CT attenuation measurements are valuable to discriminate pledgets used in prosthetic heart valve implantation from paravalvular leakage

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Objectives: Sutures with polytetrafluorethylene (PTFE) felt pledgets are commonly used in prosthetic heart valve (PHV) implantation. Paravalvular leakage can be difficult to distinguish from PTFE felt pledgets on multislice CT because both present as hyperdense structures. We assessed whether pledgets can be discriminated from contrast-enhanced solutions (blood/saline) on CT images based on attenuation difference in an *ex vivo* experiment and under *in vivo* conditions.

Methods: PTFE felt pledgets were sutured to the suture ring of a mechanical PHV and porcine aortic annulus, and immersed and scanned in four different contrast-enhanced (Ultravist®; 300 mg iopromide ml⁻¹) saline concentrations (10.0, 12.0, 13.6 and 15.0 mg ml⁻¹). Scanning was performed on a 256-slice scanner with eight different scan protocols with various tube voltage (100 kV, 120 kV) and tube current (400 mAs, 600 mAs, 800 mAs, 1000 mAs) settings. Attenuation of the pledgets and surrounding contrast-enhanced saline were measured. Additionally, the attenuation of pledgets and contrast-enhanced blood was measured on electrocardiography (ECG)-gated CTA scans of 19 patients with 22 PHVs.

Results: *Ex vivo* CT attenuation differences between the pledgets and contrast-enhanced solutions were larger by using higher tube voltages. CT attenuation values of the pledgets were higher than contrast-enhanced blood in patients: 420 ± 26 Hounsfield units (mean ± SD, range 383–494) and 288 ± 41 Hounsfield units (range 202–367), respectively.

Conclusions: PTFE felt pledgets have consistently higher attenuation than surrounding contrast-enhanced blood. CT attenuation measurements therefore may help to differentiate pledgets from paravalvular leakage, and detect paravalvular leakage in patients with suspected PHV dysfunction.

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In 2003, approximately 290 000 patients underwent prosthetic heart valve (PHV) implantation worldwide [1]. During PHV implantation, the affected native valve is excised and replaced by a mechanical or biological PHV. The PHV is fixated by sutures that are placed through the suture ring of the PHV and the aortic or mitral annulus. To prevent the suture from being pulled through the annular tissue, polytetrafluoroethylene (PTFE) pledged sutures are commonly used. These sutures have a PTFE absorbent pad attached to the suture, which disperses the pressure of the single suture on the annulus [2, 3].

Paravalvular leakage, defined as blood flow outside the suture ring through the annulus, is a relatively common echocardiographic finding after PHV implantation [4]. Paravalvular leakage is reported in up to 15% of patients after mitral valve replacement (MVR) and in up

to 10% of patients after aortic valve replacement (AVR) [5–7]. Paravalvular leakage is mainly caused by (i) incomplete apposition of the PHV suture ring to the native annular tissue, (ii) suture dehiscence or rupture, or (iii) infective PHV endocarditis [8]. Paravalvular leakage is one of the most common causes for reoperation after PHV implantation.

In daily clinical routine, suspected PHV dysfunction is evaluated by transthoracic and transoesophageal echocardiography (TTE and TOE). TTE is the first-line imaging method to detect paravalvular leakage. In patients with acoustic shadowing caused by the PHV material, TOE can be of additional diagnostic value especially for valves in the mitral position.

Multislice CT (MSCT) has recently been shown to have complementary value to echocardiography to evaluate PHV dysfunction [9, 10]. Paravalvular leakage is visualised on MSCT as contrast-enhanced blood next to the valve prosthesis at the level of the annulus. In our experience, it can be difficult to differentiate paravalvular leakage from the PTFE felt pledgets on CT angiography (CTA) scans, because of the similar

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location and hyperdense appearance. Thus diagnostic dilemmas may arise. Additional non-contrast-enhanced scans may help to differentiate paravalvular leakage from pledgets, but with the disadvantage of additional radiation exposure.

Currently no data are available on the normal MSCT imaging characteristics of PTFE felt pledgets. The purpose of this study was (i) to determine normal MSCT imaging characteristics of PTFE felt pledgets both *ex vivo* and *in vivo*, and (ii) to examine the possibility of distinguishing PTFE felt pledgets from contrast-enhanced blood (paravalvular leakage) based on the level of Hounsfield units.

Methods and materials

To determine the CT attenuation level of the contrast required for the conduction of the *ex vivo* experiment, the CT attenuation value of contrast-enhanced blood was measured in routine cardiac electrocardiography (ECG)-gated CTA scans of 50 patients including both coronary CTAs and CTAs for aortic aneurysm assessment. CT attenuation of contrast-enhanced blood was measured in the left atrium, left ventricle and proximal ascending aorta. For each patient the mean of these three measurements was calculated.

