Accuracy of multislice CT angiography for the assessment of in-stent restenoses in the iliac arteries at reduced dose: a phantom study

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Objective: We investigated the potential of low-dose CT angiography for accurate assessment of in-stent restenoses (ISRs) of the iliac artery.

Method: A Rando anthropomorphic phantom (Alderson Research Labs, Stanford, CA), custom-made wax simulating hyperplastic tissue and a nitinol stent were used to simulate a patient with clinically relevant iliac artery ISRs. The cylindrical lumen was filled with a solution of iodine contrast medium diluted in saline, representing a patient's blood during CT angiography. The phantom was subjected to standard- and low-dose angiographic exposures using a modern multidetector (MD) CT scanner. The percentage of ISR was determined using the profile along a line normal to the lumen axis on reconstructed images of 2 and 5 mm slice thickness. Percentage ISRs derived using the standard- and low-dose protocols were compared. In a preliminary study, seven patients with stents were subjected to standard- and low-dose MDCT angiography during follow-up. The resulting images were assessed and compared by two experienced radiologists.

Results: The accuracy in measuring the percentage ISR was found to be better than 12% for all simulated stenoses. The differences between percentage ISRs measured on images obtained at 120 kVp/160 mAs and 80 kVp/80 mAs were below 6%. Patient image sets acquired using low-exposure factors were judged to be of satisfactory diagnostic quality. The assessment of ISR did not differ significantly between image sets acquired using the standard factors and those acquired using the low-exposure factors, although the mean reduction in patient effective dose was 48%.

Conclusion: A reduction in exposure factors during MDCT angiography of the iliac artery is possible without affecting the accuracy in the determination of ISRs.

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Follow-up in patients treated with peripheral arterial stent implantation is usually performed with clinical examination, ankle-brachial index measurement, exercise testing and proof of patency using duplex ultrasonography. However, digital subtraction angiography (DSA) is still considered to be the best imaging technique for the assessment of in-stent restenosis (ISR) and stent patency in the iliac and proximal superficial femoral arteries following stent implantation as it offers the unique advantage of incorporating diagnostic confirmation and endovascular treatment in a single session. Apart from the relatively high patient radiation burden, the main disadvantage of DSA relates to its invasive nature. DSA is associated with a certain risk for potentially serious complications. Over the last few years, there has been a continuous effort to improve the safety and effectiveness of percutaneous revascularisation in peripheral arterial occlusive disease. A host of technological advances

associated with endovascular treatment have been recently developed including novel angioplasty balloons and "shape memory" nitinol stents [1]. Currently, nitinol stents are considered to be the most modern solution for revascularisation of aortoiliac and lower extremity arteries [1]. In addition, the advent of multislice CT angiography during the last few years has provided a non-invasive alternative for the assessment of stented vessels. The use of modern 16- and 64-slice CT systems was recently proven to significantly improve spatial resolution and lumen visualisation, rendering multidetector CT (MDCT) angiography a powerful tool for ISR assessment [2–8].

MDCT imaging is considered to be a high-dose diagnostic procedure resulting in absorbed doses to patient tissues of 10–100 mGy. The cumulative dose to patient tissues from multiple CT examinations may often approach or even exceed radiation dose levels known to significantly elevate the probability for cancer induction [9, 10]. MDCT systems are rather complicated systems, and appropriate adaptation of exposure factors to achieve optimisation of the examination is a complex task influenced strongly by the specific diagnostic

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demands [11]. Given that image quality in modern CT is often higher than that required to achieve diagnostic confidence [12], we felt that it would be interesting to study whether there is any potential for dose reduction in MDCT angiography imaging for ISR assessment. The purpose of the current study was to investigate the effect of reducing the exposure parameters during MDCT angiography on the assessment of clinically relevant ISR in patients with nitinol stents in the external iliac or proximal superficial femoral artery.

Methods and materials

The CT scanner

All CT exposures were performed on a Siemens Somatom Sensation 16 CT scanner (Siemens AG, Forchheim, Germany). Selectable X-ray tube potential values were 80, 100, 120 and 140 kVp. The half-value layer of the X-ray beam in the body mode of operation was 6.3 and 8.8 mm Al equivalent for 80 and 120 kVp, respectively.

