ANGIODROID

Carbon Dioxide Interventional Peripheral Angiography

Contents

Angiodroid: The CO^2 Injector

angiodroid

Is a ***CO2 Contrast Media Injector***
dedicated to
Interventional and **Diagnostic**
Angiographic Peripheral Procedures

Angiodroid: Main Fields of Application

angiodroid

has 3 main Fields of Application

- **Interventional Radiology**
- **Vascular Surgery**
- **Interventional Cardiology**

Angiodroid: conclusion

Carbon Dioxide (CO^2) is the only <u>Safe Contrast Agent</u> for patient with

- **Hyper sensibility to Iodinated Contrast Material**
- **Renal Failure**
- **Diabetic Diseases**

Angiodroid: conclusion

angiodroid

Is the only Device Worldwide on Market

- **100% DIGITAL**
- **100% AUTOMATIC**
- **100% SAFE**
- **100% USER FIENDLY**

Angiodroid: Business Opportunities

Single-use Kit
connection line +
4 Frenchs Catheter

Angiodroid The Injector

After sale services
- Periodical maintenance
- CO2 cylinder substitution

Interventional Peripheral Angiography

- Rising life Expectancy
- Increment of vascular diseases
- Development of sophisticated radiological interventional techniques

All those Aspects have determined an increment of Angiographic Procedures

CIN – Contrast Induced Nephropathy

Contrast-Induced Nephropathy (CIN)

Each angiographic procedure requires the injection of iodinated contrast media that, in an increasing number of procedures, has aspects of clear contraindications or quantitative limitation: the case of diseases associated with impaired renal or diabetic vascular dysfunctions.

Contrast-Induced Nephropathy (CIN) is a form of Acute Renal Failure caused by exposure to contrast media during cardiology and radiology cathetering procedures. The lack of effective treatment to prevent CIN remains problematic for patients with renal-insufficiency.

CIN – Contrast Induced Nephropathy

What are the potential consequences?

CIN is associated with increased:

- Major adverse in-hospital cardiac events
- In-hospital mortality rates
- Long-term mortality
- Risk of acceleration toward end-stage renal disease (dialysis)
- Longer and more frequent hospital stays

According to “Marenzi, et al”, hospitalized patients who received contrast media and who acquired CIN had significantly higher mortality rate (31% vs. 0.6%) than patients who did not acquire CIN.

