CO_2-Angioset

For internal use only

OptiMed
global care

Indications – when to use carbon dioxide as contrast medium:

- Diagnostic / interventional angiography
- Intolerance to iodized contrast medium
- Aortic aneurysms
- Acute / chronic renal insufficiency
- Renal transplant
- Latent / manifest hyperthyroidism
- Paraproteinemia
- Presentation of pathological shunts
- AV dialysis shunts
- Search for sources of haemorrhage
- Transjugular intrahepatic portosystemic shunt (TIPS)
- Reduction of the loading with iodized contrast medium (e.g. in cardiac insufficiency or complex interventional surgery)

Range of applications using carbon dioxide as contrast medium:

- Pelvic arteries
- Arteries of legs
- Renal arteries
- Visceral arteries
- Haemodialysis shunts
- Venous presentations (max. 40 ml per injection)
- Angiography of retrograde portal artery with TIPS

Contraindications:

- All arterial presentations above the diaphragm (with the exception of haemodialysis shunts, arteries of the forearm and hand)
- Respiratory insufficiency
- Venous infection
- Any type of arterial and ventricular septum defect
- Pulmonary AV malformation
- Restlessness in the patient
- Significantly reduced aortic drainage
- Children

Side effects:

- Nausea / vomiting
- Dizziness
- Pain
- Tachycardia
- Iatrogenic CO2 acidosis
- Urge to defecate
- Sensation of heat
- Sensation of satiety
- Vascular and neural lesions
- Hemorrhage / hematoma
- Paresthesia
- Skin discoloration
- Disturbance of acid-alkaline balance

General overview contrast media vs. CO2

Physics comparison	Contrast media	CO_2
Viscosity	+	-
Velocity	-	+
X-Ray visbility	positive CM	negative CM
Molecular structure	↑	↓
Molecular weight		$CO_2 > O_2$

Physiology comparison	Contrast media	CO_2
Excretion	Kidney	Lung
Contra indication	allergic reaction renal failure hyper/hypo thyroidism	- Arterial septal defect - Ventricular septal defect - Open foramen ovale - Poor lung function
Binding capacity to erythrocyte		CO_2 has a 3x binding capability than O_2
Henderson / Hasselbach		PH-deviation

Dosage of carbon dioxide depending on the vascular region to be displayed:

Ventral aorta	60 – 100 ml PCV
Pelvic arteries	40 - 80 ml PCV
Arteries of the leg	40 – 60 ml PCV
Renal arteries	20 – 40 ml PCV
Visceral arteries	20 – 40 ml PCV
Haemodialysis	20 ml PCV
TIPS	20 – 40 ml PCV
Venous presentation	20 – 40 ml PCV
Brachial arteries (only arteries of the forearm and hand)	20 ml PCV

(PCV =pressure chamber volume)

Recommendations:

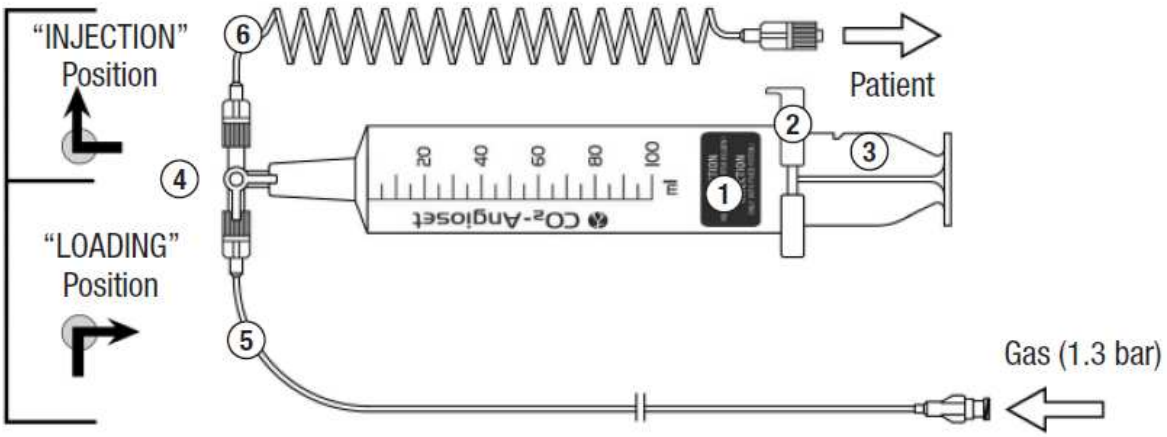
1.	Arteries of the leg	raise the legs by 15° with wedge-shaped cushion
2.	Renal arteries	raise the ipsilateral side of the body by 30° by means of a wedge-shaped cushion
3.	Invisibility caused by intestinal gases	administer 20 mg butylscopolamine (buscopane)

