). La majorité de la dose provenait du scanner cardio-vasculaire (75%), alors que la coronarographie et le TAVI représentaient 14% et 11% de la dose efficace cumulée, respectivement. En analyse multivariée la surface corporelle était le seul paramètre associé à la dose globale de rayons X.

La dose globale de rayonnements reçue par les patients bénéficiant d'un TAVI, incluant non seulement la procédure de TAVI elle-même mais également les examens réalisés en pré- et post-TAVI apparaît être acceptable en comparaison au niveau de référence des examens cardiologiques de pratique courante. La procédure de TAVI ne représente que 11% de la dose globale, alors que le scanner pré-procédural représente 75% de cette dose. Une optimisation du protocole du scanner cardiaque synchronisé sera nécessaire afin de diminuer l'exposition globale aux rayons X des patients bénéficiant d'un TAVI par voie trans-fémorale.

Publication 5 :

**“Exposure to Ionizing Radiation in Patients Undergoing Transfemoral Transcatheter
Aortic Valve Implantation”**

Aurélien Villecourt, Laurent Faroux, Thierry Blanpain, Marine Kinnel, Caroline Mora,
Sophie Tassan-Mangina, Virginie Heroguelle, Pierre Nazeyrollas, Damien Metz

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Exposure to Ionizing Radiation in Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation



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Transcatheter aortic valve implantation (TAVI) is currently becoming an alternative to surgical valve replacement for patients at low risk, a population that is likely to experience an increase in the radiation-induced cancer risk following TAVI. We aimed to evaluate the overall exposure to ionizing radiation in patients who underwent transfemoral TAVI, including the procedure itself as well as the procedures performed in the preintervention work-up and the post-TAVI interventions. All patients who underwent transfemoral TAVI for symptomatic aortic stenosis in our center over a 26 months period were included. Dosimetric indicators from preprocedural coronary angiography and computed tomography (CT), the TAVI procedure, and any postprocedural interventions (electrophysiology study and/or pacemaker implantation) were collected and converted into an effective dose. A total of 119 transfemoral TAVI procedures were included. The mean cumulative effective dose (ED) was 37.3 mSv. Three irradiating procedures were necessary for 84 patients (71% of the population, i.e., coronary angiography, CT scan and the TAVI procedure itself), whereas 30 patients (25%) required a fourth procedure, and 5 required a fifth (4%). The majority of the dose was from the CT, while only 11% of the dose derived from the TAVI procedure itself. In conclusion, overall exposure to ionizing radiation for patients who underwent transfemoral TAVI seems acceptable, and the majority of the overall ED comes from the CT scan. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;125:114–119)

Since the first description of transcatheter aortic valve implantation (TAVI) performed in man in 2002 by Alain Cribier's team,¹ this technique has developed, and its use expanded at a very rapid pace. Initially reserved for inoperable patients, TAVI is now recommended as first-line therapy in intermediate-to-high risk patients this,^{2,3} with the ultimate aim of positioning TAVI as first-line therapy in all patients over 65 years with symptomatic aortic stenosis (AS).^{4,5} In this context, study of the exposure to ionizing radiation of patients undergoing TAVI is increasingly important. Indeed, X-rays are widely used in the TAVI care pathway, for the pre-TAVI assessment (coronary angiography and computed tomography [CT]), and sometimes after the intervention (electrophysiology study, pacemaker implantation). In the past, several studies have focused on radiation exposure of patients who underwent TAVI and reported that the TAVI procedure itself was approximately equivalent to a complex percutaneous coronary intervention in terms of X-ray exposure.^{6–11} However, to the best of our knowledge, no study has investigated the cumulative

effective dose (ED) received by patients who underwent TAVI, including the procedure itself as well as the procedures performed in the preintervention work-up and the post-TAVI interventions. We sought therefore to evaluate the overall exposure to ionizing radiation of patients who underwent transfemoral TAVI. The secondary objective was to identify the factors that influence this exposure.

Methods

This was a retrospective cohort study, including 119 transfemoral TAVI performed in our center between November 2015 and December 2017. Clinical, echocardiographic, biological, and dosimetric data were retrospectively compiled using medical records and the DACS of our center (Dosimetry Archiving and Communication System, Medsquare, Paris, France). All patients have given, at the time of their hospitalisation, their informed consent for an anonymous retrospective use of their medical data.

In addition to the clinical, biological, and echocardiographic assessment, pre-TAVI assessment included at least 1 diagnostic coronary angiography, with nonsystematic ventriculography, arteriography of the ascending aorta and/or arteriography of the aortoiliac junction. If a tight stenosis was identified on a main coronary vessel, coronary angioplasty was performed during the initial coronary angiography, or during a second (subsequent) coronary angiography procedure, or in exception cases, during a third procedure. All the coronary angiographies were performed on one of the 2 catheterization laboratories (cathlab) used on a daily

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See page 118 for disclosure information.

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basis in our center and equipped with Allura Xper FD10 (cathlab A) (Philips Healthcare, The Netherlands, in service since January 2011) or Allura Xper FD10 Clarity (cathlab B) equipment (Philips Healthcare, The Netherlands, in service since March 2015). Both cathlabs are equipped with flat detectors with the same technical characteristics (frame rate of 7.5 frames-per-second [fps] for coronary angiography and 15 fps for ventricular angiography and aortography, 20 cm size of field). A retrospectively ECG-gated synchronized angiographic CT scan focused on the aortic root, immediately followed by a non-ECG-synchronized angiographic CT from the mandible to the root of the thigh for the analysis of the aortic, supra-aortic and iliofemoral arterial networks, were systematically performed on a dual energy CT Discovery 750 HD scanner (General Electric, Massachusetts, in service since April 2012). Interventional strategy, type, and size of the prosthetic valve, vascular approach (percutaneous or surgical) was determined upstream by the heart-team, based on the clinical data and the CT images. All TAVI procedures were performed in cathlab B with a frame rate of 7.5 fps (20 cm size of field), under locoregional anesthesia, by 2 interventional cardiologists assisted by a cardiothoracic surgeon and an anesthesiologist. Depending on the occurrence of conduction disorders during or after TAVI, an electrophysiology study and/or implantation of a pacemaker could be performed after collegial discussion and depending on the persistence of the conduction disorders. These interventions were performed with an Arcadis X-ray system (Siemens Healthcare, Germany, in service since January 2011), with a frame rate of 4 fps and a field size of 33 cm.

Depending of the type of irradiating procedure, 2 dose estimators are provided by the apparatus. In order to homogenize doses and to enable calculation of a cumulative dose, we converted these estimators into an ED. The Dose Area Product (DAP), expressed in $\text{cGy}\cdot\text{cm}^2$, used in cardiology and interventional radiology, is a synthetic dose indicator expressing the total amount of energy delivered to the patient. A simplified formula makes it possible to estimate the ED from the DAP: $\text{ED (mSv)} = \text{DAP (cGy}\cdot\text{cm}^2) \times 0.002 (\text{mSv}/\text{cGy}\cdot\text{cm}^2)$.^{12,13} CT uses another estimator determined by the anatomic region studied, the Dose Length Product (DLP), expressed in $\text{Gy}\cdot\text{cm}$. The following formula proposed by Christner et al directly converts DLP into ED: $\text{ED (mSv)} = \text{DLP (mGy}\cdot\text{cm}) \times 0.021 (\text{mSv}/\text{mGy}\cdot\text{cm})$.^{12–14} The primary end point was the cumulative ED, calculated by summing ED received during the TAVI procedure and those received during preintervention work-up and post-TAVI interventions.