The phantom

A Rando anthropomorphic phantom (Alderson Research Labs, Stanford, CA) was used to simulate a patient with ISR in the external iliac artery. The Rando phantom simulates a human body trunk from the upper third of the thighs to the vertex of an individual who is 73.5 kg in weight and 1.73 m in height. The phantom is constructed by three different materials equivalent to human bone, lung and soft tissue. A simulated human skeleton is adjusted in a mould to represent real human body contours. The internal organ built into the phantom in addition to the skeleton is the lung. Soft tissues are simulated by a material appropriately processed chemically and physically to achieve a density of 0.985 g cm^{-3} and an effective atomic number of 7.30. The phantom is sectioned transversely in 2.5 cm thick rigid slices numbered 0–34. Each slice has holes 5 mm in diameter drilled on a $3 \times 3 \text{ cm}$ grid to facilitate the positioning of thermoluminescence dosimeter chips. In addition, phantom slices have two holes 10 mm in diameter where two plastic cords are inserted to aid phantom assembly. As shown in Figure 1, the indicated 10 mm hole in slice 31 of the Rando phantom may be used to realistically simulate the stented external iliac artery of an average-sized patient. Moreover, the direction of the cylindrical hole axis realistically simulates the direction of the external iliac artery direction at that level.

Simulation of in-stent restenoses

A 10 mm nitinol stent (Luminex, Bard Corp., Natick, MA) was fitted in the 10 mm diameter hole of the Rando phantom slice 31 shown in Figure 1. The strut thickness was 0.24 mm. Therefore, the effective diameter of the simulated stented vessel was:

$$d_{\text{eff}} = (\text{tube diameter}) - 2 \times (\text{strut thickness})/2 \\ = 10 \text{ mm} - 0.24 \text{ mm} = 9.76 \text{ mm} \quad (1)$$

A cylindrical glass tube was inserted centrally and melted custom-made candle wax was applied circumferentially between the outer side of the glass tube and the inner side of the stent to simulate hyperplastic tissue causing a stenosis. Following wax solidification, the glass tube was gently removed. The degree of stenosis was regulated by the diameter of the cylindrical glass tube. We used 4 mm, 5 mm and 6 mm diameter cylindrical glass tubes to produce clinically relevant stenoses of different degrees. The nominal degree of simulated ISRs was calculated from:

$$\text{nominal ISR} = \frac{d_{\text{eff}} - d_l}{d_{\text{eff}}} \times 100\% \quad (2)$$

where d_{eff} is the effective diameter of the simulated stented vessel diameter and d_l is the diameter of the lumen. Thus, simulated ISR values were (1) 59%, (2) 49% and (3) 39%.

The candle wax was appropriately fabricated to result in a CT number close to 80 HU, which is the approximate value of real human hyperplastic tissue in CT angiography images. The remaining cylindrical lumen was filled with a solution of iodine contrast medium diluted in saline (Ultravist 300, Shering Inc., Berlin, Germany). A lumen attenuation of approximately 300 HU was achieved by appropriate dilution of contrast medium in saline. It is noted that patient blood in CT angiography images is visualised at approximately 300 HU. The entire stented vessel was also filled with the contrast medium in saline solution to simulate the vessel without any stenosis.

For each simulated vessel, a CT angiographic exposure was performed with the routine protocol, *i.e.* tube voltage=120 kV, tube loading=160 mAs, beam collimation= $16 \times 1.5 \text{ mm}$ and pitch=1. This protocol is in line with current clinical practice [2, 3, 13]. Additional exposures were performed with tube voltage and tube loading being subjected to systematic variation. The parameters of each exposure are shown in Table 1. Transverse images were reconstructed with 5 and 2 mm slice thicknesses. The profile along a line normal to the vessel axis was used to measure the effective diameter of the vessel (d_v') and the diameter of the lumen (d_l'). The diameter of the vessel was considered to be the distance between the peaks corresponding to the stent material, whereas the lumen diameter was considered to be the width of the area inside the vessel where the pixel value was above 100 HU. Measured percentage ISRs were calculated from:

$$\text{measured ISR} = \frac{d_v' - d_l'}{d_v'} \times 100\% \quad (3)$$

Measured percentage ISR values determined from CT images produced using the standard protocol were compared with corresponding values obtained from CT images produced using low-dose protocols. Measured percentage ISR values were compared with corresponding true values obtained from Equation 2.

Figure 1. Simulation of a stented iliac artery with in-stent restenosis using the indicated 10 mm hole in slice 31 of the Rando anthropomorphic phantom.