Necessary equipment for carbon dioxide angiographies:

1.	CO_2-Angioset	for carbon dioxide angiographies
2.	Gas bottle	highly pure medical carbon dioxide (99.5 % volume or more)
3.	Pressure reduction valve	to fix pressure at 1.3 bar
4.	CO_2 – sterile filter (Item-no..: 16596 HYK Description: Minisart NML PF Packing Unit 50 pcs. single sterile packed) Company link: http://www.sartorius.de/index.php?id=131	to prevent contamination

CO_2-Angioset

1. 100 ml syringe = dose chamber / adjustable setting in 20 ml steps
2. Locking slider for fixing the desired volume setting
3. Injection plunger with stop notches in 20 ml steps
4. Special stop-cock with valve which rotates through 90° for injecting a loading procedures
5. Gas supply line, 1.5 m long with connection to the pressure relief valve of the gas bottle
6. Connection tube to the patient 1.5 m long



Application of the CO_2-Angioset:

a. Set the syringe plunger at the required volume and lock in place using the locking slide.
Note: The slider is blocked under pressure, locking the plunger while the injection is administered.

b. Connect the gas supply line to the outlet of the pressure relief valve of the gas bottle.
Warning! The pressure of 1.3 bar must be fixed by setting the pressure relief valve on the gas supply bottle. Check that the outlet pressure gauge is correctly 1.3 bar before administering the injection.

c. Open the gas supply bottle and the pressure relief valve.

d. Flush the system by turning the special stop-cock forwards and backwards 5 times (1x flushing = 1x position "LOADING" and 1x position "INJECTION"), keeping the inflow and outflow of the dose chamber and the special stop-cock vertical.

e. After flushing, the special stop-cock is set to the "LOADING" position.

f. The connection tube to the patient is connected to the vascular access to the patient using the closed two-way stop-cock.

g. The two-way stop-cock in the vascular access is opened shortly before starting the DSA series.

h. After starting the DSA series and preparing the masking images the injection is performed by turning the special stop-cock to the "INJECTION" position.

i. After completion of the injection the special stop-cock is returned to the "LOADING" position.
Please note: The CO_2-Angioset is ready to be used for the next DSA-series.

Volume adjustment:

If the preset volume is insufficient for a continuous vascular presentation it can be increased in 20 ml steps.
Warning: check for aortic gas reflux! Reflux above the diaphragm must be avoided!

The volume is reset in the following sequence:

1. Disconnect the connection tube to the patient from the vascular access.

2. Set the special stop-cock to the "INJECTION" position.

3. Open the locking slider, set the desired volume with the plunger and re-lock the slider.

4. Continue as described above under step d.).

Important notes:

1. Before starting the system, the gas pressure should be checked; it should be set at 1.3 bar. Caution: Overdosage may be fatal.

2. Recommended dosages listed on page 3 should only be administered with a gas pressure of 1.3 bar.

3. The system should only be used on adult patients. Empirical data is not available for children.

4. CO_2 is a negative contrast medium which requires a special single-frame-addition software. The number of images should be increased to 4 per second.

5. The volume is given in ml per series. At an operating pressure of 1.3 bar, the injecting volume is about equal to the volume of the dose chamber for arterial injections (at an average pressure of 100mm Hg) and 1.3 times the volume of the dose chamber for venous injections.

