Intra-individual efficacy evaluation of Dotarem®-enhanced MRA compared to Gadovist®-enhanced MRA in the diagnosis of clinically significant abdominal or lower limb arterial diseases

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Purpose

In peripheral artery occlusive disease (PAOD), the anatomic vascular tree needs to be imaged precisely to allow exact planning of revascularization procedures [1]. Numerous imaging methods are used clinically to depict arterial diseases. Conventional X-Ray angiography is usually performed using a subtraction technique (DSA - digital subtraction angiography, the gold standard method), but DSA is limited by its invasive, expensive procedure, not without risk and requires the use of ionizing radiation [2, 3].

Computed tomography angiography (CTA) is a minimally invasive imaging test, only requiring upper extremity venous puncture and injection of an iodinated contrast agent. Advantages of CTA are the short examination time, and high diagnostic accuracy [4]. Disadvantages of CTA include the use of potentially nephrotoxic contrast agents, decreased diagnostic confidence in calcified vessels which often occurs in patients with higher grades of PAOD, and the use of ionizing radiation.

Magnetic resonance angiography (MRA) is considered as a clinically useful tool in the evaluation of vascular disease.

Today, contrast-enhanced (CE) MRA is widely used for diagnosing PAOD. Systematic reviews have assessed the diagnostic performance of peripheral CE-MRA [5-7], and its advantages are that the examination is non-invasive, has high diagnostic accuracy, is cost-effective and has a three dimensional approach to the vessel and pathology [8-10]. Moreover, moving-table MRA has gained increasing importance in diagnosis due to its ability to depict both the anatomy and pathology of the arterial tree covering the whole length of the lower extremities with higher robustness and shorter overall image acquisition times compared to conventional stepping table-techniques [11].

Due to the association of linear Gd-chelates with nephrogenic systemic fibrosis, macrocyclic Gd-chelates which are considered low-risk by the EMA are broadly used in clinical practice [12]. Therefore, the aim of this study was to compare the image quality of the two most-commonly used macrocyclic extra-cellular contrast agents gadoterate (0.5 mmol/mL) with gadobutrol (1 mmol/mL) at equimolar doses of gadolinium for peripheral MRA at 3T.
Methods and Materials

STUDY DESIGN

This was a prospective, randomised, double-blind, intra-individual, cross-over, exploratory phase IV study to compare the macrocyclic contrast agents gadobutrol [1 mmol/mL] (Gadovist® 1.0, Bayerhealthcare, Berlin, Germany) and gadoterate [0.5 mmol/mL] (Dotarem®, Guerbet, France) in terms of image quality in MRA at 3-Tesla in patients with peripheral artery disease, at a dose of 0.1 mmol/kg.

The chart shown in Figure 1 on page 9 summarizes the steps and timings of the study design. The first MRA (first procedure) occurred within 21 days, and might be done the same day, of completing screening assessments. The second MRA (second procedure) was performed within 30 days but at least 24 hours after completing the first examination.

Approval was obtained from the Institutional Review Board before the initiation of the study. The procedures set out in the trial protocol were designed in accordance with the principles of the Good Clinical Practices guidelines of the International Conference on Harmonization. The trial was carried out in keeping with local legal requirements. Informed written consent was obtained from each patient before any study specific procedure was performed.

PATIENTS

Patients eligible for the study were aged over 18 years (male or female) with peripheral arterial occlusive disease (PAOD) stage II or III. Female patients had to be using effective contraception or be surgically sterilized or post-menopausal. Women of childbearing potential were required to have a documented negative urine pregnancy test at screening. Patients with a contraindication to MRI (e.g., pacemaker, aneurysm clip, severe claustrophobia, metallic joint replacement) or patients with severely impaired renal function (eGFR < 50 mL/min, based on recent (< 21 days) serum creatinine) were excluded. Patients who had received an MRA or X-Ray contrast media within 48 hours before administration of the investigational products were also excluded. Other exclusion criteria included patients with known severe adverse drug reaction or contraindication to one of the investigational products, patients planned to undergo therapeutic intervention in the vessels of interest between the two MRA procedures, patients who had a major cardiovascular event within 30 days prior to the inclusion, pregnancy or lactation.
CONTRAST AGENTS