Quantitative variables are described as mean $\pm$ standard deviation and qualitative variables as number (percentage). Quantitative variables were compared using the Student *t* test if normally distributed, or the nonparametric Mann-Whitney test if not normally distributed. Qualitative variables were compared using Fisher's exact or the chi-square test as appropriate. Relations between quantitative variables were investigated using simple linear regression. Multivariate analysis was performed using a generalized linear regression including all variables related to the primary end point with a *p* value <0.20 by univariate analysis. All analyses were performed using SPSS version 21 (IBM SPSS

Statistics, Chicago, Illinois). A *p* value <0.05 was considered statistically significant; all tests were 2-sided.

Results

A total of 119 patients who underwent transfemoral TAVI in our center over the 26 months study period were included, aged 68 to 94 years, with a balanced distribution between male and female patients. Table 1 presents the main characteristics of the study population. Average Euroscore I was 13.3%, left ventricular ejection fraction ranged from 25% to 80% with an average mean transaortic gradient of 45 mm Hg and an average aortic valve area of 0.7 cm^2 as measured by transthoracic echocardiography. Average body mass index was $27.3 \text{ kg}/\text{m}^2$, for an average body surface area (BSA) of 1.84 m^2 .

All patients underwent at least 1 coronary angiogram, 11 patients required a second coronary angiography, and only 1 patient required a third. All patients underwent a single synchronized CT of the aortic valve and aortoiliac/femoral axis. The majority of valves implanted were balloon-expandable (81%), and balloon aortic valvuloplasty (BAV) was performed in 53% of the population. After implantation, 5 patients underwent an electrophysiology study (4%), and 24 required a pacemaker (20%). Three irradiating procedures were necessary for 84 patients (71% of the population, i.e., coronary angiography, CT scan, and the TAVI procedure itself), whereas 30 patients (25%) required a fourth procedure, and 5 required a fifth (4%).

The overall ED ranged from 15.4 to 79 mSv, with an average of 37.3 mSv. ED and DAP or DLP of each type of irradiating procedure are shown in Table 2. In the most frequent situation where only 3 procedures were necessary, the majority of the exposure was related to the CT scan (75% of the overall ED), followed by coronary angiography and TAVI, respectively 14% and 11% (Figure 1).

Table 1
Characteristics of the study population

Variable	All (n = 119)
Women	60 (51%)
Age (years)	83.9 ± 4.8
Body mass index (kg/m^2)	27.3 ± 4.9
Body surface area (m^2)	1.8 ± 0.2
Hypertension	92 (77%)
Dyslipidemia*	60 (50%)
Diabetes mellitus	39 (33%)
Chronic kidney disease	14 (12%)
Previous coronary artery disease	30 (25%)
Previous peripheral artery disease	24 (20%)
Euroscore I (%)	13.3 ± 11.3
Left ventricular ejection fraction (%)	56.9 ± 11.6
Aortic valve area (cm^2)	0.7 ± 0.2
Mean aortic valve gradient (mm Hg)	45.1 ± 14.3
NYHA >2	61 (51%)
Angina pectoris	4 (3%)
Syncopal	18 (15%)
Balloon aortic valvuloplasty	63 (53%)
Self-expanding valve	23 (19%)
Valve-in-valve	5 (4%)

* Dyslipidaemia correspond to a low-density lipoprotein cholesterol level $>3 \text{ mmol}/\text{L}$.

Table 2
Dosimetric data

Variable	All (n = 119)
Overall effective dose	119 (100%)
Min-Max	15.4 - 79.0
Mean (mSv)	37.3 ± 11.8
Coronary angiography #1	119 (100%)
DAP (cGy.cm ²)	2741.5 ± 1890.2
ED (mSv)	5.5 ± 3.8
Coronary angiography #2	10 (8%)
DAP (cGy.cm ²)	3865.2 ± 2493.5
ED (mSv)	7.7 ± 5.0
Coronary angiography #3	1 (0.8%)
DAP (cGy.cm ²)	7948.0
ED (mSv)	15.9
Computed tomography	119 (100%)
DLP (mGy.cm)	1280.2 ± 382.4
ED (mSv)	26.9 ± 8.0
TAVI procedure	119 (100%)
DAP (cGy.cm ²)	2006.3 ± 1152.2
ED (mSv)	4.0 ± 2.3
Electrophysiology study	5 (4%)
DAP (cGy.cm ²)	201.5 ± 160.0
ED (mSv)	0.4 ± 0.3
Pacemaker implantation	24 (20%)
DAP (cGy.cm ²)	396.1 ± 261.1
ED (mSv)	0.8 ± 0.5

DAP = dose area product; DLP = dose length product; ED = effective dose; Max = maximum; Min = minimum; TAVI = transcatheter aortic valve implantation.

By univariate analysis, the overall ED was significantly related to gender ($p=0.001$), age ($p=0.003$), BSA ($p<0.001$), current smoking ($p=0.03$), arterial hypertension ($p=0.02$), diabetes mellitus ($p=0.03$), and sleep apnea ($p=0.02$). It was also associated with the mean transaortic gradient as measured by transthoracic echocardiography ($p=0.003$). In contrast, left ventricular ejection fraction, chronic obstructive pulmonary disease, dyslipidemia, severe chronic kidney disease and peripheral artery disease were not related to overall ED, nor were TAVI-related parameters such as BAV, use of a self-expanding valve or valve-in-valve procedures. After adjustment, only BSA was significantly related to the overall ED ($p<0.001$) (Table 3). Figure 2 shows the linear regression curve of overall ED for

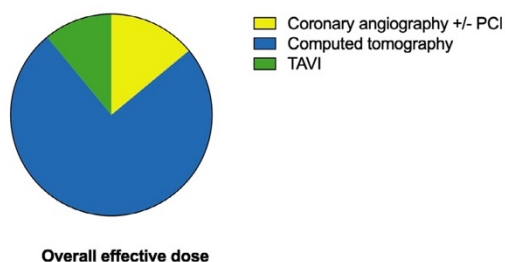


Figure 1. Graphical representation of the percentage of overall effective dose attributable to preprocedural coronary angiography, CT and TAVI procedure for patients who benefited from 3 irradiating procedures (71% of the population). CT: Computed tomography; PCI = percutaneous coronary intervention; TAVI = transcatheter aortic valve implantation.

Table 3
Multivariate analysis

Dependent variable: Overall effective dose	Beta	Standard error	p Value
Age*	-0.4	0.2	0.8
Female	-1.9	1.8	0.3
Body surface area [†]	29.6	4.4	<0.001
Current smoker	6.9	4.1	0.09
Hypertension	2.1	1.9	0.3
Diabetes mellitus	-0.3	1.9	0.9
Sleep apnea	0.8	2.7	0.8
Mean aortic valve gradient [‡]	-0.1	0.1	0.06

* Per 1 year increase.