CIN risk incidence: 30% → **higher health care costs**

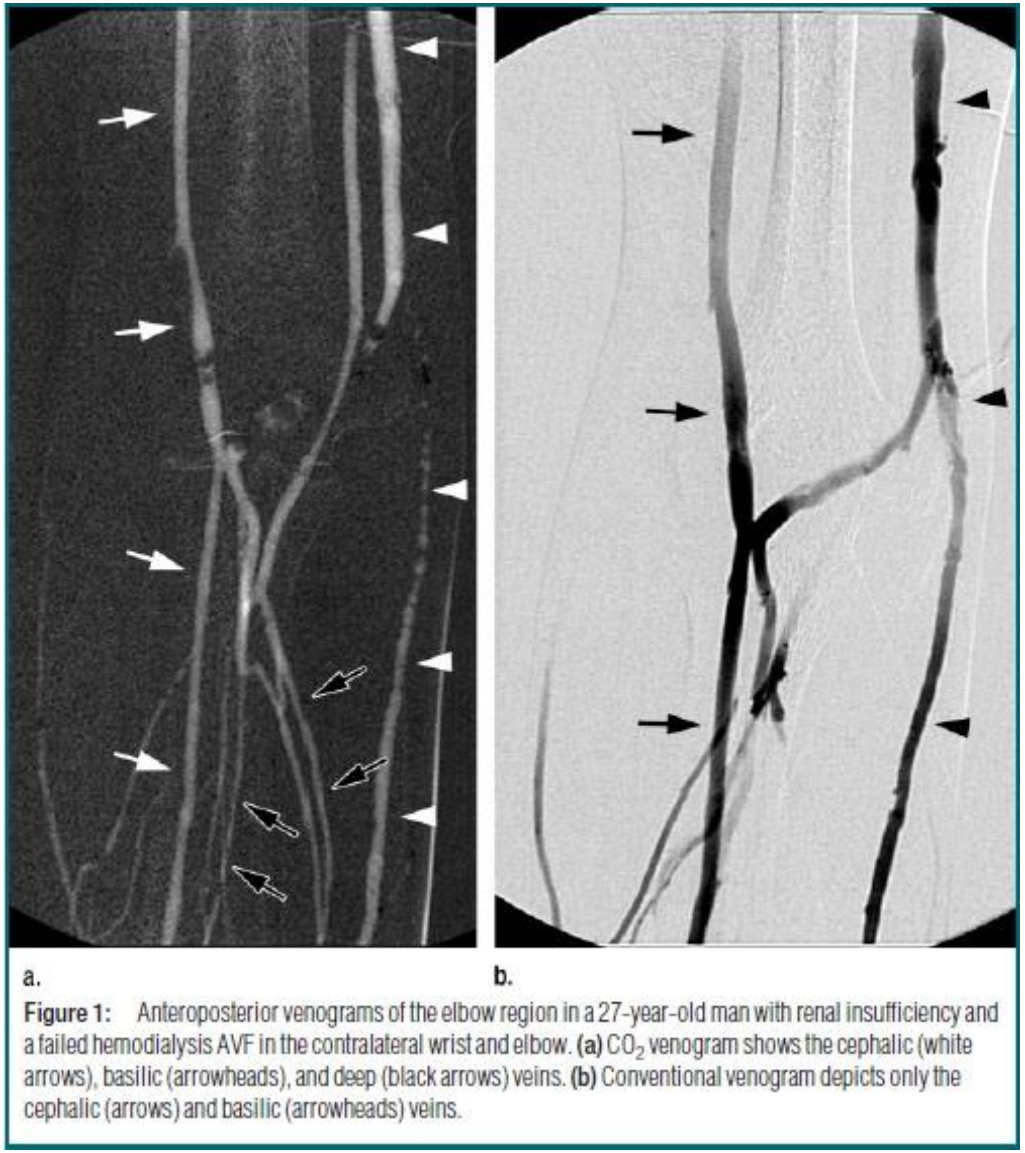
CO_2 as Solution to CIN Risk

An alternative to the use of iodinated contrast media is represented by Carbon Dioxide (CO_2), a gas injected into the vessels results in a clear contrast effect and is easily removed from the circulation via the lungs.

In the '70s, Hawkins was the pioneer in the US of CO2 angiography for high risk patients with intolerance to iodine or renal failure.
With the advent of image subtraction angiography in 1980, the use of low-density CO2 became possible, and then, through the implementation of digital technologies for image subtraction, angiography with CO2 became an applicable method in the different fields of angiography.

CO2 and Iodine angiography venograms comparison

CO2



Iodium

a. b.

Figure 1: Anteroposterior venograms of the elbow region in a 27-year-old man with renal insufficiency and a failed hemodialysis AVF in the contralateral wrist and elbow. **(a)** CO_2 venogram shows the cephalic (white arrows), basilic (arrowheads), and deep (black arrows) veins. **(b)** Conventional venogram depicts only the cephalic (arrows) and basilic (arrowheads) veins.

Carbon Dioxide: Gas Properties

Gas Properties:

- Highly compressible
- 20 times more soluble than O^2
- Non Viscous and Buoyant
- Invisible, Colourless and Odourless
- Radiopacity
- Rapidly dissolving in Blood
- Lacks both Allergic Potential & Renal Toxicity

Next:

- CO^2 doesn't mix with Blood
- It has extreme diffusibility
- None Total Maximum dosage

CO_2 angiography: critical issues

Basically there are 3 critical issues in the use of CO_2 as a contrast medium:

1. to determine the amount of injected gas and to remove the air from all over the system, in order to avoid the risk of vascular emboli

2. to inject the gas at controlled pressure in order to avoid vessel rupture in the presence of obstructions (aneurysms)

3. to properly modulate the gas injection; in order to ensure emptying of the catheter from the internal fluid, at an early stage, and to avoid the "jet", while controlling the gas injection in a second stage

The technological solutions available up to today (see *The Market: Overview*), do not solve these critical issues by relying on manual control of the operator or neglecting the variability of blood pressure during the injection phase. In fact the amount of gas injected through a syringe of known volume depends the pressure inside the vessel which is not constant over time.

CO_2 Angiography Indication

Indications

- renal failure diabetes
- intolerance to iodinated contrast
- creatinine greater than 1.8 mg / dl

Contraindications

- above diaphragm arterial studies
- pulmonary insufficiency, pulmonary AV malformation
- interauricolar or interventricular communication

Possible side effects

- nausea
- pain
- dizziness
- tachycardia

CO_2 Clinical Application

Diagnosis applications:

- pelvic arteries
- lower extremity
- renal, visceral, venous studies

Interventional applications:

- angioplasty
- stent placement
- shunt for hemodialysis
- vena cava filter placement
- ablation of renal artery
- transcatheter embolization
- endovascular treatment of abdominal aortic aneurysm

How it works

Injection Technique and Imaging

1. **Use of Closed Circuit**
2. **Pressure and Volume Control System**
3. **Selective Injection**
4. **Use of Nitro-glycerine (0,1 mg) for Blood low range Patients**
5. **Wasteless Diet to eliminate interferences**
6. **Administer Buscopan (20 mg) to reduce bowel movement**
7. **3-4 frames/sec Imaging Acquisition and 60 ms**
8. **Use Fluoroscopy mode**
9. **Wait 1-2 min between different injections**
10. **Use “stacking” software during Post processing**
11. **Trendelemburg modality while delivering (10° -15°)**