Gadoterate was administered at a dose of 0.1 mmol/kg (0.2 mL/kg), injected at a rate of exactly 1 mL/sec. Gadobutrol was administered at a dose of 0.1 mmol/kg (0.1 mL/kg), injected at a rate of exactly 0.5 mL/sec to achieve equimolar amounts of gadolinium and to obtain equal bolus lengths. The study doses were injected in an antecubital vein via a 18G iv access using a power injector (MedRad Spectris Solaris, MedRad, Indianola, PA) and followed-up by a 25-30 mL normal saline flush at the same flow rate.

MR EQUIPMENT AND IMAGING PROCEDURES

The MRA examinations were carried out using a 3T MR-scanner (Siemens MAGNETOM TimTrio, 102 X 36) using a dedicated 36-element PA coil in combination with one or two body matrix coils (depending on the patients size) and elements of the inbuilt spine coil. For MRA examinations, patients were positioned feet first supine, and a TimCT-technique was used. TimCT acquired the entire field of view in z-direction seamlessly in a single acquisition by employing a continuously moving table throughout the MRA-acquisition as described elsewhere [13]. This approach allowed for fast, time-efficient and patient friendly imaging.

The imaging protocol included the following steps: localizer (Feet to Abdomen), vessel scout localizer (Feet to Abdomen), non-enhanced TimCT MRA (acquired twice for later noise calculation), test bolus, contrast-enhanced TimCT MRA, if the calf station was not assessable a separate time-resolved TWIST MRA was ordered by the physician using 0.03 mmol/kg contrast agent. The timing of the contrast-enhanced TimCT MRA was calculated by using the test bolus information. The detailed sequence parameters were:

TR = 2.4 ms;
TE = 1 ms;
Slice thickness = 1.2 or 1.3 mm;
Matrix = 384 X 271, 384 X 248, 384 X 284, 384 X 259;
Flip angle = 21°;
FOV = 340 X 115 X 1280, 300 X 106 X 1280, 320 X 115 X 1280, 337 X 115 X 1279, 309 X 115 X 1279 or 323 X 116 X 1279 mm.
IMAGING EVALUATION CRITERIA

The primary criterion for evaluation was the overall image quality of each MRA examination. All images were displayed in a blinded and randomized manner to four radiologists (two on-site and two off-site radiologists). Each of the four readers independently assessed image quality on an ordinal 5-point scale: Excellent, More than adequate, Adequate, Less than adequate, Non-diagnostic.

One of the secondary criteria was the number of evaluated arterial segments among all the segments.

The aorto-iliac, femoral, popliteal, calf, and foot vascular territories from the leg region per patient were assessed by four independent readers. All the segments were bilateral (i.e., left and right) except the infrarenal aorta.

The infrarenal aorta was defined as from the level of the renal artery to aortic bifurcation;

The common iliac segment was defined as from the level of aorta to iliac bifurcation;

The External iliac/common femoral segment was defined as from iliac bifurcation to femoral bifurcation;

The superficial femoral segment was defined as from the femoral bifurcation to a measured point 30 cm distal to the femoral bifurcation;

The deep femoral segment was defined as from the femoral bifurcation to a measured point 30 cm distal to the femoral bifurcation;

The popliteal segment was defined as from a measured point (25 cm proximal to the popliteal bifurcation) to the popliteal bifurcation;

The posterior tibial segment was defined as from the popliteal bifurcation to the ankle (including posterior-peroneal trunk);

The anterior tibial segment was defined as from the popliteal bifurcation to the ankle;

The peroneal segment was defined as from the division of the posterior-peroneal trunk to the ankle, and the medial dorsal and dorsal pedal segments were defined as from the ankle to toes. Overall, 21 segments were defined per patient.