Determination of the patient effective dose from CT angiography

The effective dose associated with the CT angiography exposures of the lower pelvis described in Table 1 was determined by means of Monte Carlo simulation. We used the Monte Carlo N-Particle transport code (MCNP, v. 4C2) and a mathematical anthropomorphic phantom representing the average adult individual. The mathematical anthropomorphic phantom, suitable for Monte Carlo simulation, was generated by BodyBuilder software (White Rock Science, White Rock, NM). The MCNP 4C2 Monte Carlo code requires a user-defined input file containing energy spectrum data for the tube potential and filtration applied, the geometric characteristics of the X-ray beam, the geometric and material composition characteristics of the beam-shaping filter and the size and geometry of the dose detectors. Diagnostic energy spectra for 120, 100 and 80 kVp suitable for the MCNP input file were obtained from Boone and Siebert [14]. The boundaries of the imaged

body volume for CT angiography of the external iliac and proximal femoral artery were considered to be the terminal line of the lesser pelvis and the lower level of the pubic bones. Organ dose data were derived for both average-sized male and female individuals undergoing MDCT scanning for the assessment of ISR in the iliac artery. The effective dose was estimated using the recent recommendations of the International Committee on Radiological Protection (ICRP) [15]. The relative statistical errors of the dose data derived from Monte Carlo experiments were less than 1%.

Patient examinations

In our hospital there is an ongoing clinical study to compare MDCT angiography and DSA for the follow-up of patients treated for arterial occlusive disease of the renal, iliac and infrainguinal arteries. The present study was approved by the local ethics committee as part of the above broader study. From May 2008 to September 2008 seven patients (six male and one female) enrolled in the above clinical study underwent CT angiography for ISR assessment in the iliac or proximal superficial femoral artery during follow-up. The patients underwent a biphasic MDCT angiography protocol in the stent region after a single pump injection at a flow rate of 3.5 ml s^{-1} of 100 ml of iodinated contrast medium at a concentration of 370 mg of iodine per 100 ml.

The first phase was performed at 120 kVp/160 mAs with the standard arteriographic Combined Applications to Reduce Exposure (CARE) bolus-assisted technique. A late arterial scan at 100 kVp/160 mAs was carried out immediately after the minimal device delay of 6 s. The automatic exposure control system CARE Dose 4d was used during the late scan at 100 kVp with the maximum tube load set at 160 mAs. A relatively slow flow rate during injection was chosen to optimise vessel enhancement during the second scan. We used circular regions of

Table 1. Exposure factors of the scans performed on the phantom and resulting effective dose for the exposed individual. Pitch was 1 and beam configuration was $16 \times 1.5 \text{ mm}$ for all scans

Tube voltage (kV)	Tube load (mAs)	Effective dose (mSv)	
		Male	Female
120 ^a	160 ^a	2.5	2.7
	100	1.5	1.6
	80	1.3	1.4
100	160	1.6	1.7
	100	1.0	1.1
	80	0.8	0.9
80	160	0.8	0.8
	100	0.5	0.5
	80	0.4	0.4

^aThe standard protocol.

interest for the quantitative evaluation of lumen attenuation during both phases and excluded two cases which presented with lumen attenuation below the cut-off value of 250 HU in the late arterial scan. For the remaining five cases with sufficient late-arterial phase vessel enhancement, we obtained axial and multiplanar reconstructed images. The images were assessed by consensus between two radiologists, one who specialises in MDCT angiography and the other who specialises in interventional radiology, for arteriographic image quality, *i.e.* delineation of vascular segments and visibility of the stented lumen. The differences in diagnostic quality and ISR estimated values between the images obtained at 120 kVp and the corresponding images obtained at 100 kVp were also assessed.

Results

The effective dose to a modelled average adult individual from MDCT angiography exposures with several combinations of tube voltage–tube load values is shown in Table 1. The reconstructed 2 mm images of the simulated vessel with ISRs of 39%, 49% and 59%, obtained using the routine protocol, *i.e.* 120 kV and 160 mAs, as well as the minimum exposure factor protocol investigated, *i.e.* 80 kV and 80 mAs, are shown in Figure 2. The line profiles along the centre of the simulated vessel with no stenosis (ISR=0%) and that with a 49% stenosis are shown in Figure 3. The vessel diameter and the lumen diameter are also shown in Figure 3.

The measured percentage ISR values derived from the 2 mm and 5 mm CT images obtained using the MDCT angiography protocols investigated are shown in Table 2 for each simulated ISR. The difference in measured percentage ISR values from the corresponding true value was below 10%, 12% and 12% for the 39%, 49% and 59% simulated ISRs, respectively. The measured percentage ISR value obtained from the standard protocol differed by less than 6% from all the corresponding values obtained using the low-dose protocols.