How it works

Combined Approach

CO2

Indication

- ✓Borderline Renal Failure
- ✓Cronic Nepropathy
- ✓Allergic Potential
- ✓Riduzione carico rene

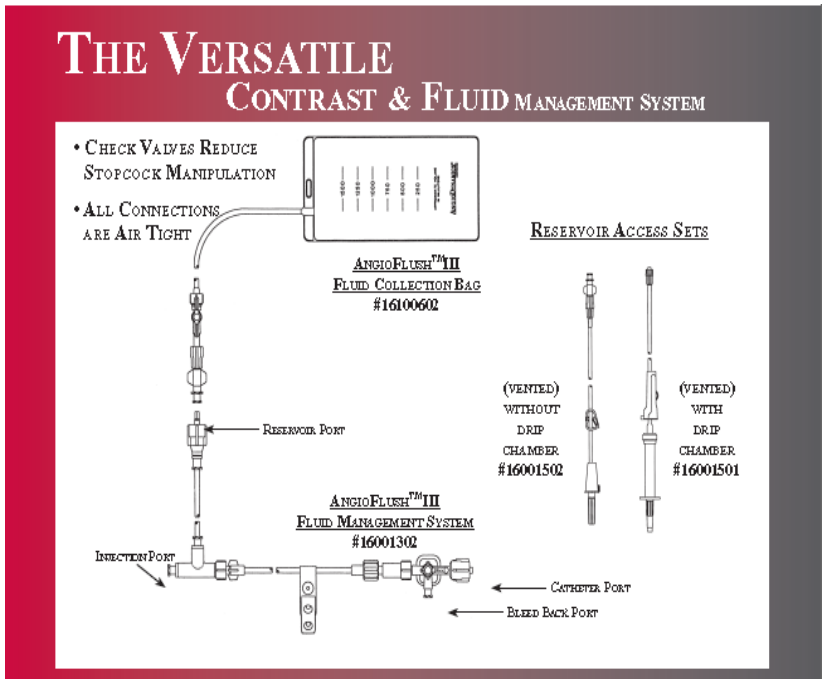
Iodinated Contrast Agent

Indication

- ✖Thoracic Angiography Procedures
- ✖Coronary Angiography
- ✖Neorovascular Studies
- ✖Non cooperative patients
- ✖Rear vessels

Peripheral Angiography
PTCA
Endoprostesys

The Market: Overview 1/3



ANGIOFLUSH III fluid collection system

- manual injection kit
- operator-dependent: no procedural repeatability

The Market: Overview 2/3

CO2 ANGIOSET

- manual injection kit
- difficulty of achieving the desired injection volume

The Market: Overview 3/3

CADDI

- automatic volume adjustment
- no control of injection pressure
- withdrawn from the market because of its complex usability
- none technical innovations: it’s a simply mechanical handling of a syringe

* Recalled Device

Angiodroid: The CO^2 Injector

angiodroid

100% DIGITAL

100% AUTOMATIC

100% SAFETY

100% USER FIENDLY

Market Overwiew Comparison

AngioDynamics® INCORPORATED

GRIFOLS

OptiMed global care

angiodroid

The Co$_2$mmander®

Products	Automatic System	Digital System	Safety System	User Friedly System	CO2 Bottle included	Air Contaminati on Safety System	Volume Definition	Pressure Definition	Constant Pressure Injection System
Angiodynamics	no	no	no	no	no	no	yes	no	no
Optimed	no	no	no	no	no	no	yes	no	no
Co2mmander	no	no	no	no	partially	no	yes	no	no
Caddy	partially	yes	no	no	yes	yes	yes	no	no
Angiodroid The CO2 Injector	yes	yes	yes	yes	yes	yes	yes	yes	yes

ANGIODROID: advantages and uniqueness

Major Technical figures:

• Definition of the amount of gas to be injected into the vessel

• Definition of Pressures and Injection volumes (automation, security and repeatability of the procedure)

• Total removal of the air contained in the catheter through the initial injection of a small quantity of gas

• Constant injection pressure of gas during the procedure, removing the risk of vessel rupture in presence of obstructive aneurysms

• Positive pressure of internal pneumatic circuit reducing to zero the risk of introducing air

Injection Systems Comparison

Manual Injection

- Anti-bacterial Filter
- Syringe
- Valves
- Check Valves
- Special Connectors

HANDICAP

- ✖ High X-ray Operator Dose Exposure
- ✖ Operator dependent
- ✖ Seroius contamination risk with ambient air
- ✖ Difficult to accurately determine the injected dose
- ✖ Increased risk of pain for the patient