Vessels segments containing metallic stents were excluded from further analysis because of the associated artefacts known to be seen at contrast-enhanced MR angiography. The four readers independently evaluated each of the 21 segments of
the peripheral arteries in terms of "assessable" or "not assessable". A segment was considered as "assessable" if its image allowed the reader to determine whether this segment is affected by a stenosis, and in case of stenosis, its image allowed the reader to measure the detected stenosis (arterial diameter and stenosis length).

Other secondary criteria included the number of significant stenosis depicted by patient (stenosis > 50 %) and their localization;

The collateral circulation visualization (yes/no);

The pedal vessel and smaller branches graded for visualization on an ordinal 5-point scale in the foot territory (Excellent, More than adequate, Adequate, Less than adequate, Non-diagnostic);

The level of diagnostic confidence assessed on a 5-point scale by patient (nil, poor, moderate, high, excellent);

The venous overlap that interfered with arterial visualization evaluated on a 4-grade scale by patient (not seen: no venous overlap depicted; partially seen: venous overlap partially depicted but not difficult to distinguish from the artery; seen: venous overlap difficult to distinguish from the artery; and unassessable);

Objective measures of enhancement (Signal to Noise ratio (SNR), Contrast to Noise ratio (CNR));

Circular regions of interest (ROI) of approximately 0.5 cm² were placed on 3 points: one on common iliac artery (right or left), one on popliteal artery (right or left), and one on the calf arteries (either anterior or posterior tibial artery, peroneal artery);

This latter ROI was to be placed in the leading vessel of the lower extremity (in the patent one) to determine the signal intensity of the vessel.

The noise was measured as follows. The two acquired non-enhanced TimCT MRA datasets were subtracted from each other yielding a noise distribution map as described elsewhere [14]. The circular ROIs were then copied from the contrast-enhanced image to be located at the same position. The standard deviation of the signal intensity measured in these ROIs was used for further noise calculation. For the CNR assessment a circular ROI was placed in the ilio-psoas muscle, the thigh muscles or the calf muscles for CNR assessment of the pelvic, thigh and calf arteries. SNR and CNR were calculated as follows:

\[
\text{SNR} = \frac{\text{SI}_{\text{artery}}}{\text{SD}_{\text{noise}}} \\
\text{CNR} = \frac{(\text{SI}_{\text{artery}} - \text{SI}_{\text{muscle}})}{\text{SD}_{\text{noise}}}
\]
SAFETY ASSESSMENT

Adverse events were assessed during the patient's study participation, from inclusion to 24±4 hours after last contrast product bolus injection. Additionally, following the contrast product bolus injection, patients were followed over a 30 minute period for clinical safety on site (vital signs and injection-site tolerance).

STATISTICAL ANALYSIS

Statistical analyses were conducted using the software SAS version 9.2 (SAS Institute Inc, Cary, NC).

Exploratory statistical tests were performed comparing the 2 contrast agents, for each reader and all reader pooled. GEE models were used to modeling the image quality or the diagnostic confidence as a function of the 2 MRA (Gd-DOTA and gadobutrol MRI) and the subject were considered as a cluster of correlated measures (MRA and readers). The following models were explored:

\[
\text{Prob(MR images = Excellent)} = a + b \text{ MRA*Group} + e \text{ Subject+}#
\]

b coefficient measures the interaction between MRA and order of contrast agent injection effects:

\((#\text{Group } i_{\text{excellent_images}} = \#\text{Gd-DOTA} - \#\text{gadobutrol}).\)

\[
\text{Prob(MR images = Excellent)} = a + b \text{ MRA*Reader} + e \text{ Subject+}#
\]

b coefficient measures the interaction between MRA and reader effects:

\((#\text{Reader } i_{\text{excellent_images}} = \#\text{Gd-DOTA} - \#\text{gadobutrol}).\)

Same models were used for testing the following probabilities:

- Prob(MR Confidence = Excellent)
- Prob(MR Assessable segment = Yes)
- Prob(MR presence of stenosis = Yes)
- Prob(MR Significant stenosis (> 50 %) = Yes)
P-values come from the Wald Chi-square statistics for correlated binary data using the SAS proc Genmod with an exchangeable correlation matrix.

