

Influence of Contrast Material Temperature on Patient Comfort and Image Quality in Computed Tomography of the Abdomen

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Influence of Contrast Material Temperature on Patient Comfort and Image Quality in Computed Tomography of the Abdomen *A Randomized Controlled Trial*

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Background: International guideline recommendations on safe use of contrast media (CM) are conflicting regarding the necessity to prewarm iodinated CM. **Purpose:** Aim of the study was to evaluate the effects of room temperature CM compared with prewarmed CM on image quality, safety, and patient comfort in abdominal computed tomography (CT).

Methods: CATCHY (Contrast Media Temperature and Patient Comfort in Computed Tomography of the Abdomen) is a double-blinded, randomized noninferiportal venous abdominal CT were prospectively and randomly assigned to 1 of portal venous abdominal CT were prospectively and randomly assigned to 1 of 2 groups. All patients received iopromide at 300 mg I/mL: group 1 at room temperature (~23°C [~73°F]) and group 2 prewarmed to body temperature (37°C [99°F]). A state-of-the-art individualized CM injection protocol was used, based bon body weight and adapted to tube voltage. Primary outcome was absolute difference in mean liver attenuation between groups, calculated with a 2-sided 95% confidence interval. The noninferiority margin was set at -10 HU. Secondary toutcomes were objective (signal-to-noise ratio and contrast-to-noise ratio) and subjective image quality; CM extravasations and other adverse events; and particbipant comfort (5-point scale questionnaire) and pain (numeric rating scale). This trial is registered with ClinicalTrials.gov (NCT04249479).

Results: The absolute difference in mean attenuation between groups was + 4.23 HU (95% confidence interval, +0.35 to +8.11; mean attenuation, 122.2 \pm 13.1 HU in group 1, 118.0 \pm 15.9 HU in group 2; *P* = 0.03). Signalto-noise ratio, contrast-to-noise ratio, and subjective image quality were not sig-Enficiently different between groups (*P* = 0.53, 0.23, and 0.99 respectively). Contrast extravasation occurred in 1 patient (group 2), and no other adverse events

occurred. Comfort scores were significantly higher in group 1 than in group 2 (P = 0.03); pain did not significantly differ (perceived P > 0.99; intensity P = 0.20).

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Conclusions: Not prewarming iodinated CM was found noninferior in abdominal CT imaging. Prewarming conferred no beneficial effect on image quality, safety, and comfort, and might therefore no longer be considered a prerequisite in state-of-the art injection protocols for parenchymal imaging.

Key Words: multidetector computed tomography, diagnostic imaging, abdomen, contrast media, image quality, contrast material warming, discomfort

(Invest Radiol 2022;57: 85-89)

omputed tomography (CT) has rapidly evolved.¹⁻³ Both scan and contrast media (CM) protocols have been individualized based on patient characteristics as well as for clinical indications.⁴⁻⁸ The effects of various characteristics of CM have been thoroughly investigated.8-16 Among these, CM viscosity is key. In general, viscosity of CM increases with higher CM concentration and is directly influenced by temperature: prewarming CM leads to decreased viscosity, which may reduce the risk of both CM extravasation and adverse events in general, increasing participant comfort.^{14,15,17} However, the necessity to prewarm CM for clinical CT applications is still under debate.^{8–13} Indeed, European and American guidelines on the use of CM are not in agreement on prewarming CM.^{12,13} The European Society of Urogenital Radiology recommends prewarming iodine-based CM in all cases.13 On the other hand, according to the American College of Radiology, prewarming CM is only necessary for concentrations of 370 mg I/mL or higher, injection rates above 5 mL/s, or if small-gauge catheters are used.^{12,18,19} The latter advice is primarily based on a large retrospective study by Davenport et al¹¹ comparing 12,682 injections with prewarmed CM to 12,138 injections without prewarmed CM. Adverse event rates were not different for iopamidol 300 injections of less than 6 mL/s but were significantly reduced by prewarming for iopamidol 370 injections.

Prewarming CM requires special equipment and more complex planning and logistics. On the other hand, prewarming CM may yield higher attenuation levels, image quality, and comfort.²⁰ The question remains whether prewarming CM is necessary when moderate flow rates (<6 mL/s) are used, as is the case in abdominal imaging.

