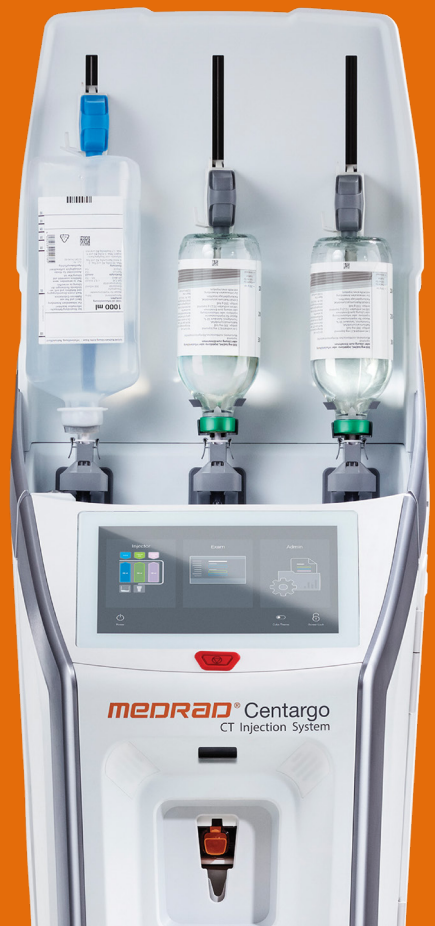
InnoVatE Study

The impact of CT injection system technology and contrast media viscosity on vascular enhancement



Clear Direction. From Diagnosis to Care.

medrad® Centargo
CT Injection System

InnoVatE Study: The first peer-reviewed publication investigating combined performance of CT injection systems and contrast media[1]

Evaluating key performance metrics for vascular imaging

- Maximum achievable iodine delivery rates (IDRs)
- Peak vascular enhancement

By comparing

- Piston-based vs. peristaltic pump injection system technology[2]
- Contrast media across a broad range of concentrations and viscosities

1 McDermott et al. Impact of CT Injector Technology and Contrast Media Viscosity on Vascular Enhancement: Evaluation in a Circulation Phantom. Br J Radiol 2020;93: 20190868

2 MEDRAD® Centargo CT Injection System ('Centargo'), MEDRAD® Stellant CT Injection System with the Multi Patient Kit ('Stellant MP'), Bracco CT Exprès® Contrast Injection System with Multi Patient Set ('CT Exprès'), ulrich CT motion™ Contrast Media Injector ('CT motion')

What is Iodine Delivery Rate (IDR)?

Injection protocols are programmed in terms of flow rate and volume, however this convention ignores the impact of contrast concentration.

IDR represents the **amount of iodine delivered to the patient per second**. It is the product of injection flow rate and contrast media concentration.

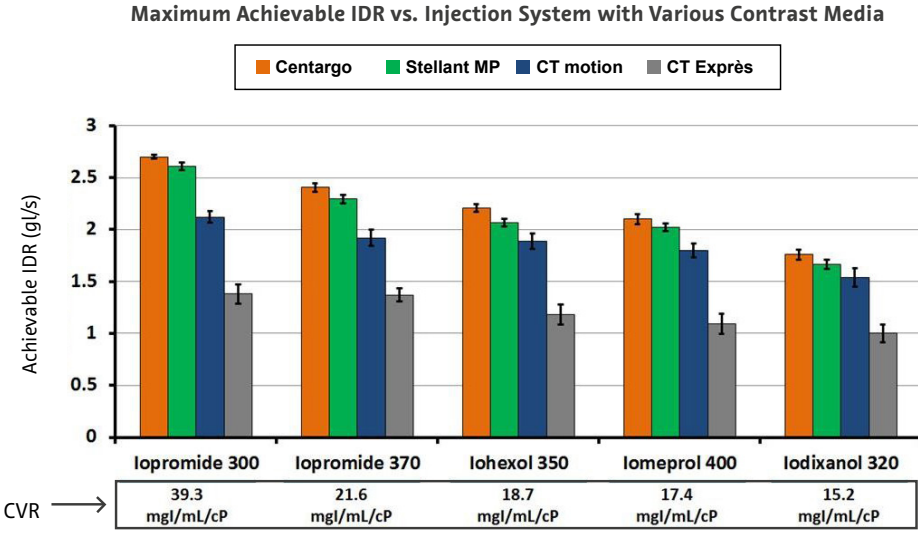
Concentration		Flow Rate		IDR
0.37 370 milligrams Or 0.37 grams of iodine per milliliter	X	**5** milliliters per second	=	**1.85** grams of iodine per second

Example

- IDR is the key parameter in first-pass imaging, such as CT Angiography.
- Typical clinical ranges are 1.0 – 2.0 gI/s, with variability based on indication, patient size, and scanner settings.
- The ability to achieve a wide range of IDRs provides the most flexibility for challenging studies, especially for larger patients.