Digital Automatic Injection

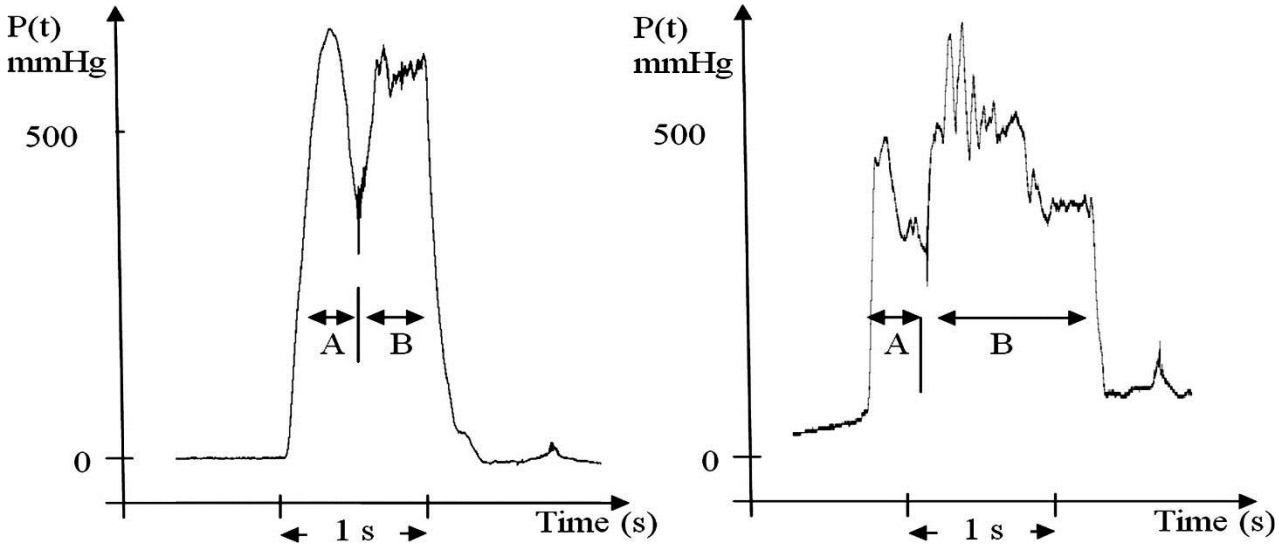
Digital Automatic injector that accurately determines Volume and Pressure

UNIQUENESS

- ✓ Reduced X-ray exposure
- ✓ Locked and Safe System
- ✓ Automatic cleaning of Internal circuit
- ✓ User friendly
- ✓ None risks of Air Ambient Contamination

Manual Injection

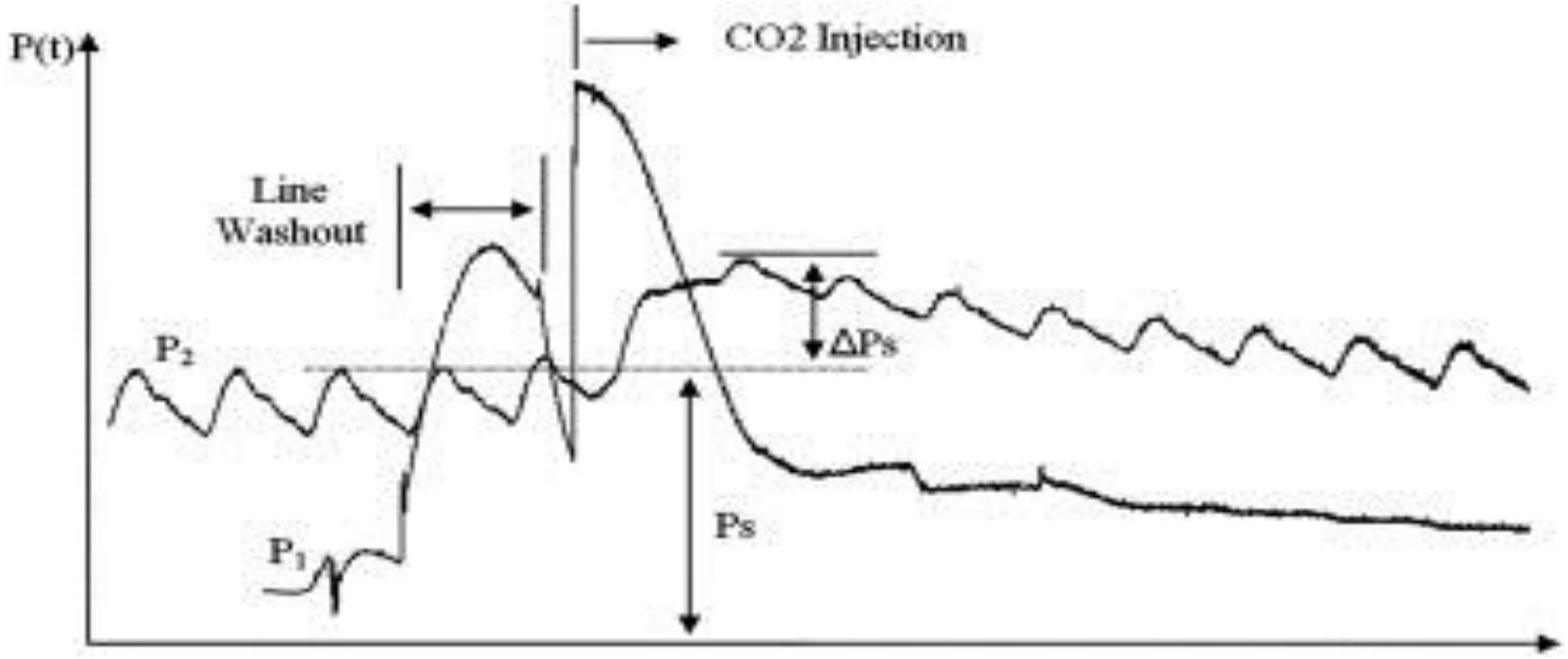
The CO_2 manual Injection doesn't allow an optimal Gas release control, it exposes to the risk of Contamination and requires a long training period