The aim of the study CATCHY (Contrast Media Temperature and Patient Comfort in Computed Tomography of the Abdomen) was to prospectively compare room temperature CM to prewarmed CM with regard to image quality, safety, and participant comfort in portal venous abdominal imaging.

MATERIALS AND METHODS

Ethics

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This double-blinded randomized controlled noninferiority trial was approved by the local ethics committee and the institutional review board, and is registered on ClinicalTrials.gov (NCT04249479). Written informed consent was obtained before inclusion in the clinical trial. The study did not receive any industry support.

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Study Design and Study Population

Using CM at room temperature (~23°C [~73°F]) might result in lower attenuation than would be achieved using CM prewarmed to body temperature.²⁰ The hypothesis of the CATCHY trial is that using CM at room temperature does not compromise diagnostic image quality, patient safety, or comfort in the setting of abdominal imaging. The sampple size was calculated to enable detection of an absolute difference of 10 HU in mean attenuation of the liver. This noninferiority margin awas chosen based on earlier studies where mean attenuation of 120 HU was found sufficient and a decrease in attenuation of 10% was pronounced clinically significant.²¹ To be able to detect a differmence greater than 10 HU with a power of 90% and 2-sided α of 5%, 98 participants per group are required. We recruited an additional 10% to account for potential loss to follow-up.

Participants referred for an abdominal CT in portal venous phase were prospectively included between February and August 2020 at our center. Exclusion criteria were hemodynamic instability, pregnancy, real insufficiency (estimated glomerular filtration rate <30 mL/min per [1.73 m²), prior adverse reactions to iodinated CM, age younger than 18 years, and inability to place an 18-gauge needle.^{22,23} Additional scanning was no reason for exclusion unless it altered the underlying CM injection protocol. Repeated inclusion was allowed, as it was not expected to influence outcome. Body weight (in kilograms) of the parcticipant was measured before scanning on a calibrated scale. As the maximum level of the dual head injector syringes is 200 mL, participants with a body weight greater than 115 kg were excluded from this study. Participants' height (in meters) was checked, and body mass in-Edex was calculated. A 1:1 computer-generated randomization schedule was used (TENALEA [Trans European Network for Clinical Trials Ser- \overrightarrow{w} vices]). Stratification factors were age (<60 and ≥60 years) and weight $\geq (<75 \text{ and } \geq 75 \text{ kg})$. Participants were equally divided in 2 groups by varable block randomization.

All data were collected by 1 blinded researcher (B.M.) using electronic case report forms and checked by an independent study monlitor. Patients were blinded as to the allocated treatment. A written questionnaire evaluating comfort was filled in by the participant directly after each CT examination.

Scan and Contrast Media Injection Protocol

A third-generation dual-source CT scanner (Somatom Force; Siemens Healthineers, Forchheim, Germany) with automated tube current modulation (CareDose4D, Siemens) and automated tube voltage selection (CarekV; Siemens) techniques was used: 120 kV_{ref} and 150 mAs_{ref}, 192 \times 0.6 mm slice collimation, gantry rotation time of 0.5 seconds.

Group 1 received CM at room temperature (~23°C [~73.4°F]), and group 2 received prewarmed CM (37°C [99°F]). An 18-gauge catheter (Vasofix Safety; B Braun, Melsungen, Germany) was placed by the radiographer in the participants' arm (eg, antecubital vein, forearm, or wrist) before scanning. For both groups, the CM injection protocol (300 mg/mL of iopromide [Ultravist 300; Bayer Healthcare, Berlin, Germany]) was adapted to the participants' body weight and the tube voltage used (at a tube voltage of 120, 110, 100, and 90 kV, a respective dosing factor of 0.521, 0.469, 0.417, and 0.365 g I/kg was used).^{8,21} The scan was performed 70 seconds after start of the CM injection using a dual head power injector (Stellant; Bayer Healthcare, Berlin, Germany) followed by a saline flush with the same injection speed and an overall volume of 40 mL.

Image reconstruction parameters were as follows: 3-mm slice thickness, 2-mm increment, soft tissue kernel (Br40), and iterative reconstruction (IR) strengths 2/3 (Siemens; Advanced Modeled Iterative Reconstruction).

A dedicated data acquisition program (Certegra Informatics Solution; Bayer) monitored the CM parameters. Radiation dose and reconstruction settings were collected from the dose sheet at the PACS workstation (IMPAX version 6.6.1.5003; AGFA HealthCare N.V., Mortsel, Belgium).