Descriptive statistics were also performed on other parameters.
Fig. 0: Study design

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Results

PATIENTS AND EXAMINATION CONDITIONS

A total of 20 patients (15 male, 5 female) were enrolled in this study. Their mean age was 61.5 years [45-77] and mean body mass index was 27.0 [19.0-37.1].

A total of 14 patients who had both MRA performed completed the study and there were 6 withdrawals. The main reasons for withdrawal were withdrawal of patient's consent (3), patient lost to follow-up (1), technical incident (1), other reason (conventional angiography) (1).

Therefore the efficacy analysis was carried out on 14 patients by the four readers.

**Figure 1 on page 14** shows the areas of the main stenoses explored at screening time.

As expected due to the different concentration used of both products, the volume administered was higher with Gd-DOTA (18.3 ± 4.1 mL, range [10.0-24.8]) as compared to gadobutrol (9.5 ± 2.0 mL, range [7.0-13.5]).

The duration of acquisition was slightly shorter with Gd-DOTA (2.7 ± 3.4 min, range [0-13]) as compared to gadobutrol (3.5 ± 3.1 min, range [0-10]).

**PRIMARY CRITERION : IMAGE QUALITY**

As shown in **Figure 2 on page 14**, the overall image quality obtained was slightly better rated with Gd-DOTA than with gadobutrol. All of the readers assessed all of the images using Gd-DOTA as "more than adequate" or "excellent" (100 %). All of the readers assessed between 78 % and 86 % of the images as "more than adequate" or "excellent" using gadobutrol.

Regarding excellent image quality by reader, no statistically significant difference was observed between groups.

All of the readers assessed between 7 % and 22 % of the images rated as "adequate" for gadobutrol and 0 % for Gd-DOTA.
When pooling all readers, the overall image quality ("more than adequate" and "excellent") remained rated better with Gd-DOTA than with gadobutrol (100 % versus 85.7 %).

The Wald Chi-2 test analysis on excellent image quality showed that whatever the reader no statistical significance between both contrast agents was observed.

SECONDARY CRITERIA

Diagnostic confidence

As shown in Figure 3 on page 14, the diagnostic confidence obtained was slightly better rated with Gd-DOTA than with gadobutrol. Diagnostic confidence was "high" or "excellent" in 100 % (Readers 1, 2 and 3) and 92.9 % (Reader 4), of patients diagnosed using Gd-DOTA-enhanced MRA compared with 92.9 % (Readers 1 and 2) and 85.7 % (Readers 3 and 4) using gadobutrol-enhanced MRA.

All of the readers assessed between 7 % and 15 % of the images rated as "moderate" using gadobutrol, and from 0 % to 7.1 % for Gd-DOTA.

When pooling all readers, the excellent diagnostic confidence remained rated better with Gd-DOTA than with gadobutrol without any statistically significant difference (53.6 % vs 48.2 %, p = 0.48).

The Wald Chi-2 test analysis on excellent diagnostic confidence showed that whatever the reader no statistical significance between both contrast agents was observed (except for Reader 1).

Visualization of collateral circulation

As shown in Figure 4 on page 15, the collateral circulation was visualized in 100 % (Readers 1 and 3), 85.7 % (Reader 2) and 78.6 % (Reader 4), of patients diagnosed using Gd-DOTA-enhanced MRA compared with 100 % (Readers 1 and 2) and 92.9 % (Readers 3 and 4) using gadobutrol-enhanced MRA.

Pedal vessel and smaller branches in the foot territory assessment were rated as "more than adequate" or "excellent" in 100 % (Reader 3), 92.9 % (Reader 1), 85.7 % (Reader 4), and 28.6 % (Reader 2) of patients diagnosed using Gd-DOTA-enhanced...
MRA compared with 92.9 % (Reader 3), 85.8 % (Reader 4), 62.3 % (Reader 1) and 42.9 % (Reader 2) using gadobutrol-enhanced MRA (Figure 5 on page 16).