Pressure/time graph of two manual CO_2 injections. Phase A corresponds to line washing; phase B corresponds to gas injection –Corazza et al 2013

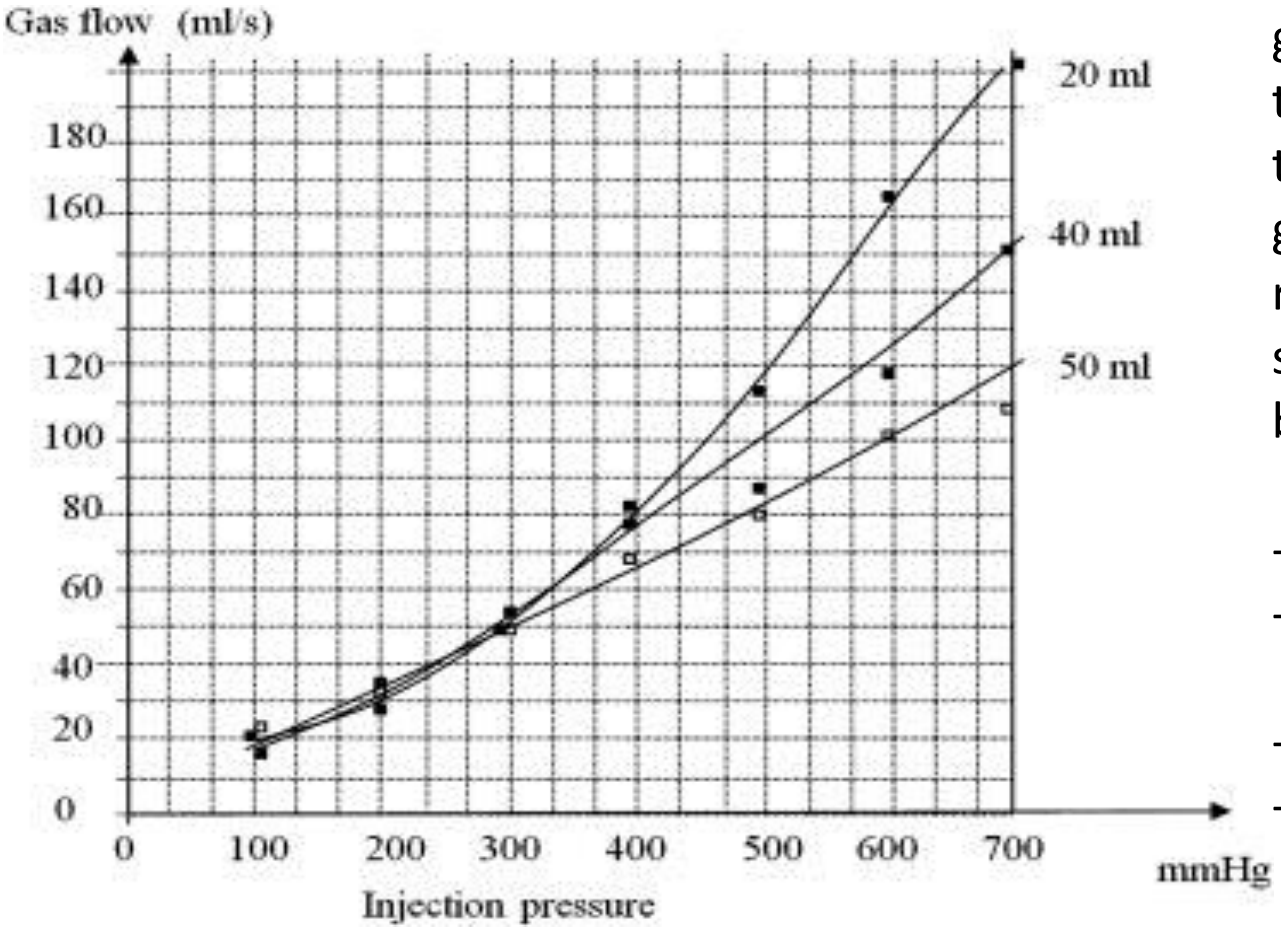
Digital Automatic Injection

Angiodroid The CO_2 Injector has exceeded all those problems (Angiodroid®, Angiodroid SRL, Bologna, ITALIA)