[†] Per 1 m² increase.

[‡] Per 1 mm Hg increase.

the BSA, with a strong correlation between these 2 variables ($R^2 = 0.46$).

Discussion

In the present study, the overall ED received by patients undergoing transfemoral TAVI seems acceptable, with an average overall ED of 37.3 mSv. The average ED of irradiating procedures frequently performed in cardiology is presented in Figure 3.¹² The mean cumulative ED appears to be greater than ED during coronary angioplasty (15 mSv), atrial fibrillation ablation (15.2 mSv) or cardiac resynchronization therapy implantation (22 mSv). However, mean cumulative ED was lower than ED during Thallium stress/rest reinjection myocardial perfusion SPECT (40.7 mSv), iliac angioplasty (58 mSv) or coronary chronic total occlusion angioplasty (81 mSv).¹² To the best of our knowledge, our study is the first to consider the overall ED received by patients undergoing TAVI, and not only the DAP or Air Kerma during the TAVI procedure.

Medical procedures are the primary source of exposure to ionizing radiation in the general population, with an average ED of 3 mSv per person per year (equivalent to 150 chest X-rays) compared with 2.4 mSv of natural irradiation.^{12,13} Given the absence of a known threshold dose for the occurrence of stochastic effects (primarily

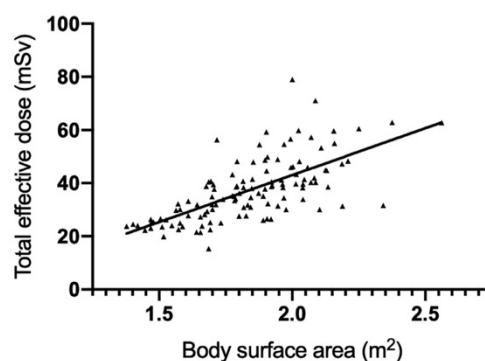


Figure 2. Linear regression of the overall effective dose and the body surface area ($R^2 = 0.46$).

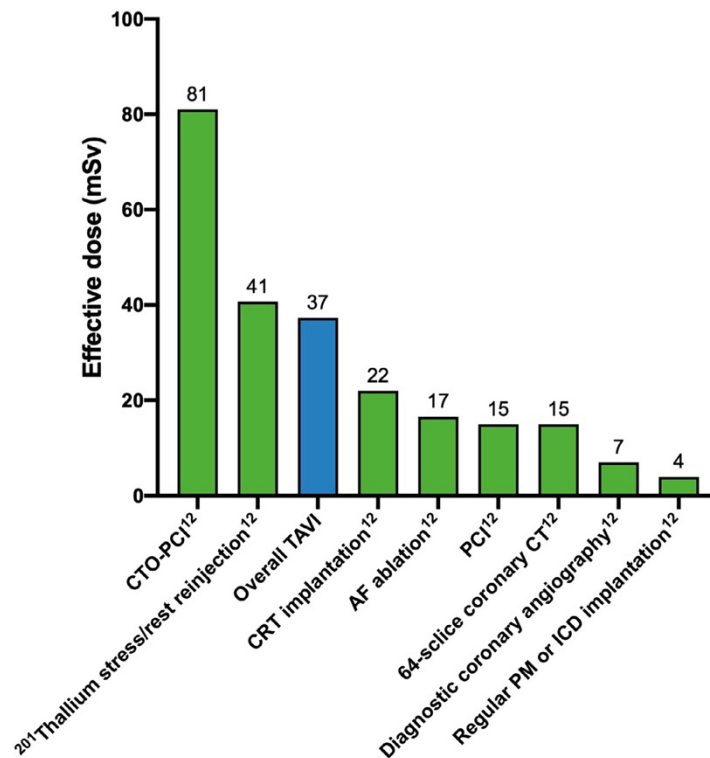


Figure 3. Comparison of the overall effective dose received by patients benefiting from a TAVI with the reference standards for daily cardiologic procedures.¹² AF = atrial fibrillation; CRT = cardiac resynchronization therapy; CT = computed tomography; CTO = chronic total occlusion; ICD = implantable cardioverter-defibrillator; PCI = percutaneous coronary intervention; PM = pacemaker; TAVI = transcatheter aortic valve implantation.

radiation-induced cancers), the ALARA principle (As Low As Reasonably Achievable) is recommended for all medical procedures using ionizing radiation.^{13,15–17} TAVI exposes patients to repeated irradiating procedures, and the extension of its indications to patients at intermediate-to-low surgical risk prompted us to study the exposure of these patients to ionizing radiation, particularly the risk of occurrence of stochastic effects estimated by the ED. As intermediate and low risk patients are generally younger, they are likely to experience an increase in their risk of radiation-induced cancer following TAVI. The overall radiation exposure has therefore to be included in the decision making of TAVI in young patients such as valve-in-valve TAVI.

When 3 irradiations procedures were performed during the work-up for TAVI (71% of the population), patients were exposed to only 11% of the overall ED during the TAVI procedure itself, whereas the CT scan accounted for 75% of the overall ED. Although patient exposure to X-rays during TAVI remains a potential subject of interest, it seems that in the future, if the objective is to reduce patients' exposure to radiation, then it will be necessary to concentrate greater efforts on the dose delivered during CT. Patients who underwent TAVI were ever younger, and it

behaves manufacturers to propose innovative CT machines that will make it possible to reduce the dose deliver, and thus contribution to preventing the potential side effects related to radiation for our patients. Prospective gating for the chest portion of the CT scan,¹⁸ dual source multidetector CT-angiography using a high-pitch spiral acquisition mode^{19,20} and the use of an automated tube voltage selection²¹ have promising clinical data. Finally, CT remains the cornerstone of the pre-TAVI work-up since it provides information about annulus size, peripheral access, coexisting coronary artery disease,²² and the calcium score, particularly in paradoxical low-flow low-gradient aortic stenosis.^{2,3}

In the present study, mean DAP during TAVI procedures was about 2000 cGy.cm² whereas several studies reported a higher DAP, between 5000 and 10000 cGy.cm².^{10,23,24} This difference could be explained by the fact that all our TAVI procedures was performed in a modern cathlab equipped with a dose-reduction system that has been shown to achieve a spectacular reduction in the estimated dose of radiation received by both patient and physician.^{9,25,26}

In our study, only the BSA was independently and strongly correlated with the overall ED. In contrast, while some variables were associated with the ED by univariate

analysis, they were no longer associated by multivariate analysis. As the majority of the cumulative ED was accounted for by the CT, it is not surprising to find that technical procedure-related criteria such as the mean trans-aortic gradient, the presence of peripheral artery disease, the need for BAV or a valve-in-valve procedure were not related to the overall ED by multivariate analysis.