General precautionary measures for carbon dioxide angiography

(see Caridi and Hawkins, JVIR 1997; 8:383-391).

1. Maximum amount of injection per series 100 ml.

2. Wait at least 2 minutes between each series (longer for patient with pulmonary disease).

3. Avoid brachial gas reflux angiographies of arm (or shunt).

4. In case of venous overdosage (gas in the right ventricle or pulmonic truncus) position the patient on his left side.

5. Alleviate gas trapping, e.g. in aortal aneurysm, by changing the patient's position.

6. In case of severe leg pains (due to trapping), position legs level, or lower.

7. Use the injection system as soon as possible after preparing and rinsing it. CO_2 will diffuse from the dose chamber over time.

8. Use only purely medical sources of carbon dioxide (stainless steel cylinders).

9. Connect a sterile filter to the pressure relief valve.

Safety features of the CO_2 – Angiography:

1. Special stop-cock — this special stop-cock is constructed in such a way that an injection directly from the gas supply is impossible.

2. Locking slider — a buffer which offers additional safety

Air is reduced when the storage chamber is rinsed with CO_2 at an operating pressure of 1.3 bar:

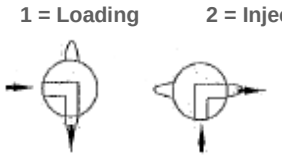
Decrease of air ratio at 1.3 bar working pressure

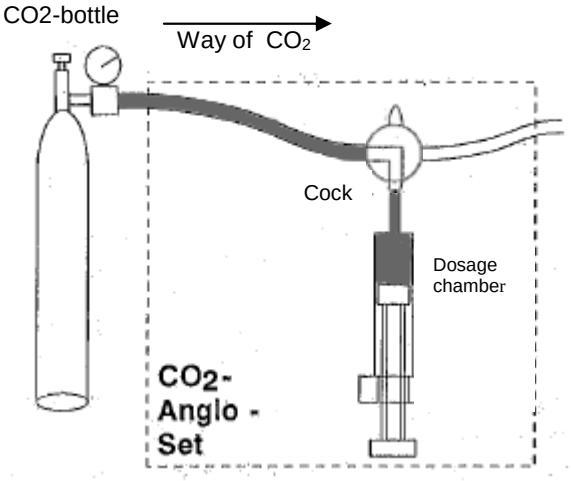
Chamber volume: 100 ml
Air pressure: 1.0 bar absolute
Filling pressure: 2.3 bar absolute

Initial position			After CO_2-filling			
No. Of rinses	Air in ml at 1,0 bar	CO_2 in ml at 1,0 bar	Relaxed total volume in ml at 2.3 bar	Relaxed air volume in ml at 2.3 bar	Air volume equivalence in %	Maximum injectable, relaxed air volume in ml
0	100.0	0.0	230	100.0	43.48	24.58
1	43.5	56.5	230	43.5	18.90	10.68
2	19.0	81.0	230	19.0	8.22	4.65
3	8.3	91.7	230	8.3	3.57	2.02
4	3.6	96.4	230	3.6	1.55	0.88
5	1.6	98.4	230	1.6	0.68	0.38

Schematic description of charging process and injection:

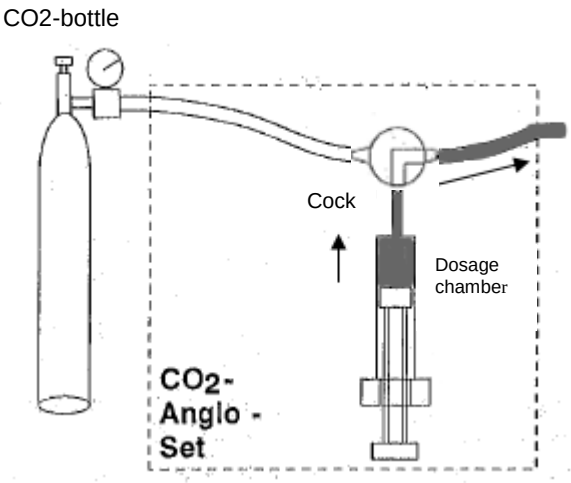
Cock position:





At the setting „Loading" (1) the feed line which is attached to the gas bottle is connected with the dosage chamber (via the L-drilling cock).
The dosage chamber fills with pressurized carbon dioxide out of the gas bottle (1.3 bar).