Experiment I – Maximum Achievable Iodine Delivery Rates (IDRs)

- Piston-based injection systems achieve significantly higher IDRs than the peristaltic pumps ($p < 0.05$). Also, increasing contrast media concentration does not increase the achievable IDR, as higher viscosities require higher pressures to achieve the same flow rates.
- This study introduces a new parameter to better predict performance: the **concentration/viscosity ratio (CVR)**.



Piston-based injection systems, MEDRAD® Centargo and MEDRAD® Stellant MP provide higher achievable IDRs as compared to the peristaltic pump-based systems, CT motion and CT Exprès.

What is Concentration / Viscosity Ratio (CVR)?

Concentration and viscosity are two physical properties of CT contrast media.

The InnoVatE study introduces the concentration/viscosity ratio (CVR) as a new parameter for comparing contrast media performance in achievable IDRs.

Concentration
370
370 milligrams of Iodide per milliliter (mgI/mL)

÷

Viscosity
17.10
Measured viscosity in centipoise (cP)

=

CVR
21.6
Concentration/ Viscosity Ratio (mgI/mL/cP)

Example

Generic	Brandname	Concentration (mgI/mL)	Published Viscosity (cP)*	Measured Viscosity (cP)**	Concentration / Viscosity Ratio (mgI/mL/cP)***	Concentration / Viscosity Ratio (mgI/mL/cP) at 37°C****
Iopromide	Ultravist	300	9.2	7.64	39.3	61.2
Iodixanol	Visipaque	320	26.6	21.10	15.2	27.1
Iohexol	Omnipaque	350	20.4	18.70	18.7	33.7
Iopromide	Ultravist	370	22.0	17.10	21.6	37.0
Iomeprol	Iomeron	400	27.5	23.00	17.4	31.7

* Official data from manufacturers at 20°C
** Measured data using Brookfield DV-II+ Pro Viscometer at tested temperature of 21.5°C
*** Determined using measured contrast media viscosity
**** Calculated from manufacturer reported viscosities at 37°C

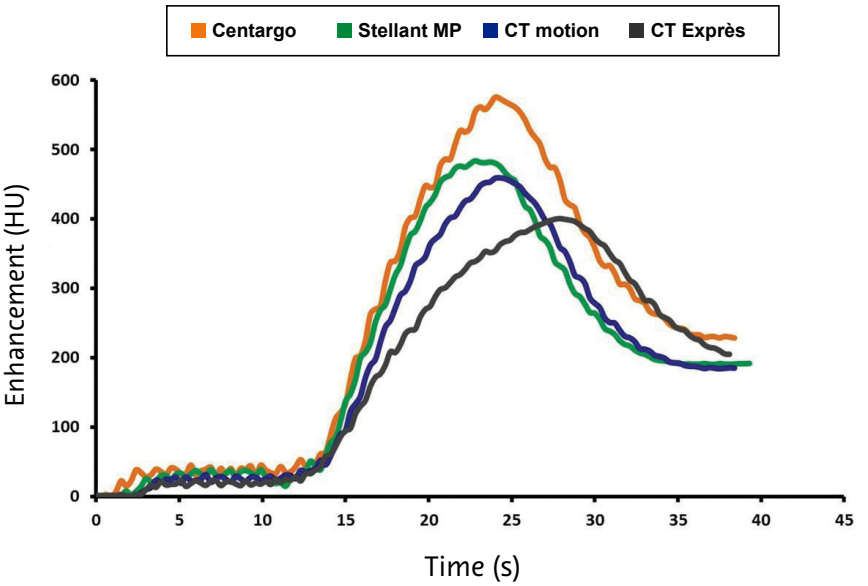
The results in this study show that CVR better predicts achievable IDRs than concentration alone.

Experiment II – Effect of Achievable IDR on Peak Vascular Enhancement

Key Term: A cardiovascular circulation phantom is a well-accepted research tool that simulates the transport and distribution of contrast material through the human circulatory system.

- The phantom provides a link between achievable IDRs and image enhancement, by allowing measurement of enhancement in large vessels.
- Centargo provides the highest peak vascular enhancement (up to a 48% increase) when compared to the tested peristaltic injectors with programmed IDRs from 1.8 – 2.4gl/s ($p < 0.05$).