This study had the limitations inherent to a retrospective observational study without randomization. However, we present complete dosimetric data (with no missing data) from a homogeneous cohort of patients who underwent transfemoral TAVI. We thus provide an estimation of the overall ED received by the patients, which has never previously been reported, to the best of our knowledge. Coronary CT has emerged as a reasonable alternative to coronary angiography for the evaluation of coronary artery disease pre-TAVI,²² and some centers decide to perform a pre-TAVI coronary angiography depending on patient's history, symptoms, and pre-TAVI coronary CT findings. In our study, all patients benefited from a pre-TAVI coronary angiography, thus we may slightly overestimate the overall ED. Finally, some patients had cardiologic and noncardio-vascular conditions which could have exposed them to examinations using ionizing radiations in the months before TAVI, but this previous burden was not taken into account in the present study. This limitation led us to underestimate the overall ED.

The overall exposure to ionizing radiation for patients who underwent TAVI, including not only the TAVI procedure itself, but also the pre-TAVI work-up and post-TAVI interventions (e.g., in case of conduction disorders) appears to be acceptable in relation to the reference standards for irradiating procedures performed in cardiology. Patients were exposed to only 11% of the overall ED during the TAVI procedure itself, whereas the CT scan accounted for 75% of the overall ED.

Disclosures

There are no relationships with industry to disclose.

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2. Impact de l'approche artérielle et du type de valve sur l'exposition aux rayons X au cours du remplacement valvulaire aortique percutané

Enfin, nous avons étudié l'impact de l'approche artérielle (fémorale versus carotide) et du type de valve (expansible par ballonnet versus auto-expansible) sur l'exposition aux rayons X au cours des procédures TAVI. Ce travail a fait l'objet d'une publication dans *Annals of Thoracic Surgery* (50).

RÉSUMÉ

Plusieurs types de valves prothétiques sont actuellement disponible pour la réalisation d'un TAVI, avec des différences importantes dans la gestion des abords artériels, les manœuvres nécessaires pour amener la prothèse valvulaire jusqu'à la valve native du patient ainsi que dans la technique pour délivrer la prothèse. Cependant, l'impact du type de valve sur l'exposition aux rayonnements des patients et des opérateurs n'a jamais été étudiée. Par ailleurs, les accès alternatifs carotide et sous-clavier s'imposent actuellement comme étant les approches à privilégier lorsqu'un TAVI par voie trans-fémorale (TF) n'est pas faisable (48, 49). Cependant, l'impact de ces nouveaux accès artériels sur l'exposition aux rayons X des patients et des opérateurs est inconnu. Nous avons donc souhaité déterminer l'impact de l'approche artérielle et du type de prothèse valvulaire sur l'exposition aux rayonnements des opérateurs et des patients au cours des TAVI.

Par conséquent, nous avons mis en place une étude prospective incluant 140 procédures de TAVI consécutives réalisées par voie TF (n=102) ou trans-carotide (TC) (n=38) dans 2 centres (Institut de Cardiologie et de Pneumologie de Québec, Québec, Canada, et Centre Hospitalier Universitaire de Reims, France). Les valves implantées étaient les valves auto-expansibles Evolut R/PRO (Medtronic, Minneapolis, Minnesota, USA; n=38) ainsi que les valves expansibles par ballonnet SAPIEN 3 (Edwards Lifesciences, Irvine, Californie, USA; n=102). Le critère de jugement principal était l'exposition aux rayonnements des opérateurs, évaluées à l'aide d'un dosimètre électronique positionné à l'extérieur de tout dispositif de protection individuel. Le critère de jugement secondaire était l'exposition aux rayons X des patients estimée par le PDS.

Au cours des TAVI réalisés par voie TC, l'exposition des opérateurs était 4 fois plus important qu'au cours des TAVI réalisés par voie TF ($p<0,001$). L'utilisation d'une valve auto-expansible était associée à un temps de rayons X plus important ($p=0,015$) et à une dose reçue par le premier opérateur 2 fois plus importante qu'avec les valves expansibles par ballonnet ($p=0,018$). L'exposition des patients n'était pas significativement associée à l'approche artérielle ($p=0,055$) ou au type de valve ($p=0,095$). Après ajustement sur les potentiels facteurs de confusion, l'approche TC restait associée à une dose reçue par le premier opérateur 174,8% (intervalle de confiance à 95% : 80,6 à 318,3%, $p<0,001$) supérieure à celle reçue au cours des TAVI par voie TF, alors que le type de valve n'influait plus l'exposition des opérateurs ($p=0,630$).

Nos résultats soulignent la nécessité de développer de nouveaux outils de protection afin de diminuer la dose de rayonnements reçue par les opérateurs au cours des TAVI réalisés par un abord non-TF. Par ailleurs, l'exposition des patients aux rayonnements n'était pas significativement influencée par l'abord artériel. Ces résultats fournissent une preuve supplémentaire de la sécurité des TAVI réalisés par voie trans-carotide.

Publication 6 :

“Radiation Exposure During TAVR: Impact of Arterial Approach and Prosthesis Type”

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Annals of Thoracic Surgery. 2021;111:1601-1606. (IF=3,639)

Radiation Exposure During Transcatheter Aortic Valve Replacement: Impact of Arterial Approach and Prosthesis Type

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Background. The impact of novel alternative access and valve type on radiation exposure during transcatheter aortic valve replacement (TAVR) has not yet been evaluated. This study sought to determine the impact of a transarterial approach and prosthesis type on physician and patient exposure to radiation during TAVR.

Methods. This was a prospective study including 140 consecutive patients undergoing TAVR by transfemoral ($n = 102$) or transcarotid (TC) ($n = 38$) access at 2 centers. Implanted valves were the self-expanding Evolut R/PRO system (Medtronic, Minneapolis, MN; $n = 38$) and the balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA; $n = 102$). The primary endpoint was first operator radiation exposure. The secondary endpoint was patient radiation exposure.

Results. First operator radiation exposure was 4-fold greater during TC TAVR ($P < .001$). The use of a self-expanding valve was associated with a longer x-ray

time ($P = .015$) and a 2-fold greater first operator radiation dose ($P = .018$). Patient radiation dose was not significantly affected by an arterial approach ($P = .055$) or valve type ($P = .095$). After adjustment for potential confounders, the TC approach remained associated with a 174.8% (95% confidence interval, 80.6-318.3, $P < .001$) increase in first operator radiation dose, whereas the use of a self-expanding valve no longer influenced the first operator dose ($P = .630$).

Conclusions. TC access and the use of a self-expanding valve were associated with a 4- and 2-fold greater first operator radiation exposure during TAVR procedures, respectively. Unlike the arterial approach, the effect of bioprosthesis type on radiation exposure was mainly related to x-ray time and was no longer significant after adjustment.

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Numerous studies have investigated radiation exposure during coronary angiography and percutaneous coronary intervention,¹ but scarce data exist on radiation exposure during transcatheter aortic valve replacement (TAVR). This topic is of growing interest because the expansion of TAVR toward the treatment of younger and lower risk patients with a much longer life expectancy may be associated with an increased risk of stochastic adverse effects related to x-rays (ie, radiation-induced neoplasm).^{2,3} In addition, heart team operators are exposed to important doses of radiation that may

increase their risk of developing cataracts and left-sided brain and neck tumors,⁴⁻⁶ and the current expansion of TAVR indications and volume is likely to further increase such exposure.