Both the standard and low-exposure patient image sets were judged to be of satisfactory quality and adequate for safe diagnosis. Estimated values of ISR using the low-exposure image sets did not differ from corresponding values estimated using the standard exposure image sets. Images of the same patient with ISR in the proximal superficial femoral artery obtained with 120 kVp/160 mAs and 100 kV/mean tube loading =100 mAs are presented in Figure 4a and b, respectively. The average tube loading for the late scan of patients included in the current study was 132 mAs. The mean difference in effective dose to the average adult individual between the standard and the low-exposure protocol was 48%; this difference would be much higher if the tube voltage selected was 80 kVp.

Discussion

Although DSA is an invasive technique associated with a certain risk of potentially serious complications, it is still considered to be the standard imaging reference for the assessment of stent firmness and ISRs of the iliac and lower limb arteries. Most interventional radiologists would prefer to image non-invasively, plan the procedure and then proceed to DSA only with a view to intervention at the same sitting. Undoubtedly, there is a need for a non-invasive imaging technique to be used during follow-up of iliac and proximal femoral artery stents. Over the last few years, there have been several investigations of the evaluation of Doppler ultrasonography, MDCT angiography and MR angiography as alternatives to DSA for the assessment of lower limb artery ISRs [16, 17]. Despite the “blooming artefact”, which reduces the accuracy of the method in the case of heavy calcification, the use of 16-slice MDCT systems or higher has increasingly gained approval of the radiology community as a valuable alternative to DSA for the follow-up of stents in lower limb arteries [2–4, 16]. However, mixed reviews can be found in the literature

Figure 2. Images of the simulated stented iliac artery with in-stent stenosis of 39%, 49% and 59%. The first row of images were produced with 120 kVp and 160 mAs, whereas the second row of images were produced with 80 kVp and 80 mAs. The white line indicates the line along which the pixel value profile on the image was generated.

Figure 3. Pixel value profiles generated from the images of the stented iliac artery without restenosis (a) and with an in-stent restenosis of 49% (b). The measured vessel diameter and the lumen diameter are also depicted.

regarding the usefulness of MR angiography and Doppler ultrasonography [13, 16–22].

In the current study we attempted to investigate the effect of decreasing patient exposure during MDCT angiography on the assessment accuracy of the degree of ISR of the lower limb arteries. We used an anthropomorphic phantom to simulate the average patient with ISR in the iliac or proximal superficial femoral artery.

Phantom ISRs were meticulously constructed to closely mimic human ISRs by fabricating a wax with similar attenuation characteristics regarding the CT X-ray beam of our scanner to simulate the hyperplastic tissue and a contrast medium solution in normal saline with similar attenuation characteristics regarding the CT X-ray beam of our scanner to simulate the contrast medium solution in arterial blood during CT angiography imaging of a

Table 2. Measured effective vessel diameter, lumen diameter and in-stent restenosis (ISR) obtained for both 2 mm and 5 mm CT images derived from each exposure

% ISR	Tube voltage (kV)	Tube load (mAs)	Effective vessel diameter (mm)		Lumen diameter (mm)		Measured % ISR	
			ST=2 mm	ST=5 mm	ST=2 mm	ST=5 mm	ST=2 mm	ST=5 mm
39%	120	160	9.19	9.21	5.86	5.86	36	36
		100	9.16	9.16	5.96	5.57	35	39
		80	9.12	9.22	5.96	5.76	35	38
	100	160	9.14	9.18	5.96	5.66	35	38
		100	9.09	9.12	5.76	5.86	37	36
		80	9.15	9.14	5.86	5.86	36	36
	80	160	9.14	9.16	5.86	5.86	36	36
		100	9.11	9.06	5.76	5.86	37	35
		80	9.13	9.08	5.76	5.90	37	35
	120	160	9.25	9.06	5.08	4.98	45	45
		100	9.26	9.25	5.27	5.18	43	44
		80	9.35	9.25	5.27	5.27	44	43
49%	100	160	9.21	9.45	5.21	5.37	43	43
		100	9.23	9.35	5.16	5.37	44	43
		80	9.18	9.35	5.19	5.27	43	44
	80	160	9.24	9.45	5.27	5.27	43	44
		100	9.20	9.16	5.18	5.08	44	45
		80	9.18	9.45	5.27	5.37	43	43
	120	160	9.25	9.26	4.42	4.31	52	53
		100	9.21	9.22	4.41	4.39	52	52
		80	9.18	9.19	4.14	4.12	55	55
	100	160	9.20	9.27	4.23	4.23	54	54
		100	9.21	9.24	4.34	4.31	53	53
		80	9.18	9.22	4.11	4.18	55	55
59%	80	160	9.18	9.23	4.23	4.41	54	52
		100	9.14	9.26	4.18	4.25	54	54
		80	9.18	9.31	4.15	4.16	55	55

ST, slice thickness; % ISR, percentage in-stent restenosis.