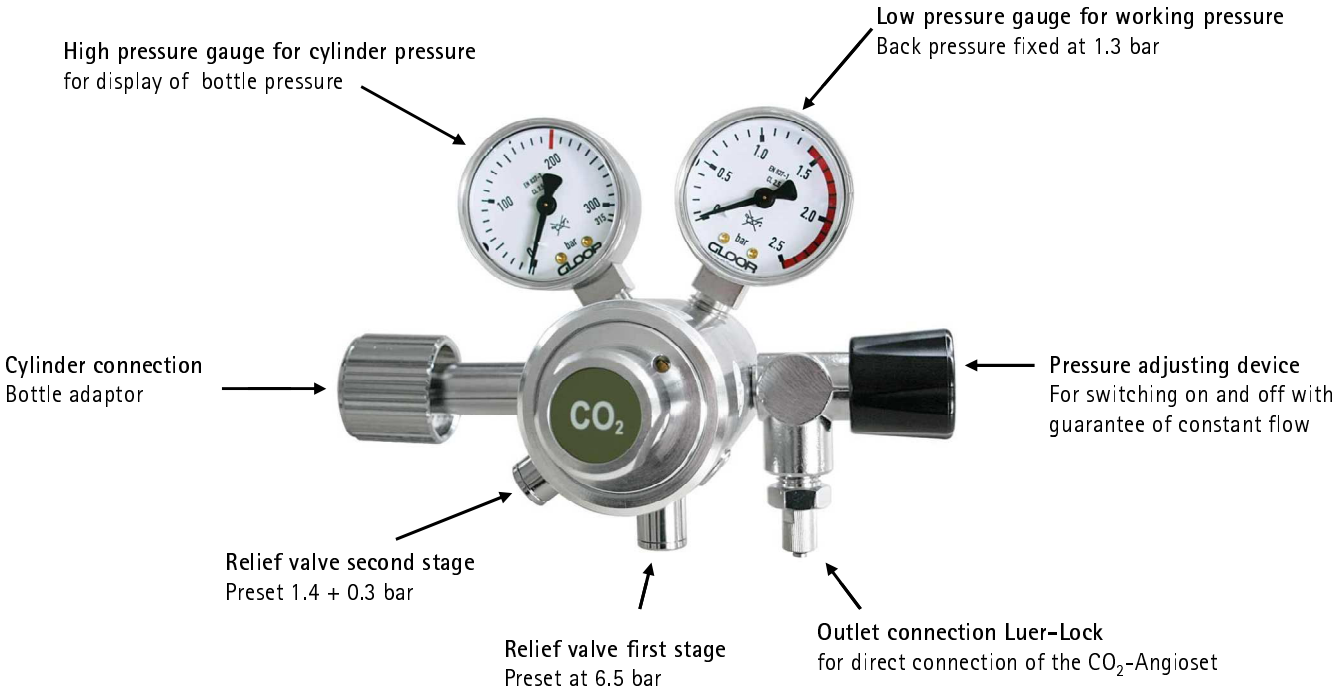
Connection via Luer-lock to the angiography-catheter.



At the setting „Injection" (2), the dosage chamber is being connected with the drain (2).
The portioned amount of gas deflates into the vascular system by the inherent pressure.
A direct connection from feed line to the drain is excluded for safety reason.

Connection via Luer-Lock to the angiography-catheter.

Pressure reduction valve of GLOOR Medical for medical carbon dioxide (CO_2):



Description:

The pressure reduction valve of GLOOR Medical is produced exclusively for Opti*Med*. It consists of a two-stage pressure cylinder with:

- inlet pressure and outlet pressure manometer
- security blow-off valve (1.8 bar)
- shut-off valve
- Luer-Lock Connector
- Bottle adapter

Application / purpose:

The pressure reduction valve is used to reduce the pressure when pure medical carbon dioxid (CO_2) is tapped from pressurized gas cylinders and may only be used in conjunction with "Opti*Med* CO_2-Angioset according to Schmitz-Rode/Alzen".