Dr Rodés-Cabau discloses a financial relationship with Edwards Lifesciences, Medtronic, and Boston Scientific; Dr Faroux with Biotronik, Edwards Lifesciences, and Medtronic.

The Supplemental Table can be viewed in the online version of this article [<https://doi.org/10.1016/j.athoracsurg.2020.06.114>] on <http://www.annalsthoracicsurgery.org>.

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Transcatheter (TC) and transsubclavian approaches offer a direct route to the aortic valve while avoiding thoracotomy, and recent data suggest that these arterial approaches should be the preferred alternative access in patients not suitable for transfemoral (TF) TAVR.⁷⁻¹⁰ Data on radiation exposure during TAVR procedures have been limited to TF, transaortic, and transapical approaches.¹¹⁻¹⁶ Also it has been shown that patient radiation exposure was greater with the use of the self-expanding CoreValve Revalving system (Medtronic, Minneapolis, MN) compared with balloon-expandable SAPIEN valves (Edwards Lifesciences, Irvine, CA),^{17,18} but the impact of newer generation prosthesis type on physician radiation exposure remains unclear. The aim of this study was to investigate the impact of the transarterial approach and prosthesis type on physician and patient exposure to radiation during TAVR.

Patients and Methods

Study Population

The present study prospectively collected data on 140 consecutive patients undergoing TAVR at 2 centers between February and July 2019. Patients received either self-expanding (Evolut R or Evolut Pro; Medtronic) or balloon-expandable (SAPIEN 3; Edwards Lifesciences) valves.

TAVR Procedures

Type and size of the prosthetic valve, interventional strategy, and arterial approach were determined by the multidisciplinary heart team at each center. Whenever anatomically feasible TF was considered as the default approach. TC access was the favored alternative approach in both centers, and no transaortic or transapical TAVR procedures were performed during the study period. TAVR procedures were performed in a hybrid operating room equipped with a Philips Azurion Clarity IQ system (Philips Healthcare, Eindhoven, The Netherlands), a

catheterization laboratory equipped with a Siemens Axiom Artis system (Siemens Healthineers, Erlangen, Germany), or an operating room equipped with a Philips Veradius system (Philips Healthcare). Frame rates were 7.5 fps for fluoroscopy and 7.5 to 15 fps for cine acquisition. All rooms were equipped with lead screens and table drapes, and all operators wore a leaded apron and a thyroid shield. Standard protective measures, such as keeping a maximum distance between the patient's thorax and the operator and minimization of the field of view, were equally applied in all cases.

Radiation Dose Measurement

The primary endpoint was first operator radiation exposure measured using personal electronic dosimeters (EPD Mk2; APVL, Saint-Cyr-sur-Loire, France) following International Electrotechnical Commission 61526:2010 standards. This dosimeter has an energy response between 15 keV and 1.5 MeV and a dose range from 0 to 9999 mSv in increments of 0.1 μ Sv. To optimize angular response the dosimeter position has to be at an angle of 0 degrees in relation to the radiation source, namely the patient's chest in this instance. The dosimeter was therefore located on the physician's chest for the first and second operator during TC TAVR and on the physician's left arm for the third operator during TC TAVR and for all operators during TF TAVR (Figure 1). The dosimeters were located outside of personal protective equipment (leaded apron and thyroid shield) to avoid any variation in relation to the thickness of leaded apron.

Radiation doses were recorded at the end of each procedure and entered in a dedicated dataset. This radiation dose corresponded to the dose received at 10 mm under the site of the dosimeter (HP10) and represents the probability of stochastic health effects from radiation (ie, radio-induced neoplasm). The secondary endpoint was patient radiation exposure assessed by the dose-area product calculated on the basis of the ionization chamber at the tube's exit.

Figure 1. Position of the first, second, and third operators during transcatheter aortic valve replacement. (A) Transfemoral procedures; (B) transcatheter procedures. (Op, operator.)

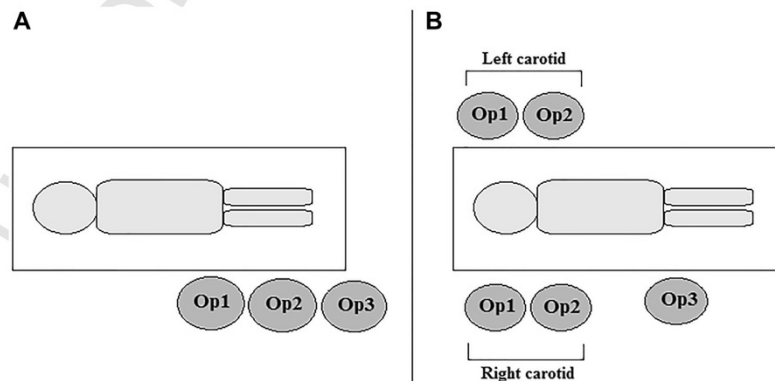


Table 1. Population and Procedural Characteristics (N = 140)

Characteristic	Value
Age, y	81 (74-85)
Male	81 (57.9)
Weight, kg	75 (63.5-87.5)
Height, cm	165 (157-172)
Body mass index, kg/m ²	27.0 (23.9-31.3)
Euroscore I, %	9.6 (5.8-17.8)
Left ventricular ejection fraction, %	60 (50-60)
Mean aortic valve gradient, mm Hg	44 (34-55)
Aortic valve area, cm ²	0.70 (0.60-0.80)
Arterial approach	
Transfemoral	102 (72.9)
Right side/left side	77 (75.5)/25 (24.5)
Transcarotid	38 (27.1)
Right side/left side	12 (31.6)/26 (68.4)
Valve type	
Self-expanding	38 (27.1)
Balloon-expandable	102 (72.9)
Valve size	
23 mm	45 (32.1)
26 mm	54 (38.6)
29 mm	36 (25.7)
34 mm	5 (3.6)
Procedural characteristics	
Hybrid operating room	98 (70)
Catheterization laboratory	21 (22.1)
Operating room	11 (7.9)
Predilatation	49 (35)
Valve-in-valve	14 (10)

Values are n (%) or median (interquartile range) unless otherwise defined.

Statistical Analysis

Categorical variables were expressed as number (percentage) and continuous variables as median (interquartile range). Categorical variables were compared using a χ^2 or Fisher exact test as appropriate. Numerical variables were compared with the Student *t* test or Mann-Whitney nonparametric U test according to their distribution (assessed by the Kolmogorov-Smirnov test). To identify factors independently associated with first operator radiation exposure, a multivariable analysis was

performed using a generalized linear regression model adjusted for the room (ie, hybrid room, catheterization laboratory, or operating room). The response in the multiple regression model needed to be log transformed for normality of residuals to be met. The final model was selected with backward elimination, with valve type (balloon-expandable or self-expanding) as a forced variable and keeping only the significant variables at $P < .05$. In view of the risk of collinearity between first operator and patient radiation exposure, dose-area product was not included in the multivariable model. Statistical analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC) and Prism version 8.1.2 (GraphPad Software, San Diego, CA).