Ex vivo imaging

A cardiothoracic surgeon (RM) implanted an ON-X (ON-X Life Technologies Inc., Austin, TX) mechanical prosthetic valve in the aortic position in an *ex vivo* porcine heart. The porcine cardiac tissue was acquired from a butcher. No permission by the animal ethical committee was required. The native valve leaflets were excised. The annulus was encircled with multiple interrupted pledgeted mattress sutures (2-0 Ticon 8×30" 75cm Y-31 tapercutting, double armed with 7×3×1.5mm PTFE pledget; Syneture™; Covidien, Mansfield, MA). Pledgets were positioned at the ventricular side of the porcine annulus. Most of the adjacent cardiac tissue was excised leaving the aortic root and periannular myocardial tissue (Figure 1). The implanted valve was suspended in a paper cup containing contrast-enhanced saline solutions (10.0, 12.0, 13.6 and 15.0 mg ml⁻¹ iodine) and scanned. Several supporting sutures prevented contact between the cardiac tissue and the bottom of the cup. CT attenuation of the pledgets was measured at five separate points in various pledgets. The attenuation of contrast-enhanced saline was measured at five separate points in the surroundings of the pledgets. The location of these five separate points was selected by the single observer (TSM).

MSCT scanner parameters

Ex vivo imaging was performed on a 256-slice CT scanner (Brilliance iCT; Philips Healthcare, Best, Netherlands). Various scan parameters were used: two tube voltage settings (100 and 120 kV) and four tube current settings (400, 600, 800 and 1000 mAs), resulting in a total of eight combinations of kV and mAs. Scanning was based on a retrospectively ECG-gated

Figure 1. Image of an ON-X valve (ON-X Life Technologies Inc., Austin, TX), implanted in a porcine heart, with polytetrafluoroethylene (PTFE) felt pledgets at the ventricular side of the suture ring.

acquisition protocol. Other scan settings were: slice collimation 128×0.625 mm; gantry rotation time 0.33 s; matrix size of 512×512 pixels; and pitch 0.18. An ECG signal was continuously simulated with a frequency of 60 beats per minute to enable ECG-gated scanning (Model 430B 12 Lead ECG Simulator; Medi Cal Instruments Inc., Lewis Center, OH).

In vivo imaging

All ECG-gated MSCT scans of patients who underwent PHV implantation with pledgets were selected from the PHV ECG-gated CTA database in our hospital. These scans were performed with a dedicated cardiac CT protocol (120 kV, 400–600 mAs, pitch 0.16–0.18, slice thickness 0.9 mm, collimation 64–128×0.625, gantry rotation 0.27–0.40, matrix 512×512) or aortic CT angiography protocol (120 kV, 200–250 mAs, pitch 0.25–0.30, collimation 64–128×0.625, gantry rotation 0.27–0.40, matrix 512×512) on a 256 slice or 64 slice CT scanner. Intravenous contrast (Ultravist® 300 mg iopromide ml⁻¹; Bayer Schering Pharma AG, Berlin, Germany) was administered. A three-phase contrast injection protocol was used for the dedicated cardiac scans. The protocol started with 100% contrast injection (Phase 1), followed by a 30%/70% contrast/saline mixture and finally a saline flush. The volumes were adjusted for the patient's body weight with an iodine flow of 1.6 g s⁻¹ for patients under 70 kg, 1.8 g s⁻¹ for patients weighing 70–85 kg and 2.0 g s⁻¹ for patients over 85 kg. For the aortic CTAs a fixed bolus of 100 cc contrast followed by a 50 ml saline flush was administered. In general, injection flow rates were set at 5–6 ml s⁻¹. A trigger was placed in the aorta, which monitored when the level reached the predefined 100 HU threshold. After reaching the threshold the scan

was started automatically. Patient and specific valve data were collected from the medical files. Heart rate during the CT scan was recorded from the CT data. The study was performed under a waiver from the institutional reviewing board.

Image analysis

Image analysis was performed on a dedicated workstation (Philips Extended Brilliance Workspace; Philips Healthcare). CT attenuation values were determined using the cursor available in the analysis software. All measurements in the *ex vivo* experiment were done by a single observer (TSM). Centre- and window-level settings were visually adjusted before each measurement to optimally visualise and measure the attenuation of the pledget. In the *in vivo* scans, CT attenuation of pledgets and contrast-enhanced blood surrounding the pledgets were measured for each PHV at five different points (in different pledgets) by a single observer (JH). The five different pledgets were randomly selected by the single observer (JH).