The two-stage performance protects the constancy of the outlet pressure independent of the pressure measured inside the cylinder.

The pressure regulator is set to 1.3 bar for operation.

Safety features of the pressure reduction valve:

1. Luer-Lock connection	CO2 – Angioset can be connected directly (eliminating need for connection tube)
2. Pressure relief valve	can be fixed at 1.3 bar eliminating risk of overdosage.
3. Pressure adjusting device	to switch on and off, guarantees consistent gas flow.

GLOOR MEDICAL Quality Standard:

The swiss producer GLOOR MEDICAL is specialized in development, production / confection and selling of medical engineering products for the respiratory area, as well as pressure regulating devices for related areas.
With 70 years of experience, GLOOR MEDICAL is well grounded in the area of pressure and flow regulation.

Special characteristics:

- Application only in connection with „OptiMed CO_2-Angioset according to Schmitz-Rode/Alzen"
- High back pressure constancy by two-stage performance
- Increased operation safety by relief valve

Technical Data of OptiMed´s pressure reduction valve:

Classification:	device class according to EG-Guideline 93/42 EWG, Annex IX, → Class IIb
Construction:	two-stage membrane pressure reduction valve
Body:	brass 2.0401.26, specially cleaned, nickel- and chrome-plated
Character of gas:	medical gas as O_2, CO_2, N_2O, Air, He, Xe
Flow:	max. 28m^3/h
Primary pressure:	max. 200 bar (1 bar = 1kPax100)

Backward pressure:	stage 1: 20 bar stage 2: 0-10 bar (optionally other nuances are possible)
Working pressure:	1.3 bar, factory made fixed at 1.3 bar pressure fluctuation of ±0,1 bar is tolerable
Operating temperature:	-20°C to +60°C
Weight:	2.0 kg
Measurements (WxHxD):	150 x 125 x 150 mm
Bottle adapter:	country- and gas specific screw adapter (hand- or key tightener) according to DIN 477-1, optionally other connectors are available
Outlet adapter:	G ¼" internal thread (lateral)
Back pressure adapter:	Luer-Lock connector

Material:

Body:	brass
Diaphragm:	Hastelloy
Seat:	PCTFE/PTFE
Gasket:	PVDF

Ordering information:

Since the connecting piece of the CO_2-pressure reduction valve to the gas supply varies from country to country, GLOOR supplies various versions specific to each nation.
The required connecting piece comes mounted to the CO_2-pressure reduction valve depending on the nation´s need.
Kindly inform Customer Service Export of your requirements when ordering (i.e.: GB10877, BS 341, DIN EN 850, etc.).

Order code	Product description	Units per package
2100-0000	CO_2-Angioset	1

Pressure reduction valve:

Country	item number	article text / additional information
Germany / Schwitzerland / Austria:	**6676-530001010**	Bottle-pressure reduction Opti 500, Standard DIN 477-1
Europe:	**6202-35841002-EU**	GM6202-35841002-O-EU Bottle-pressure reduction Opti 500, EU-Standard ISO 5145 (Adapter FTSC 0110 of the standard ISO5145 with adaptor thread W27×2)
France:	**6202-35221002-O**	GM6202-35221002-O Bottle-pressure reduction Opti 500, French-Standard AFNOR C
England:	**6202-35201002-O**	GM6202-35201002-O Bottle-pressure reduction Opti 500, British-Standard BS 341,3HW
	6202-35231002-O	GM6202-35231002-O Bottle-pressure reduction Opti 500, British-Standard BS 341,3TF
USA:	**6202-35991002-US**	GM6202-35991002-O-US-940 Bottle-pressure reduction Opti 500, US-Standard, Pin Index CGA 940
	6202-35851002-US	GM6202-35851002-O-US-320 Bottle-pressure reduction Opti 500, US-Standard, CGA 320 (Attention: according to the standard documents of the company Gloor AG, the adapter number is 320. 580 is only defined for N2 and Argon.)
Australia:	**6202-35201002-AS**	GM6202-35201002-O-AS Bottle-pressure reduction Opti 500, Australian-Standard HW
	6202-35231002-AS	GM6202-35231002-O-AS Bottle-pressure reduction Opti 500, Australian-Standard TF