Results

Study Population

Main baseline and procedural data are shown in Table 1. During the study period 102 TF and 38 TC consecutive patients underwent TAVR at the 2 participating centers and were included in the study. TF TAVR was performed in a hybrid operating room and catheterization laboratory in 69.6% and 30.4% of cases, respectively. TC TAVR was performed in a hybrid operating room and an operating room in 71.1% and 28.9% of cases, respectively. Comparison of procedural characteristics according to participating center are presented in Supplemental Table 1. Neither median x-ray time nor valve type (self-expanding or balloon-expandable) differed between the 2 centers ($P = .494$ and $P = .064$, respectively), but rate of TC access was different (33.3% vs 13.6%, $P = .023$).

Impact of Arterial Access

Comparison between TF and TC access is presented in Table 2. The radiation dose received by the first operator was 4-fold greater during TC TAVR ($P < .001$) (Figure 2). In addition second and third operator radiation doses were also significantly greater during TC procedures ($P < .001$). X-ray time and patient radiation tended to be higher in TF (vs TC) procedures ($P = .058$ and $P = .055$, respectively).

Impact of Valve Type

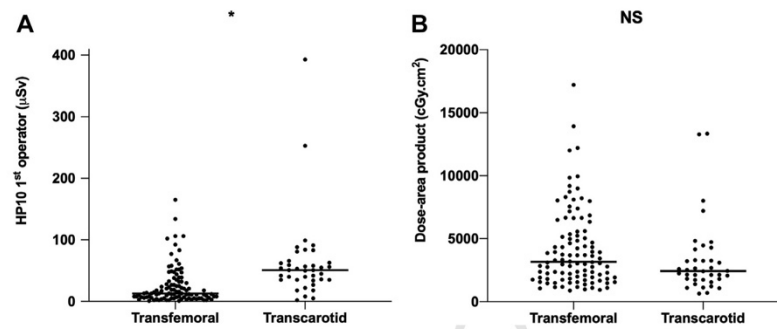
Table 3 shows the comparison of procedures with self-expanding (27.1%) and balloon-expandable (72.9%)

Table 2. Radiation Exposure According to Arterial Approach

	Overall (N = 140)	Transfemoral (n = 102)	Transcarotid (n = 38)	P
X-ray time, min	12.2 (9.3-17.0)	11.8 (8.6-15.4)	14.6 (9.8-20.5)	.058
Patient exposure				
Dose-area product, cGy/cm ²	2983.5 (1821.3-4823.5)	3169.6 (1910.0-5356.5)	2437.5 (1741.0-3300.0)	.055
Operator exposure				
HP10 first operator, μ Sv	21 (8-51)	13 (6-32)	51 (35-63)	<.001
HP10 second operator, μ Sv	6 (2-18)	5 (2-14)	14 (6-27)	<.001
HP10 third operator, μ Sv	2 (0-7)	1 (0-3)	16 (7-31)	<.001

Values are median (interquartile range).

Figure 2. Comparison of transfemoral and transcatheter aortic valve replacement. (A) First operator radiation dose. (B) Patient radiation dose. * $P < .001$. (NS, not significant.)



valves. The first operator received twice as much radiation dose with the use of self-expanding versus balloon-expandable valves ($P = .018$), but patient radiation dose did not differ between valve types ($P = .095$) (Figure 3). The x-ray time was significantly higher during TAVR with a self-expanding valve ($P = .015$).

Multivariable Analysis

Results of the multivariable analysis adjusted for room are shown in Table 4. TC approach, x-ray time, and body mass index were associated with first operator radiation exposure, whereas the association with prosthesis type was no longer significant after adjustment for potential confounders. As compared with TF TAVR, TC access was associated with a 174.8% increase (95% confidence interval, 80.6-318.3; $P < .001$) in first operator radiation dose. Each 1-unit increase in x-ray time and patient and body mass index were associated with 5.9% (95% confidence interval, 3.8-7.9; $P < .001$) and 2.9% (95% confidence interval, 0.8-5.0; $P = .006$) increases in first operator radiation dose, respectively.

Comment

The present study evaluates radiation exposure during TAVR procedures according to different transarterial approaches and newer generation valve types. The main findings of the study can be summarized as follows. The

first main finding was that first operator radiation exposure was 4-fold greater during TC TAVR (vs TF TAVR). Second the use of a self-expanding valve increased the radiation exposure of the first operator as much as twice compared with procedures performed with a balloon-expandable valve, and this appeared to be mainly related to an increased x-ray time. Third patient radiation exposure was not significantly influenced by arterial access or prosthesis type.

Radiation exposure of the 3 operators was significantly higher during TC versus TF TAVR, and after adjustment for the room, x-ray time, body mass index, and prosthesis type, TC TAVR remained significantly associated with an increased radiation dose received by the first operator. This difference could be explained by the inverse quadratic relation between dose and distance from the source,¹⁹ with operators being closer to the patient's chest during TC than TF TAVR. In addition the use of collective protective equipment such as a lead screen was difficult or even impossible during TC TAVR because of the proximity between the operative field and the patient's thorax. Operator radiation dose during transapical and transaortic TAVR have been reported to be higher than in TF procedures,^{11,12} and radiation exposure to physicians seems to be greater during thoracic and cervical approaches compared with the TF approach. Innovating technologies such as image noise reduction technology,²⁰ advanced image processing with fusion and calcification

Table 3. Radiation Exposure According to Valve Type

	Overall (N = 140)	Self-expanding (n = 38)	Balloon-expandable (n = 102)	P
X-ray time, min	12.2 (9.3-17.0)	15.1 (9.7-20.5)	11.6 (9.3-15.0)	.015
Patient exposure				
Dose-area product, cGy/cm ²	2983.5 (1821.3-4823.5)	4358.0 (1990.0-6492.0)	2810.5 (1809.0-4233.0)	.095
Operator exposure				
HP10 first operator, μSv	21 (8-51)	35 (17-57)	17 (7-49)	.018
HP10 second operator, μSv	6 (2-18)	13 (6-23)	2 (1-6)	.002
HP10 third operator, μSv	2 (0-7)	4 (1-11)	1 (0-7)	.095

Values are median (interquartile range).

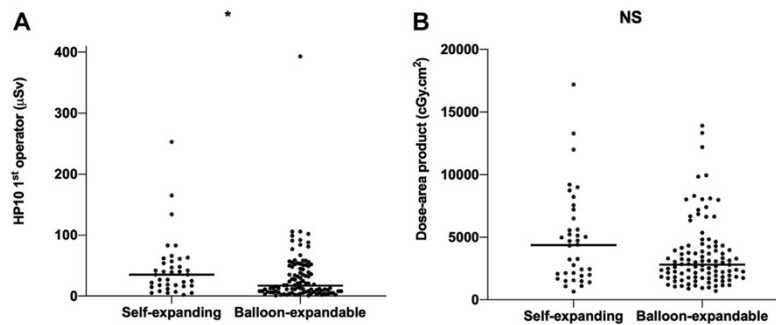


Figure 3. Comparison of self-expanding and balloon-expandable valves. (A) First operator radiation dose. (B) Patient radiation dose. * $P = .018$. (NS, not significant.)

enhancement²¹ and the RADPAD protection drape (Worldwide Innovations & Technologies, Inc, Lenexa, KS)^{13,22} are expected to reduce operator exposure during TC TAVR.