Primary Outcome

Absolute difference in mean attenuation of the liver parenchyma between groups was calculated with a 2-sided 95% confidence interval

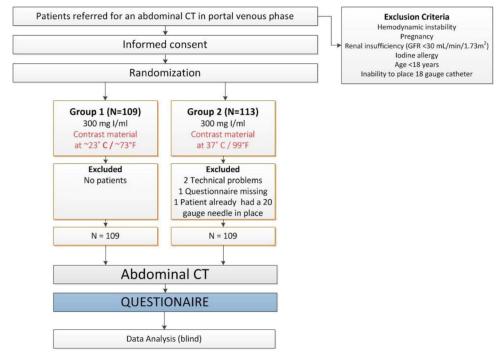


FIGURE 1. Trial profile. GFR, glomerular filtration rate.

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TABLE 1.	Key Demographic and Clinical Characteristics of
	ed Groups

Characteristics	Group 1 (Room Temperature) N = 109	Group 2 (37°C [99°F]) N = 113
Excluded participants	0	4
Age, y	66.3 ± 10.6	65.1 ± 11.1
Age, y Sex (% male)	56.0%	64.2%
Body weight, kg	79.7 ± 13.7	78.4 ± 12.8
Height, m	1.72 ± 0.09	1.72 ± 0.08
BMI, kg/m ²	26.8 ± 3.7	26.5 ± 4.0
Scan indication, %		
Oncology	97.2%	92.7%
Infection	0.9%	2.8%
Other	1.8%	4.6%
BMI, body mass index.		
based on 3 liver segment classification ²⁴). A regio	Aean attenuation in Hounsfints, preferably segments 2, 5 on of interest was drawn in e g vessels, bile ducts, or lesio nes	5, and 8 (Couinaud each segment (area:
Objective image	quality was rated using sign divided by the mean	ignal-to-noise ratio

Secondary Outcomes

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Objective image quality was rated using signal-to-noise ratio (SNR; mean attenuation divided by the mean standard deviation [SD]) and contrast-to-noise ratio (CNR; mean liver attenuation minus ^THU of the left paraspinal muscle, divided by the SD of the attenuation ³of the paraspinal muscle). Subjective image quality was rated in consensus on a 5-point Likert scale by 2 readers, B.M. and C.M. (5 and 10 years) Experience in abdominal imaging, respectively). Readers were blinded to the allocated protocol. Overall image quality was rated on a 5-point Elikert scale (1 = excellent, 2 = good, 3 = moderate, 4 = poor, and 5 = very poor).²¹ Readers were allowed to level window settings individually.

All adverse events, including contrast extravasation, were reported by the radiographer.

Comfort was rated by the patient on the questionnaire provided by the radiographer directly after the scan was performed (1 = very)bad, 2 = bad, 3 = neutral, 4 = good, 5 = excellent). An 11-point numeric rating scale was used to evaluate pain during injection (0 = no pain, 10 = very severe pain).¹⁷ Feelings of shivering, goosebumps, or cold were evaluated, and an open field was provided for the patient to record any other experiences. The questionnaire is given in the Supplemental Digital Content, http://links.lww.com/RLI/A638.

Statistical Analysis

Dichotomous outcomes are reported as absolute numbers with percentages; continuous outcome variables are reported as mean \pm SD. Results are stratified by treatment allocation. To test for noninferiority, a CI approach was used on an analysis of covariance model, with a 2-sided 5% level of significance. For the primary end point, noninferiority of room temperature CM to prewarmed CM could be claimed if the lower limit of the CI for the absolute difference in mean liver attenuation (room temperature CM group minus prewarmed CM group) falls above -10 HU. This test for noninferiority was only performed for the primary outcome.

Participant comfort and pain intensity were compared between groups using the Mann-Whitney U test. The χ^2 test, and in case of expected cell counts of less than 5, Fisher exact test, was used for dichotomized variables. Continuous normally distributed variables were compared between groups using the independent samples t test. The Mann-Whitney U test was used for not normally distributed variables.

RESULTS

Baseline Characteristics

Two-hundred twenty-two participants were enrolled. Four participants were excluded: 2 due to technical problems-in 1 participant, the questionnaire form was missing, and 1 participant already had a 20-gauge needle in place and therefore had to be excluded (Fig. 1). All patients received their allocated treatment. Therefore, in this study, the intention-to-treat population is the same as the per-protocol population. Key demographic and clinical characteristics are detailed in Table 1.