Literature about CO_2 Angiography:

[1] J. Textor, B. Hinterthaner, K. Wilhelm, H. Strunk, H. Schüller, H. Schild, Bonn:
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Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161
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[2] D. Wagner, K. Rauber, S. Matthes, W.S. Rau, Giessen/Germany
CO_2 gas versus contrast medium containing iodine in PTA
Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161
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[6] Goldyn, G.L.;
Diagnostische Angiographien: Becken-Bein-Angiographie
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[7] Caridi,J.G.; Hawkins, I.F.;
CO2 Digital Substraction Angiography: Potential Complications and their Prevention,
Journal of Vascular and Interventional Radiology, Vascular Diagnosis, S.383-391

[8] Heinrich M.; Uder M.
Nephrogene systemische Fibrose nach Anwendung gadoliniumhaltiger Kontrastmittel - ein Statuspapier zum aktuellen Stand des Wissens
RöFo, Georg Thieme Verlag KG, Stuttgart 2007, Band 179, S. 613-617

Literature:

CO_2 cholangiography (V0586)
J. Textor, B. Hinterthaner, K. Wilhelm, H. Strunk, H. Schüller, H. Schild, Bonn/Germany
Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161

Aim: To test the benefits of carbon dioxide (CO_2) as a contrast medium to set up external-internal drainage of the bile ducts.
Materials and methods: Following percutaneous transhepatic injection of 10 - 25 ml of a contrast medium containing iodine, bile duct occlusion was diagnosed in 8 patients (6 women, 2 men; average age 63 years). The same access was used subsequently for a manual bolus injection of 30 - 50 ml CO_2. It was investigated whether CO_2 can pass the duct segment closed for liquid contrast medium.
Results: In 5 of the 8 patients, additional parts of the obstructed bile duct segment (n = 1) or a post-stenotic duct course near the papilla (n = 4) could be recognized in CO_2 angiography. The intrahepatic bile ducts could not be evaluated with CO_2. **Discussion:** CO_2 has 400 times less viscosity than contrast medium containing iodine. This enables visualization of obstructed duct segments. However, dorsal intrahepatic duct segments are not sufficiently contrasted.
Main statements: Due to its low viscosity, CO_2 can pass bile duct occlusion, even when this is not possible for a contrast medium containing iodine. In particularly difficult anatomical situations, the knowledge of the duct course can improve orientation and reduce the number and duration of intraductal manipulations.

CO_2 gas versus contrast medium containing iodine in PTA (V0585)
D. Wagner, K. Rauber, S. Matthes, W.S. Rau, Giessen/Germany
Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161

Aim: Percutaneous transluminal angioplasty (PTA) using non-ionic contrast medium is a routine procedure. However, the use of contrast medium containing iodine may be contraindicated due to renal failure, allergy or hyperthyroidism. Thus we investigated CO_2 gas for its suitability as a contrast medium in PTA and other indications.
Materials and methods: We initially treated a control group of 20 patients with arterial stenosis or occlusion (16 cases involving the femoral superior artery, 3 cases involving the iliac artery, 3 cases involving the popliteal artery/anterior tibial artery) using PTA from May to September 1996. We performed angiography using contrast medium containing iodine (Ultravist 370, Schering) and directly afterwards 30 - 50 cm^3 CO_2 gas manually from a 50 cm^3 syringe (Messer Griesheim). The total CO_2 dose was 299 $\pm$ 53 cm^3. The gas was taken from a 10-litre bottle via a pressure reducing valve, connection hose and three-way stopcock. A further 22 patients with various syndromes were treated exclusively with CO_2 as contrast medium containing iodine was contraindicated in their cases. In a double-blind manner, three experienced interventional radiologists evaluated the films with respect to their diagnostic quality.