The Wald Chi-2 test analysis on excellent image quality of pedal vessel and smaller branches in the foot territory showed that whatever the reader no statistical significance between both contrast agents was observed.

Venous overlap that interfered with arterial visualization assessment was "partially seen" or "not seen" in 100 % (Readers 1, 2 and 4) and 92.8 % (Reader 3), of patients diagnosed using Gd-DOTA-enhanced MRA compared with 100 % (Readers 2, 3 and 4) and 85.7 % (Reader 1) using gadobutrol-enhanced MRA. The results from individual readers are given in Figure 6 on page 16.

Overall evaluable segments (n = 294) and depiction of stenosis

Rates of evaluable segments were 95.6 % (Reader 1), 93.9 % (Reader 2), 96.3 % (Reader 3) and 97.6 % (Reader 4), for patients diagnosed using Gd-DOTA-enhanced MRA compared with 94.2 % (Reader 1), 94.9 % (Reader 2), 95.2 % (Reader 3) and 96.9 % (Reader 4) for patients using gadobutrol-enhanced MRA.

When pooling all readers, the Wald Chi-2 test analysis showed that no statistical significance (p = 0.58) between both contrast agents was observed.

Figure 7 on page 17 shows the depiction of stenosis assessed by each reader. The results were comparable between Gd-DOTA and gadobutrol for each reader.

Significant stenosis (> 50 %) was noted in 37.1 % with Gd-DOTA vs 43.9 % with gadobutrol for Reader 1 (p = 0.04), 53.8 % vs 45.0 % for Reader 2 (p = 0.53), 41.9 % vs 46.2 % for Reader 3 (p = 0.17), 54.4 % vs 48.7 % for Reader 4 (p = 0.41).

When pooling all readers, no statistical significance between both contrast agents was observed (45.8 % with Gd-DOTA vs 46.2 % with gadobutrol, p = 0.81).

Signal intensity

The signal intensity is shown in Figure 8 on page 17. The intensity of the signal detected was high with both contrast agents, slightly higher with gadobutrol. The SNR
was 22.7 ± 10.3 with gadoterate and 26.1 ± 10.5 with gadobutrol (# = #3.4, p = 0.01). The CNR was 20.2 ± 9.7 with gadoterate and 23.4 ± 9.9 with gadobutrol (# = #3.2, p = 0.01).

Safety Results

There were no reported adverse events and no injection site reactions during this study.
Fig. 0: Territory of the main stenosis explored (n=20)

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<table>
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<th>READERS</th>
<th>IMAGE QUALITY</th>
<th>GADOTERATE</th>
<th>GADOBUTROL</th>
<th>Wald Chi - 2 test only on item &quot;excellent&quot; Estimated difference: Pr (Gadoterate) – Pr (Gadobutrol) and p-value</th>
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<td>42.9 %</td>
<td>42.9 %</td>
<td>0 %, p = 1.00</td>
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<td></td>
<td>Excellent</td>
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Fig. 0: Overall image quality results per reader and by pooling all readers

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### Fig. 0: Diagnostic confidence results per reader and by pooling all readers

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<table>
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<th>Wald Chi - 2 test only on item &quot;excellent&quot; Estimated difference : Pr (Gadoterate) − Pr (Gadobutrol) and p - value</th>
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<td>85.7 %</td>
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### Fig. 0: Collateral circulation visualized per reader

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Fig. 0: Pedal vessel and smaller branches in the foot territory results per reader and by pooling all readers

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Fig. 0: Venous overlap rated as "partially seen" or "not seen" per reader

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Fig. 0: Depiction of stenosis on evaluable segments

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Fig. 0: Signal intensity - overall

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Conclusion

Gadobutrol yielded statistically significantly higher SNR/CNR while gadoterate was better rated in terms of overall image quality and diagnostic confidence.
References


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