On the other hand the observed lower patient radiation exposure during TC TAVR did not reach statistical significance ($P = .055$). This could be explained by the procedural similarity between these 2 pure vascular approaches that share the same technique and steps and by the relatively small sample size of the present study. Finally this finding provides an additional evidence of the safety of TC approaches because patient radiation exposure is similar to the (gold standard) TF approach.

During TAVR using a self-expanding valve, first and second operators were exposed to a significantly higher x-ray dose compared with those procedures performed with a balloon-expandable valve. However this relationship was no longer significant after adjustment for potential confounders including x-ray time. This could be explained by the observed longer x-ray time during TAVR with a self-expanding valve, likely related to the longer bioprosthesis deployment and the possibility of valve recapture and repositioning, both requiring fluoroscopy guidance. Finally contrary to what has been shown in the past,^{17,18} the use of a self-expanding valve was not associated with increased radiation to the patient. The improved characteristics of the Evolut R/Pro system (vs the prior generation CoreValve system) facilitating appropriate valve positioning and deployment, along with the increased experience of operators, may partially explain such findings.

Study Limitations

This report consists of a prospective multicenter cohort. However data acquisition was not blinded, and a performance bias after the first included cases cannot be excluded. This bias could have decreased the observed impact of arterial approach and bioprosthesis type on radiation exposure during TAVR. Radiation exposure varies widely with beam angulation, and left anterior oblique projection is associated with the highest amount of radiation scattered because of spine interposition.²³ Tube angulation was not recorded in the present study, and this may have constituted a bias. However the 3-cusp view (which is usually a slight left anterior oblique angulation) was systematically used as the implantation projection whatever the approach or the device in both centers. Other alternative approaches, such as the subclavian route, were not evaluated because of the limited number of patients undergoing TAVR by subclavian access at participating centers. Finally differences in patient radiation exposure according to arterial approach and valve type may have not reached statistical significance because of the relatively small sample size.

Conclusion

TC (vs TF) access for TAVR was associated with a 4-fold greater operator radiation exposure of the first operator, and this increased radiation exposure remained significant after adjustment for potential confounders. These results highlight the importance of continuous efforts to improve radioprotection of heart team operators involved

Table 4. Variables Independently Associated With Log of First Operator HP10 by Multivariable Linear Regression Adjusted for the Room

	Effect (%)	95% Confidence Interval	P
X-ray time (per additional minute)	5.9	3.8-7.9	<.001
Body mass index (per 1-kg/m ² increase)	2.9	0.8-5.0	.006
Transcarotid access (vs transfemoral access)	174.8	80.6-318.3	<.001
Self-expanding valve (vs balloon-expandable)	9.0	-23.1 to 54.5	.63

in non-TF procedures. Also a higher radiation exposure of the first TAVR operator was observed with the use of the Evolut R/Pro system (vs SAPIEN 3 valve), likely secondary to a longer x-ray time. However patient radiation exposure was not significantly influenced by the arterial approach or valve type, which provides further reassurance regarding non-TF arterial alternative access during TAVR procedures.



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Discussion et perspectives

Nos travaux ont démontré que, dans le domaine de la cardiologie interventionnelle coronaire, le niveau moyen d'exposition des patients et des opérateurs avait diminué de façon importante au cours de la dernière décennie, et sera appelé à diminuer encore davantage grâce à l'amélioration constante des systèmes de rayons X. De plus, une meilleure connaissance des mesures dont dispose l'opérateur pour diminuer la dose de rayonnements délivrée, incluant une position haute de la table du patient, permettra également de réduire au niveau minimum l'exposition des patients et des praticiens aux rayons X.

Cependant, certaines procédures telles que les angioplasties de CTO et celles réalisées chez les patients ayant des pontages aorto-coronariens se distinguent par un risque de surexposition aux rayonnements, en lien avec leur complexité potentielle. Ainsi, nous sommes en attente d'obtenir les autorisations réglementaires pour débiter une étude qui visera à confronter la dose cutanée estimée par l'AK à la dose cutanée mesurée par un film Gafchromic au cours des procédures d'angioplastie de CTO. Par ailleurs, nous sommes en train de rédiger le protocole d'une étude qui visera à étudier l'impact de la stratégie de cathétérisation (fémorale, double radiale, radiale droite avec cross-over) sur les performances procédurales incluant le niveau d'exposition aux rayonnements chez les patients porteurs de pontages avec des conduits artériels mammaires gauche et droit. Les résultats de ces deux travaux apporteront des informations précieuses pour optimiser les stratégies de réduction de l'exposition aux rayonnements des patients et des opérateurs au cours des procédures les plus à risque de surexposition.

D'importantes disparités en termes de niveau d'exposition aux rayonnements ionisants en fonction du type de procédure de rythmologie et d'électrophysiologie ont été démontrées. En ce qui concerne les procédures d'électrophysiologie et les implantations de PM/DAI sans fonction de resynchronisation, l'exposition des patients est très nettement inférieure à celle observée dans le domaine de la cardiologie interventionnelle coronaire, alors que l'exposition des rythmologues est semblable à celle des cardiologues interventionnels coronaires. En revanche, au cours des procédures d'implantation de PM/DAI avec resynchronisation ventriculaire, l'exposition des patients est semblable à celle en cardiologie interventionnelle coronaire alors que l'exposition des rythmologues est très nettement supérieure à celle des cardiologues interventionnels coronaires. Certaines mesures telles que le mapping électro-anatomique (39, 40) et la reconstruction tridimensionnelle (41, 42) pourraient permettre de réduire l'exposition des patients et des opérateurs au cours des procédures de resynchronisation

ventriculaire, alors que l'utilisation de cabine de radioprotection permettrait de réduire l'exposition de l'opérateur (43).

Les procédures d'ablation de tachycardie jonctionnelle sont celles où l'exposition des patients est la plus importante, alors qu'elles s'adressent généralement à des patients jeunes, susceptibles de présenter des effets stochastiques liés aux rayonnements. Une étude visant à étudier l'impact de la voie d'abord lors de l'ablation des voies accessoires gauches (antérograde par une ponction trans-septale versus rétrograde en franchissant la valve aortique) sur l'exposition des patients aux rayonnements, le succès de procédure, les complications et les récurrences est actuellement en cours dans notre institution. Les résultats de ce travail aideront à diminuer l'exposition des patients aux rayonnements lors des procédures d'ablation de tachycardie jonctionnelle. Enfin, le fait que 95% de la dose de rayonnements reçue par les patients bénéficiant d'une ablation de fibrillation atriale par radiofréquence provienne du scanner cardiaque pré-procédural souligne l'importance d'optimiser les protocoles de scanner, de moderniser les installations, voire d'envisager le recours à une imagerie non-irradiante telle que l'imagerie par résonance magnétique.