Results: Road map, visualization of stenosis/occlusion, reconnection and catheter positioning were successful using only CO_2. Film quality improved with increasing vascular diameter. There was insufficient contrast of CO_2 in fluoroscopy. Vascular constrictions before PTA were assessed similarly using CO_2 and contrast medium containing iodine. Vascular irregularities after PTA were mostly overestimated when visualized with CO_2. Film processing, a learning effect and the surface structure of the stenosis were more important than with contrast medium containing iodine. The contrast to the bloodstream was clearly superior with the contrast medium containing iodine. In the end, approx. 80 % of the interventions could have been possible using only CO_2. 25 % of the patients indicated stinging in the dependent flow area. This led to discontinuation of CO_2 administration in 14 % of cases.
Discussion: In PTA of the femoral and pelvic vessels, CO_2 gas is a good alternative to contrast medium containing iodine. In patients with relevant contraindications, it may be used to clearly reduce the amount of contrast medium containing iodine or even dispense with it altogether.

Carbon dioxide (CO_2) in the diagnosis of intra-abdominal bleeding (VO584)
J. Textor, K. Wilhelm, H. Strunk, H. Schüller, H. Schild, Bonn/Germany
Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161

Aim: To test the benefits of CO_2 as a contrast medium to detect intra-abdominal bleeding. **Materials and methods:** Twelve DSA investigations to localize blood were performed in 10 patients with intra-abdominal bleeding (five cases in upper gastrointestinal tract, five cases in lower gastrointestinal tract, one case in spleen). Both CO_2 (manual injection of 20 - 50 ml) and contrast medium containing iodine (manual injection of 10 - 30 ml) were used. **Results:** Blood could be detected in 6 of the 10 cases (4 using contrast medium containing iodine and 6 using CO_2). There were no complaints as a result of CO_2 injection. No further blood transfusions were required in 4 patients in which the search for blood was not successful with CO_2. **Discussion:** CO_2 has 400 times less viscosity than contrast medium containing iodine and is thus able to escape through very small vascular defects. As it is compressible because it is a gas, immediate spread occurs after escape in the intestinal space, This additionally facilitates detection of bleeding. Contrasting of the organ parenchyma was not performed with CO_2 to prevent disturbing overshadowing which could make detection of blood more difficult. **Main statements:** CO_2 is suitable as a contrast medium for intra-abdominal search for blood and should always be used when the source of bleeding cannot be determined using contrast medium containing iodine.

Initial experience with CO_2 angiography in diagnostics and PTA in coronary AOD (VO583)
M. Braunschweig, J. Triller, D. Dai-Do, F. Mahler, Bern/Switzerland
Varia Sitzung 2, Fortschr. Röntgenstr. 166 (1997), S 161

Aim: Angiography using contrast medium containing iodine is the standard method used in the diagnosis of vascular abnormalities. Despite the use of low osmolar contrast medium, nephropathy induced by contrast medium occurs. CO_2 does not involve this risk. In our investigation, we compared the findings of CO_2 angiography to those of contrast-medium angiography.

Materials and methods: Both CO_2 and contrast medium containing iodine were injected in 120 patients who were candidates for angiography and/or PTA of the infrarenal aorta, the renal arteries and the pelvic and leg vessels. The investigations relating to CO_2 and contrast medium were documented separately and evaluated by two radiologists independent of each other. The findings were divided into: 1. Normal findings, 2. Stenosis below 50 %, 3. Stenosis above 50 %, 4. Vascular occlusion. **Impulses:** In relation to the large vessels, the results of contrast medium angiography and CO_2 angiography corresponded in over 85 % of cases in all patients. The usefulness of CO_2 angiography was limited in the intrarenal arterial branches and in the tibial vessels from the level of the ankle joint. There were no incidents in the patients during CO_2 injection. **Discussion:** CO_2 angiography may replace contrast medium containing iodine in risk patients. The favourable results indicate that interventions without the use of contrast medium containing iodine may be performed.