Mean CM volume was 103.6 ± 21.7 mL in group 1 and 100.8 ± 21.4 mL in group 2 (P = 0.33). Mean flow rate was 3.4 ± 0.7 in group 1 and 3.3 ± 0.7 mL/s in group 2 (P = 0.31). Other CM and radiation dose parameters are shown in Table 2. There were no significant differences between groups, except peak pressure (in psi), which was significantly higher in group 1: 63.1 ± 19.7 psi (room temperature CM) versus 54.9 ± 18.4 psi (prewarmed CM) (P = 0.001).

Primary Outcome

The percentage difference in mean attenuation (group 1 minus group 2) was + 4.23 HU with 95% CI + 0.35 to + 8.11. The lower limit of the CI of the difference falls within the noninferiority margin, indicating noninferiority of room temperature CM with respect to attenuation (Fig. 2).

Secondary Outcomes

Objective and subjective image quality results are shown in Table 3. Mean attenuation was 122.2 ± 13.1 in group 1 and 118.0 ± 15.9 in group 2

CM and Radiation Dose Parameters	Group 1 (Room Temperature) N = 109	Group 2 (37°C) N = 109	Р
CM volume, mL	103.6 ± 21.7	100.8 ± 21.4	0.33
TIL, g	31.1 ± 6.5	30.2 ± 6.4	0.34
Flow rate, mL/s	3.4 ± 0.7	3.3 ± 0.7	0.31
Peak flow rate, mL/s	3.8 ± 0.9	3.8 ± 0.8	0.89
Peak pressure, psi	63.1 ± 19.7	54.9 ± 18.4	0.001
IDR, g I/s	1.0 ± 0.2	1.0 ± 0.2	0.33
Tube voltage, kV			0.84
90 kV, %	64.2%	67.9%	
100 kV, %	33.9%	30.3%	
110 kV, %	1.8%	1.8%	
120 kV, %	0%	0%	
Mean mAs _{ref}	293.4 ± 55.9	300.7 ± 57.2	0.29
Mean mAseff	217.1 ± 51.6	208.4 ± 47.0	0.20
CTDI _{vol} , mGy	7.2 ± 2.3	6.9 ± 2.0	0.31
DLP, mGy·cm	386.5 ± 133.6	390.4 ± 136.8	0.83
IR2 (%)/IR3 (%)	60.6%/39.4%	54.1%/45.9%	0.34

CM volume, TIL, mAseff and DLP, mean liver attenuation (HU), SNR, and CNR were normally distributed and compared using the independent samples ttest. Flow rate, peak flow rate, peak pressure, mAsref, and CTDIvol were not normally distributed and the Mann-Whitney U test was used.

CM, contrast media; TIL, total iodine load; IDR, iodine delivery rate; mAs_{ref}, quality reference mAs; mAseff, effective mAs; CTDIvol, CT dose index; DLP, dose length product; IR, iterative reconstruction.

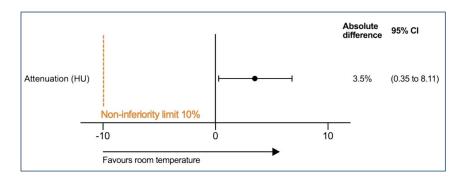


FIGURE 2. Absolute difference in mean attenuation of the liver (room temperature CM group minus prewarmed CM group). The dashed line shows the noninferiority margin, set at –10 HU. Error bars indicate the 95% confidence interval (CI) of the difference; the bullet shows the point estimate. HU, Hounsfield units.

 $\tilde{\mathbb{S}}(P=0.03)$. Signal-to-noise ratio, CNR, and subjective image quality did not significantly differ between groups (P=0.53, 0.23, and 0.99 respectively). There was 1 person with a contrast extravasation in group 2. No pother adverse events were reported.

Patient comfort and pain results are shown in Table 4. Comfort of scores were higher in group 1 than in group 2 (P = 0.03). Comfort was graded excellent or good by 91.7% of the participants in group 1 and by 86.2% of the participants in group 2. Comfort was rated bad For very bad by 1 participant (0.9%) in each group. In group 1, 3 patients (3.3%) and in group 2, 4 patients (4.4%) perceived pain (P > 0.99). Pain fintensity scores were not significantly different between groups (P = 0.20). Four participants had a feeling of being cold, of which 3 were randomized in group 1 (Table 4).