Dans le domaine de la cardiologie interventionnelle structurale, nos travaux ont mis en évidence la participation très importante du scanner cardiaque pré-procédural à la dose globale de rayonnements reçue par les patients bénéficiant d'un TAVI par voie TF. Un nombre croissant de patients jeunes à bas risque chirurgical vont bénéficier d'un TAVI dans les années à venir, et afin de diminuer leur exposition aux rayons X (et donc leur risque de présenter un effet stochastique), il conviendra d'optimiser les protocoles scannographiques et de considérer l'utilisation d'une synchronisation prospective. Par ailleurs, les opérateurs effectuant des TAVI par voie TC sont très largement surexposés aux rayonnements ionisants, et cela s'explique par le fait que les équipements de protection utilisés au cours des TAVI TF ne sont pas utilisables lorsque l'approche est TC. Il nous faudra donc imaginer de nouvelles stratégies de radioprotection afin de diminuer l'exposition des opérateurs. Par ailleurs, la mise en place d'une valve auto-expansible est associée à un temps de rayons X plus long, et donc à une exposition plus importante aux rayonnements ionisants. La simplification de la technique de mise en place de ces dispositifs pourra permettre de diminuer la dose de rayonnements.

Enfin, outre le TAVI, de nombreuses procédures de cardiologie interventionnelle structurale ont été développées au cours de la dernière décennie. Elles portent sur les valves

mitrale et tricuspide, le septum inter-atrial ou l'auricule gauche. Ces procédures impliquent la présence d'un anesthésiste et d'un cardiologue spécialisé en échocardiographie, qui sont eux aussi exposés aux rayons X. De plus, certaines de ces procédures s'adressent à des patients jeunes, chez qui il conviendra de réduire au minimum la dose de rayonnements. Ces perspectives ouvrent la voie à de nouveaux projets de recherche dans ce domaine.

Conclusion

Les innovations dans le domaine de la cardiologie ont conduit à la réalisation d'un nombre toujours croissant de procédures faisant appel aux rayons X. Une dermite radique au niveau du dos des patients peut être observée dans les semaines suivant une procédure particulièrement longue, alors que les cardiologues présentent un risque augmenté de déclarer une cataracte radio-induite. Une augmentation du risque de cancer radio-induit lié aux procédures cardiologiques est possible pour les patients comme pour les cardiologues, mais cela n'a à ce jour pas été formellement démontré. Finalement, une connaissance précise du niveau d'exposition aux rayonnements ionisants et de ses déterminants est indispensable afin que le principe ALARA (As Low As Reasonably Achievable) puisse être appliqué en tout temps.

Les travaux menés dans le cadre de cette thèse ont démontré que, même si le niveau d'exposition a diminué au cours de la dernière décennie, des progrès peuvent encore être réalisés en modernisant les appareils à rayons X et en optimisant les pratiques de radioprotection. De même, certaines procédures sont associées à des niveaux de rayonnement particulièrement élevés (implantation de PM/DAI avec resynchronisation ventriculaire, TAVI par voie TC) et nécessitent le développement de technologies de réduction de dose telles que la cartographie et l'imagerie de fusion, ainsi que de dispositifs de protection dédiés à ces procédures qui partagent la spécificité d'une proximité importante entre le champ d'intervention et le champ d'irradiation. Enfin, lorsqu'il est requis, le scanner cardiaque pré-procédural participe de façon prédominante à la dose globale de rayonnements reçue par les patients, et de nouvelles stratégies devront être mises en œuvre afin de réduire l'exposition des patients au moment de cet examen.

L'étude de l'exposition aux rayonnements ionisants au cours des procédures émergentes de cardiologie interventionnelle structurée (MitraClip, fermeture percutanée d'appendice auriculaire gauche, fermeture percutanée du foramen ovale ou d'une communication inter-atriale) devra être réalisée. De même, des investigations visant à préciser l'impact des lunettes et visières plombées sur l'exposition du cristallin aux rayons X devront être effectuées, afin que le port de ce type de dispositif de protection individuel soit plus largement recommandé, et que son financement par les équipes de radioprotection soit généralisé. Enfin, le développement d'un carnet d'irradiation patient centralisé qui pourrait être rempli par toutes les structures médicales effectuant des actes médicaux irradiants permettrait de mieux connaître l'exposition cumulée globale des patients, et pourrait ainsi contribuer à limiter la réalisation d'examens irradiants rapprochés lorsque cela est possible.

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Les innovations dans le domaine de la cardiologie ont conduit à la réalisation d'un nombre toujours croissant de procédures faisant appel aux rayons X. Ainsi, des effets déterministes de l'exposition aux rayonnements peuvent survenir chez les patients et les opérateurs, et une augmentation du risque de cancer radio-induit est suspectée dans ce contexte. Une connaissance précise du niveau d'exposition aux rayonnements ionisants et de ses déterminants est donc indispensable afin que le principe ALARA (As Low As Reasonably Achievable) puisse être appliqué. L'objectif de ce travail de thèse était donc d'étudier le niveau d'exposition aux rayonnement ionisants des patients et des opérateurs au cours des procédures de cardiologie faisant appel aux rayons X, ainsi que de préciser les déterminants de cette exposition.

Les travaux menés dans le cadre de cette thèse ont démontré que le niveau d'exposition aux rayonnements a diminué de façon importante au cours de la dernière décennie. Toutefois, des progrès peuvent encore être réalisés, notamment en modernisant les appareils à rayons X et en appliquant les règles de radioprotection. De même, nous avons identifié des procédures associées à de hauts niveaux d'exposition aux rayonnements pour lesquelles le développement de technologies de réduction de dose et de dispositifs de protection adaptés s'impose. Enfin, lorsqu'il est requis, le scanner cardiaque pré-procédural participe de façon prédominante à la dose globale de rayonnements reçue par les patients, et de nouvelles stratégies devront être mise en œuvre afin de réduire l'exposition des patients au moment de cet examen.

Radioprotection; Cardiologie; Innovation

Radiation Protection in Interventional Cardiology: Ensuring the safety of patients and physicians to promote innovation

Innovations in cardiology have led to the performance of an ever-increasing number of procedures using X-rays. Thus, deterministic effects of radiation exposure can occur in both patients and operators, and an increased risk of radiation-induced neoplasm is suspected in this setting. An accurate knowledge of the level of exposure to ionizing radiation along with its determinants is critical in order to the ALARA (As Low As Reasonably Achievable) principle to be applied. Thus, we sought to determine the level of exposure to ionizing radiation of patients and operators during cardiology procedures using X-rays, and to assess the determinants of this exposure.

The present research showed that the level of radiation exposure has decreased significantly over the last decade. However, further progress can be achieved by modernizing X-ray equipment and applying radiation protection rules. Similarly, we have identified procedures associated with high levels of radiation exposure for which the development of dose reduction technologies and suitable protective devices is required. When performed, the pre-procedural cardiac computed tomography is the main contributor to the overall radiation dose received by patients, and new strategies will have to be implemented to reduce the exposure of patients undergoing a pre-procedural computed tomography.

Radiation protection; Cardiology; Innovation

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