Statistical analysis

Statistical analyses were performed using SPSS v. 15.0 software (SPSS Inc, Chicago, IL). CT attenuation values were expressed as mean $\pm$ standard deviation with a range (minimal and maximal value). To compare *in vivo* CT attenuation of the pledgets and the contrast-enhanced blood, a paired Student's *t*-test was performed. A *p*-value of <0.05 was considered statistically significant.

Results

50 ECG-gated CTA scans with different tube voltages (100 kV, $n=23$; 120 kV, $n=27$) were analysed. Mean attenuation values for contrast-enhanced blood in the scans performed with 100 kV and 120 kV were 434 ± 69 HU and 306 ± 43 HU, respectively.

Ex vivo imaging

No substantial artefacts were generated by the PHV. Pledgets presented as hyperdense structures (Figure 2a,

b). In all scan settings, the attenuation of the pledgets was consistently higher than the attenuation of the surrounding contrast-saline solution (Table 1).

In the 12.0 mg ml^{-1} contrast-enhanced saline solution, scanned with 120 kV, the mean attenuation was 296 ± 2 HU (range 294–296) for the contrast-enhanced solution, and 388 ± 9 HU (377–397) for the pledgets (Figure 3). This attenuation value for the contrast-enhanced solution approximates the attenuation of contrast-enhanced blood measured in the cardiac CTA scans, performed with 120 kV. At 100 kV, the mean attenuation was 431 ± 3 HU (range 429–435) for the 15.0 mg ml^{-1} contrast-enhanced saline solution, and 460 ± 4 HU (455–464) for the pledgets.

In vivo imaging

19 patients with 22 PHVs (17 mechanical PHVs and 5 biological PHVs) were available for analysis. The mechanical PHV group comprised 15 bileaflet PHVs and 2 Medtronic Hall tilting disc PHVs. Of the 15 bileaflet PHVs, 6 were manufactured by Carbomedics (Carbomedics Inc., Austin, TX), 4 by St Jude (St Jude Medical Inc., St Paul, MN), 3 by Sorin (Sorin SpA, Milan, Italy) and 2 by ON-X (ON-X Life Technologies Inc., Austin, TX). The PHVs were located in the aortic ($n=13$), mitral ($n=7$), pulmonary ($n=1$) and the tricuspid ($n=1$) position. MSCT scans were performed on a 256 slice ($n=17$) or 64 slice scanner ($n=2$) with a dedicated cardiac CT protocol ($n=15$) or aortic CTA protocol ($n=4$). Mean heart rate during the CT scan was 72 ± 18 beats per minute (mean $\pm$ SD). The pledgets presented as hyperdense structures in all patients (Figure 4). The mean attenuation values of pledgets and contrast-enhanced blood that we measured in 22 PHVs were 420 ± 26 HU (range 383–494) and 288 ± 41 HU (range 202–367), respectively (Figures 5 and 6). CT attenuation of pledgets was significantly higher (mean difference of 132 ± 51 HU, $p < 0.001$) than the contrast-enhanced blood, without an overlap in attenuation values.

Discussion

The principal finding of the study is that PTFE felt pledgets have a consistently higher CT attenuation than

Figure 2. (a) CT image reconstruction of the valve implanted in the aortic porcine annulus perpendicular to the valve leaflets. (b) CT image reconstruction of the valve in plane with valve leaflets. Note the pledgets are visualised as hyperdense structures (arrows), with the hypodense myocardial tissue (asterisks) at one side, and at the other side the more hyperdense ring of the ON-X valve (ON-X Life Technologies Inc., Austin, TX).

Table 1. Mean CT attenuation differences (in HU) measured in the pledgets and the surrounding contrast-enhanced fluid

Measurement	Tube voltage (kV)	10.0 mg ml ⁻¹	12.0 mg ml ⁻¹	13.6 mg ml ⁻¹	15.0 mg ml ⁻¹
<i>Ex vivo</i> experiment ^a	120	112	92	79	73
	100	87	55	42	29
<i>In vivo</i> measurements	120	132			

For the *ex vivo* experiment, attenuation differences were calculated for the four contrast-enhanced saline solutions, and for 120 kV and 100 kV. Since tube current did not significantly affect the attenuation level, the means for the various currents were pooled.

In vivo CT attenuation measurements were done in CT scans performed with 120 kV.

^aProsthetic heart valve in porcine aortic annulus.

Figure 3. Box plot with range bars. This figure shows the mean attenuation of polytetrafluorethylene (PTFE) felt pledgets and contrast-enhanced saline surrounding the pledgets in the *ex vivo* experiment (PHV with pledgets surrounded by porcine cardiac tissue). Attenuation values measured in solution 12.0 mg ml⁻¹, scanned at 120 kV. Note that there is no overlap between the ranges of the mean attenuation value of the pledgets and the surrounding fluid.

contrast-enhanced blood in patients after PHV implantation. In our study, the *ex vivo* experiments demonstrated the same findings.