Figure 4. Images of a patient with in-stent restenosis in the proximal superficial femoral artery obtained with the standard acquisition protocol 120 kVp/160 mAs (a) and lower exposure factors 100 kV/100 mAs (b).

patient. The above anthropomorphic phantom simulating a patient with ISR was subjected to standard and several low-exposure CT angiography protocols on a 16-slice CT scanner. The ISR values estimated quantitatively on the images produced using the exposure factors of the standard protocol, *i.e.* 120 kVp/160 mAs, were found to differ by less than 6% from the corresponding values estimated from images produced by each of the low-exposure protocols investigated, even for 80 kVp/80 mAs. This finding reveals a high potential for reducing exposure factors, and thus patient radiation dose burden, during MDCT angiographic studies.

In an attempt to confirm the adequacy of low-exposure protocols for MDCT angiography, we performed a preliminary patient study. A small number of patients who had undergone endovascular treatment for atherosclerotic obstructions in the iliac or proximal femoral artery were subjected, during their follow-up, to CT angiographic imaging with different exposure factors. This was achieved by performing in all these patients a biphasic CT angiography study in which a set of angiographic images was acquired with the standard protocol exposure factors, *i.e.* 120 kVp/160 mAs, and another set of angiographic images was acquired with lower exposure factors. The above image sets were evaluated by two experienced radiologists and were found to be of similar arteriographic image quality, and similarly enabled the presence and significance of ISRs to be identified. The use of a low-exposure protocol instead of the standard protocol exposure factors resulted in a mean reduction in patient effective dose burden of 48%. This is a considerable reduction in patient radiation burden given that multiple angiographic studies may be performed in the same patient during follow-up of a stented lower limb artery. The patient effective dose value from the standard protocol of MDCT angiography of the lower limb arteries was estimated in the current study to be 2.7 mSv, whereas the typical patient effective dose values from DSA has been reported to be approximately 10 mSv [2, 23]. The latter value may be considered as representative for diagnostic DSA performed in our institution given that the use of dose area product (DAP) to effective dose conversion coefficients previously published [24] for the technique and

range of DAP values recorded in our institution yield a patient effective dose range of 4–15 mSv. According to current results, the difference between the patient radiation burden associated with DSA and MDCT angiography may be significantly elevated if MDCT angiography is appropriately optimised. Apart from its non-invasiveness, an optimised MDCT angiography study is associated with a significantly lower patient radiation burden than that associated with DSA.

In our study, the degree of ISR measured on the CT images produced was in general moderately underestimated. This underestimation was in the range of 0–14%. In a previous publication, Herzog et al [13] evaluated *in vitro* to what extent 16-slice MDCT angiography allows accurate assessment of different peripheral artery stents. Their results revealed an overestimation of the ISR when the MDCT angiography images were used. For similar stents to those used in the present study, they reported the least overestimation (1.5% for the 40% and 5.3% for the 60% nominal stenoses). The different trend observed in the current study may be attributed to the different phantom simulating ISR and mainly to the different method of assessing the degree of stenosis used in the present phantom study. The standardised quantitative method for ISR estimation described in the current study is apparently different in nature from the visual assessment performed by a radiologist. Nevertheless, the absolute deviation from the nominal stenosis degree is rather minor in both studies, which enhances the evidence that the accuracy of MDCT angiography is adequate for the evaluation of the ISR. It is noted that changes in the degree of stenoses below 10% cannot be considered clinically significant.

Despite efforts to closely represent a patient with ISR in the iliac or proximal superficial femoral artery, there were still differences between the static phantom used in the current study and real human subjects regarding tissue and stent composition, presence of calcification, size, anatomy and physiological motion and flow. In addition, our model simulated only symmetrical concentric restenoses. Asymmetrical eccentric restenoses were not investigated. Finally, the effect of varying the orientation of the artery with respect to the z-axis on the ISR evaluation was not

investigated. All the above limitations inhibit direct application of the current results to MDCT angiography imaging of real human subjects. Further studies with a higher number of stented patients in the iliac or proximal superficial femoral artery should be performed to verify the adequacy of low-dose MDCT angiography protocols in the assessment of stent patency and ISR.

Conclusion

The exposure factors during MDCT angiography for the evaluation of a stented iliac or proximal superficial femoral artery may be significantly reduced without affecting the accuracy in determining the degree of ISR. Our results revealed a high potential for reducing the patient radiation burden from MDCT angiography for the evaluation of ISR to significantly less than that associated with DSA.

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