Example Aortic Enhancement Graph Comparing Injection Systems



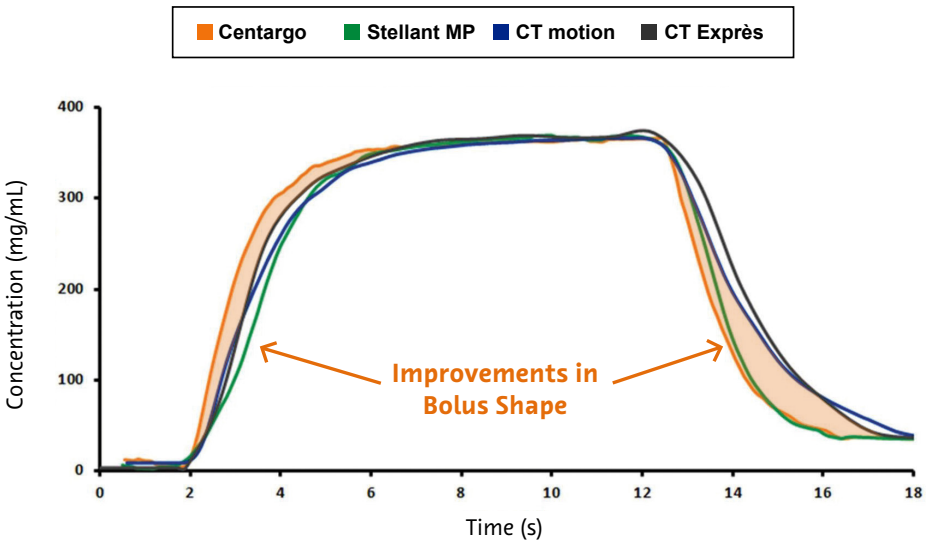
Centargo is capable of achieving higher IDRs, providing significantly higher enhancement for a longer duration.

Experiment III – Effect of Bolus Shape on Peak Vascular Enhancement

Key Term: Bolus shape represents the iodine concentration entering the patient over the duration of the injection.

- Centargo demonstrates a sharper and more compact bolus, with a faster rise time and fall time.
- The orange highlighted portion of the graph represents the bolus shape improvement of Centargo vs. the peristaltic pumps.
- This improvement in bolus shape leads to significant increases in enhancement in most tested protocols from 1.5 – 2.0 gI/s ($p < 0.05$).

Example Graph of Bolus Shape vs. Injection System



Centargo demonstrates improved bolus shape as compared to the other tested systems, exhibiting a faster rise time and faster fall time.

The results demonstrate superiority of piston-based injection systems and the importance of contrast media viscosity.

- Piston-based injection systems allow for higher achievable IDRs than the tested peristaltic pumps, leading to significantly increased peak vascular enhancement (up to 48%).
- Contrast media viscosity is more important than concentration, as higher concentration/viscosity ratios (CVRs) allow for higher achievable IDRs.