DISCUSSION

Contrast media at room temperature was found to be noninferior to prewarmed CM in mean attenuation of the liver. Furthermore, the present study found no evidence or benefits from prewarming iodinated CM with regard to image quality, safety, and patient comfort in portal venous abdominal CT imaging. Mean attenuation was significantly higher in the room temperature CM group. Differences in SNR, CNR, and subjective image quality between groups were small and nonsignificant. Injecting CM at room temperature did not result in CM extravasations or other adverse events at the given IDR of 1.0 g J/s, which is in line with the results of the study by Davenport et al.^{11–13} Contrast media at room temperature yielded significantly higher

	Group 1 (Room Temperature) N = 109	Group 2 (37°C [99°F]) N = 109	Р
Objective image quality			
Mean attenuation, HU	122.2 ± 13.1	118.0 ± 15.9	0.03
SNR	9.8 ± 2.1	9.6 ± 2.1	0.53
CNR	6.2 ± 2.4	5.8 ± 2.2	0.23
Subjective image quality			
Excellent (%)	26.6%	25.7%	0.99
Good (%)	66.1%	66.1%	
Moderate (%)	6.4%	7.3%	
Poor (%)	0.9%	0.9%	
Very poor (%)	0%	0%	

HU, Hounsfield units; SNR, signal-to-noise ratio; CNR, contrast-to-noise ratio.

participant comfort scores, although absolute differences are small and may not be clinically relevant.

This is the first prospective randomized trial providing high level evidence that participant comfort and image quality are not increased by prewarming CM in this setting. The European and American guidelines have a conflicting opinion on this subject.^{12,13} Based on the results of the current study, it seems that the American College of Radiology guidelines is the one to follow. Contrast media extravasation, other adverse events, and participant comfort are not adversely affected by administering CM at room temperature. As a consequence, one may forego prewarming for CM injections with low iodine concentration of 300 mg/mL, at moderate flow rates and an 18-gauge catheter.

Peak pressure was significantly higher for CM at room temperature compared with prewarmed CM. Mean flow rate in present study was quite low (mean flow rate of 3.4 mL/s ranging from 2.0 mL/s up to a maximum of 5.3 mL/s). A higher flow rate is expected to further increase peak pressure and therefore might negatively influence participant comfort. However, at our center, more than 90% of the scans performed between 2013 and 2019 had a flow rate below 6 mL/s with rather low psi and IDR values, and the results of the current trial will apply. Accordingly, future research could focus on participant comfort when CM is injected at room temperature with higher flow rates, for example, in cardiovascular imaging. As shown by Davenport et al,¹¹ increasing flow rates increases incidences of CM extravasation and

TABLE 4. Participant Comfort

Comfort	Group 1 (Room Temperature) N = 109		Р
Contrast extravasation	0	1	
Comfort (median, IQR)	4 (4–5)	4 (4–5)	0.03
Excellent (N)	54	39	
Good (N)	46	55	
Neutral (N)	8	14	
Bad (N)	1	0	
Very bad (N)	0	1	
Pain intensity (median, IQR)	0 (0–0)	0 (0-0)	0.20
Pain (yes/no)	3/106	4/105	>0.99
Feeling cold			
Shivering (N)	0	0	
Goosebumps (N)	0	0	
Cold (N)	3	1	

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other adverse events in specific settings, most likely also decreasing participant comfort.

The study has some limitations. First, it is a single-center randomized controlled trial. Generalizability to other centers might be limited. Intraindividual comparison may have been preferable but is not readily feasible in clinical setting. Second, the sample size was based on a noninferiority margin for objective image quality, because not much is known about patient comfort margins, which was the main ostudy outcome. In addition, CM temperature was measured in the botette. Prewarmed CM might cool down when traveling through the tubing from the bottle to the patient. Therefore, injected CM temperature may have been overestimated. Lastly, the mean flow rate was quite low and presults might have been different if CM injection protocols with higher offlow rate were used.

Prewarming CM is not beneficial in terms of image quality, safety, and participant comfort in portal venous phase abdominal CT orimaging. Prewarming CM should therefore not be a prerequisite in state-of-the art injection protocols for parenchymal imaging for CM inbegie concentrations, at moderate flow rates, and a greasonable catheter size.

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