Although echocardiography is the gold standard for the evaluation of PHV dysfunction, including paravalvular leakage, MSCT evaluation of patients with suspected PHV dysfunction has complementary diagnostic value [9, 10]. Furthermore, MSCT offers anatomical information valuable for the surgical planning (e.g. the presence of coronary artery disease and volume rendered three-dimensional images of the affected cardiac region in case of reoperation). The clinical value of MSCT for the detection of paravalvular leakage remains unclear. This study demonstrates that the differentiation between contrast-enhanced blood (appearance of paravalvular leakage on MSCT) and PTFE pledgets may be possible based on CT attenuation measurements (Figures 5 and 6). This contributes to making the correct diagnosis of paravalvular leakage on MSCT scans.

In both the *ex vivo* experiment and the *in vivo* measurements, the pledgets were visualised as hyperdense structures. The mean attenuation value of the pledgets was consistently higher than the mean attenuation value of the contrast-enhanced fluid/blood surrounding the pledgets. Moreover, the ranges of the attenuation of the pledgets and the contrast-enhanced fluid showed no overlap (Figures 3 and 5). With a difference of approximately 130 HU, pledgets were generally well differentiated from the contrast-enhanced blood in patients who underwent mechanical PHV implantation and were scanned with 120 kV.

Our *in vivo* results suggest that CT attenuation measurements with a value above 380 HU excludes the presence of paravalvular leakage in patients scanned with a tube voltage of 120 kV. This attenuation difference between contrast-enhanced blood and the pledget is important because of the potential ability to distinguish paravalvular leakage from PTFE pledgets based on

Figure 4. *In vivo* images of a St Jude mechanical bileaflet prosthetic heart valve (St Jude Medical Inc., St Paul, MN), implanted in the aortic position with polytetrafluorethylene (PTFE) felt pledgets (arrows). (a) CT image reconstruction of the valve perpendicular to the valve leaflets. (b) CT image reconstruction of the valve in plane (short axis view).

Figure 5. CT attenuation of polytetrafluorethylene (PTFE) felt pledgets and contrast-enhanced blood in patients who underwent prosthetic heart valve (PHV) implantation. The two dotted lines show the range for the pledgets and the contrast-enhanced blood that was determined for all valves as a group. The attenuation of pledgets and contrast-enhanced blood for all PHVs was 420 ± 26 HU (range 383–494 HU) and 288 ± 41 HU (range 202–367 HU), respectively. Note that the ranges show no overlap.

straightforward HU measurements. However, these HU values are applicable only for the specific contrast CTA protocol applied in our patients. In clinical practice, the attenuation value for PTFE felt pledgets and contrast-enhanced blood depends on the contrast protocol applied.

Limitations

This study has several limitations. First, in this study the *ex vivo* experiment was conducted under static conditions. The possible effects of annular and valvular motion on the assessment of CT attenuation of the pledgets were not taken into account. However, attenuation measurements were performed in patients scanned under dynamic conditions. The reconstruction phase with the least amount of motion artefacts was selected to perform CT attenuation measurements. In this selected imaging phase, attenuation measurements were easy to perform.

Another limitation of this study is the use of only one mechanical PHV type in the *ex vivo* experiment. The ON-X valve causes fewer artefacts than other valve types, resulting in a better periprosthetic image quality.

However, measurements in patients were done in CT images of nine different PHV types. Most PHV types did not generate extensive artefacts that are likely to affect pledget attenuation measurements, except for the Bjork–Shiley tilting disc valve. This valve type prohibits assessment of the periprosthetic anatomy due to severe artefacts [11]. Bjork–Shiley tilting disc valves were not included in the *in vivo* measurements. A previous study demonstrated that the periprosthetic image quality of most commonly implanted PHVs is good, which enables clinical application of the attenuation measurements [11]. To determine the diagnostic value of MSCT in the detection of paravalvular leakages, prospective studies should be performed comparing MSCT with echocardiography.

Conclusion

PTFE felt pledgets present with consistently higher CT attenuation values than contrast-enhanced blood using our specific CT scan protocol. In clinical practice, this attenuation difference can help to distinguish paravalvular leakage from PTFE felt pledgets on CT scans.

Figure 6. *In vivo* images of a Carbomedics bileaflet mechanical prosthetic heart valve (Carbomedics Inc, Austin, TX) implanted in the aortic position with polytetrafluorethylene (PTFE) felt pledgets [right arrow in (b)] and paravalvular leakage [asterisks and left arrow in (b)]. The paravalvular leak was proven echocardiographically. (a) CT attenuation measurement of both the pledget (406 HU) and the paravalvular leakage (288 HU), indicating the difference in Hounsfield units. (b) CT image reconstruction of the valve in plane (short axis view).

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