P1 and P2 pressure recordings during automated line washout and CO_2 gas injection. (Corazza et. al 2013)

Digital Automatic Injection



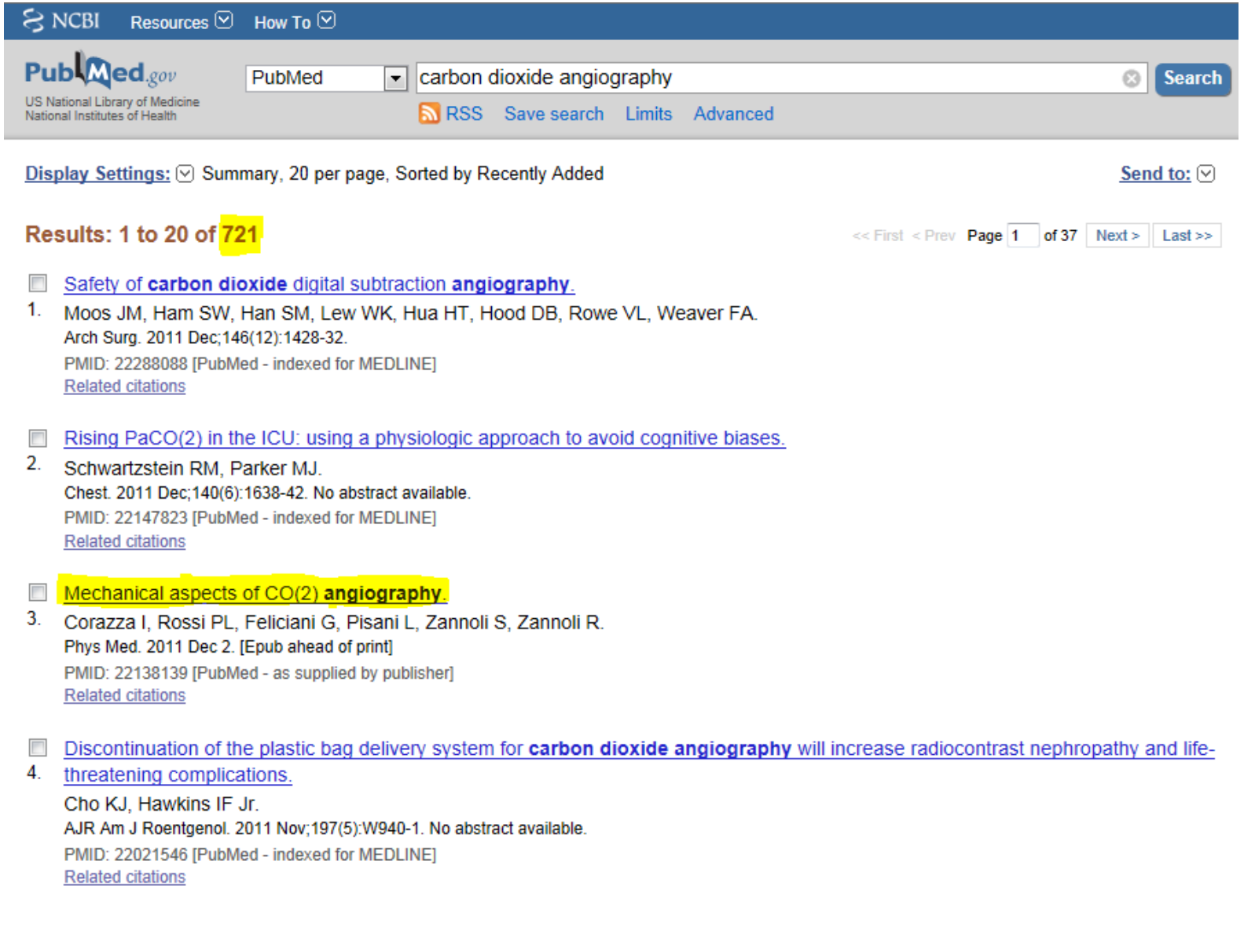
The amount of injected gas should be proportional to the volume of the vessel to have in view, while the gas pressure, which regulates the gas flow, should be proportional to blood flow in the vessel.