Ultravist (iopromid) injektions-/infusionsvæske, opløsning. D.SP.NR 6355. Ultravist 150 mg iod /ml, 240 mg iod/ml, 300 mg iod/ml, 370 mg iod/ml. Indikationer: Dette lægemiddel er kun til diagnostisk brug. Dosis kan variere afhængig af alder, vægt, kliniske problem, undersøgelsesmetoden og det område, der skal undersøges. Terapeutiske indikationer: Digital subtraktions-angiografi, computertomografi, flebografi, urografi, artrografi, hysterosalpingografi, fistulografi, cerebral angiografi, angiokardiografi. Oplysninger om særlige populationer: Unge spædbørn (< 1 år), og især nyfødte, er modtagelige over for elektrolytforstyrrelser og hæmodynamiske ændringer. Ældre patienter eller patienter med nedsat leverfunktion: Dosisjustering er ikke nødvendig. Nedsat nyrefunktion: Da Ultravist næsten udelukkende udskilles i uændret form via nyrerne, forlænges elimineringen af iopromid hos patienter med nedsat nyrefunktion. For at reducere risikoen for kontrastmiddelinduceret nedsat nyrefunktion hos patienter med eksisterende nedsat nyrefunktion, skal den mindste mulige dosis anvendes. Ultravist er dialysabel. Kontraindikationer: Overfølsomhed over for iopromid, andre ioderede kontraststoffer eller over for et eller flere af hjælpestofferne (natriumcalciumedetat, trometamol, saltsyre (10 % w/v). Særlige advarsler og forsigtighedsregler vedrørende brugen: Patienter, der oplever overfølsomhedsreaktioner, mens de tager beta-blokkere, kan være resistente over for behandling af overfølsomhedsreaktionen med beta-agonister. Hos patienter med kendt hyperthyreoidisme eller mistanke om samme, bør det overvejes at teste thyroideafunktionen før Ultravist administreres. Hos neonatale, især præmature spædbørn, der har fået Ultravist, enten gennem moderen under graviditeten eller i den neonatale periode, anbefales det at overvåge thyroideafunktionen, da en eksponering for for megen iod kan forårsage hypothyreodisme, der muligvis kræver behandling. Patienter med CNS-forstyrrelser kan have en øget risiko for neurologiske komplikationer i forbindelse med administration af iopromid. Patienter med moderat til svært (eGFR 44-30 mL/min/1,73 m2) eller svært nedsat nyrefunktion (eGFR <30 ml/min/1,73 m2) har øget risiko for post kontrast akut nyreskade (PC-AKI) ved administration af intraarteriel kontrastmiddel og first pass nyreeksponering. Patienter med svært nedsat nyrefunktion (eGFR <30 mL/min/1,73 m2) har øget risiko for PC-AKI ved administration af intravenøs eller intraarteriel kontrastmiddel med second pass nyreeksponering. Hydrering: Der skal sikres tilstrækkelig hydrering før og efter intravaskulær indgivelse af Ultravist. Dette gælder især for patienter med multipel myeloma, diabetes mellitus, polyuri, oliguri, hyperurikæmi samt for nyfødte, spædbørn, små børn og ældre patienter. Prætestning: Sensitivitetstestning med en lille dosis kontrastmiddel anbefales ikke, da det ikke har nogen prædiktiv værdi. Interaktion: Biguanider/Metformin: Hos patienter med akut nyresvigt eller alvorlig kronisk nyresygdom kan biguanid elimineringen blive reduceret, hvilket fører til akkumulering og udvikling af mælkesyreacidose. Radioaktive isotoper: På grund af nedsat optagelse af radioaktive isotoper kan diagnose og behandling af thyroideaforstyrrelser med thyreotrope radioaktive isotoper hæmmes i op til flere uger efter administration af Ultravist. Bivirkninger: De hyppigst observerede bivirkninger (≥ 4 %) hos patienter, der får Ultravist, er hovedpine, kvalme og vasodilatation. De mest alvorlige bivirkninger hos patienter, der får Ultravist er anafylaktisk shock, åndedrætsstop, bronkospasmer, laryngealt ødem, faryngealt ødem, astma, koma, hjerneinfarkt, slagtilfælde, hjerneødem, kramper, arytmier, hjertestop, myokardiel iskæmi myokardieinfarkt, hjertesvigt, bradykardi, cyanose, hypotension, shock, dyspnø, lungeødem, respirationsinsufficiens og aspiration. Fordeling: Efter intravaskulær indgivelse distribueres Ultravist hurtigt til det extracellulære rum med en halveringstid på 3 minutter. Proteinbindingen i plasma ved en koncentration på 1,2 mg I/ml plasma er 0,9 ± 0,2 %. Det kan ikke gennemtrænge den intakte blodhjernebarriere. Biotransformation: Der kunne ikke konstateres metabolitter hos mennesker efter administration af den klinisk relevante dosis af Ultravist. Elimination: Eliminationshalveringstiden hos patienter med normal nyrefunktion er ca. to timer uanset dosis. Opbevaringstid: 3 år. Pakninger, priser, tilskud, udlevering: Ultravist 370 mg iod/ml: 10 × 100 ml, 8 × 500 ml. For aktuel pris se www.medicinpriser.dk. Receptpligtigt. Udleveringsgruppe B. Ikke generelt tilskud. Indehaver af markedsføringstilladelsen: Bayer AB, Box 606, 169 26 Solna, Sverige. Dansk repræsentant: Bayer A/S, Arne Jacobsens Allé 13, 7. DK-2300 København S. Tlf. +45 45 23 50 00. Teksten er forkortet i forhold til det godkendte produktresume. Fuldstændigt produktresume kan rekvireres vederlagsfrit fra Bayer A/S, Tlf. 45 23 50 00. Læs venligst produktresumeet inden ordinering af lægemidlet. Dato for SPC: 9 november 2022. (PP-M_ULT-DK-0002-1)

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