- Vessel volume
- Gas volume

- Blood flow
- Gas pressure

Corazza et al, 2013

Clinical validation and scientific resources



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   Related citations

Clinical Validation

Physica Medica
In Press, Corrected Proof - Note to users

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ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Original Paper

Mechanical aspects of CO_2 angiography

Ivan Corazza[a,], Pier Luca Rossi[a], Giacomo Feliciani[a], Luca Pisani[b], Sebastiano Zannoli[b], Romano Zannoli[a]

[a] Cardiovascular Dept., University of Bologna, Via Massarenti, 9, 40138 Bologna, Italy

[b] Spark SrL, Bologna, Italy

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Abstract

The aim of this paper is to clarify some physical–mechanical aspects involved in the carbon dioxide angiography procedure (CO_2 angiography), with a particular attention to a possible damage of the vascular wall.

CO_2 angiography is widely used on patients with iodine intolerance. The injection of a gaseous element, in most cases manually performed, requires a long training period. Automatic systems allow better control of the injection and the study of the mechanical behaviour of the gas.

CO_2 injections have been studied by using manual and automatic systems. Pressures, flows and jet shapes have been monitored by using a cardiovascular mock. Photographic images of liquid and gaseous jet have been recorded in different conditions, and the vascular pressure rises during injection have been monitored.

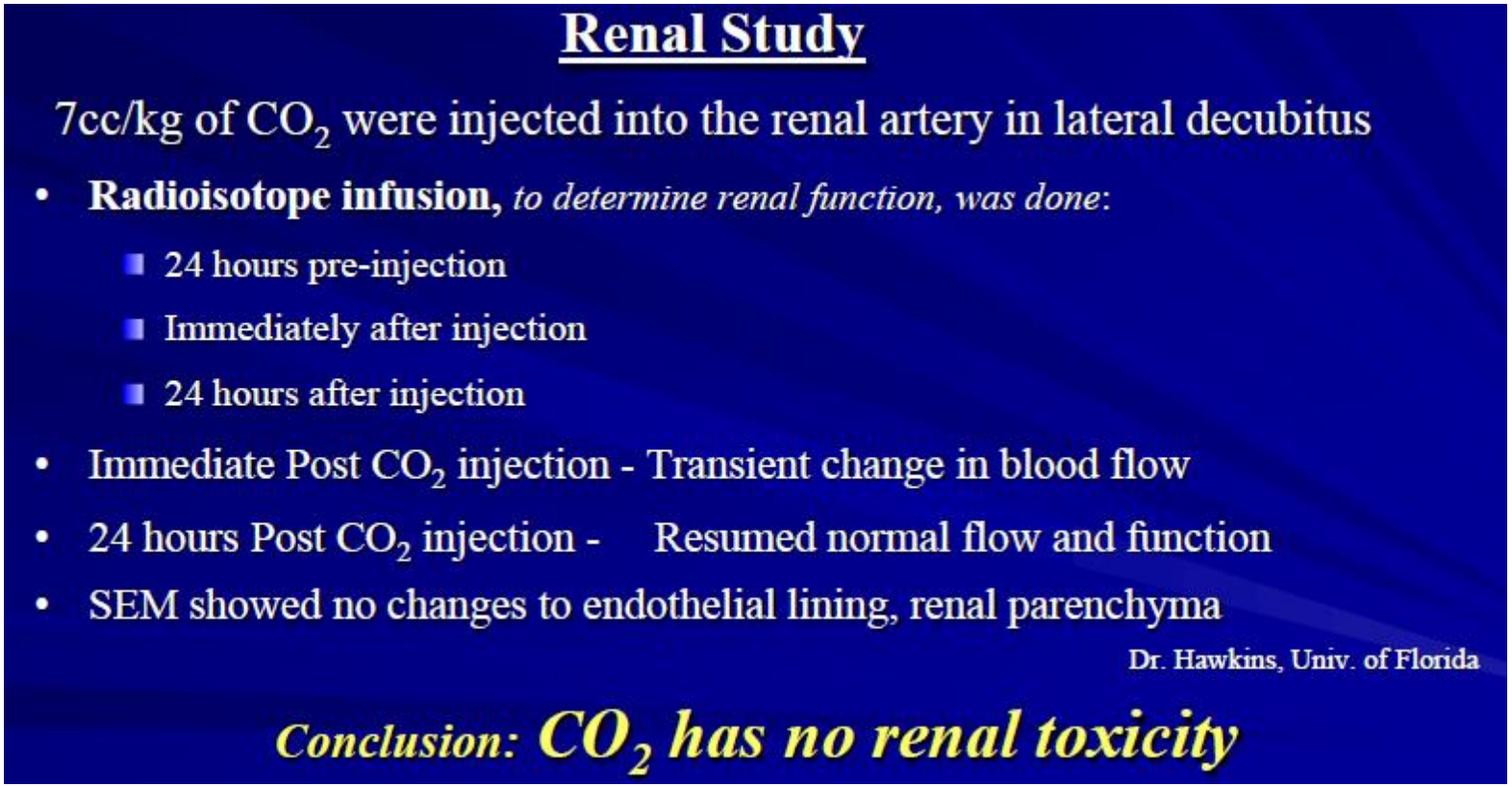
The shape of the liquid jet during the catheter washing phase is straight in the catheter direction and there is no jet during gas injection. Gas bubbles are suddenly formed at the catheter's hole and move upwards: buoyancy is the only governing phenomenon and no bubbles fragmentation is detected. The pressure rise in the vessel depends on the injection pressure and volume and in some cases of manual injection it may double the basal vascular pressure values.

CO_2 angiography is a powerful and safe procedure which diffusion will certainly increase, although some aspects related to gas injection and chamber filling are not jet well known. The use of an automatic system permits better results, shorter training period and limitation of vascular wall damage risk.

Keywords: Angiography; CO_2 angiography; Interventional radiology

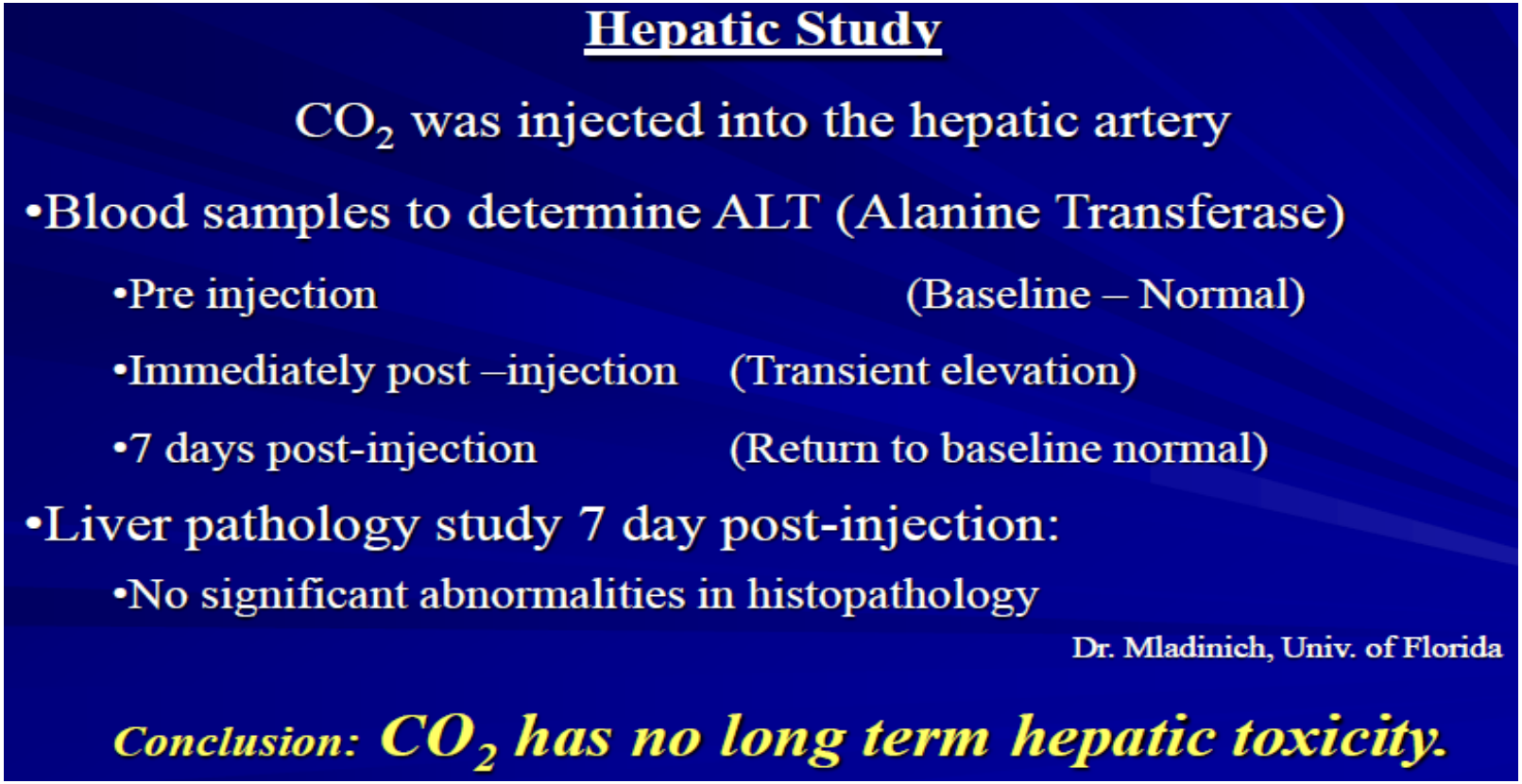
Carbon Dioxide Toxicity Analysis

Dogs accomplished Studies



Carbon Dioxide Toxicity Analysis

Rubbits accomplished Studies



Carbon Dioxide Toxicity Analysis

Pigs accomplished Studies

Venous Study

15 CO_2 / 5 IC, (0.2cc/kg - 6.4cc/kg) IVC

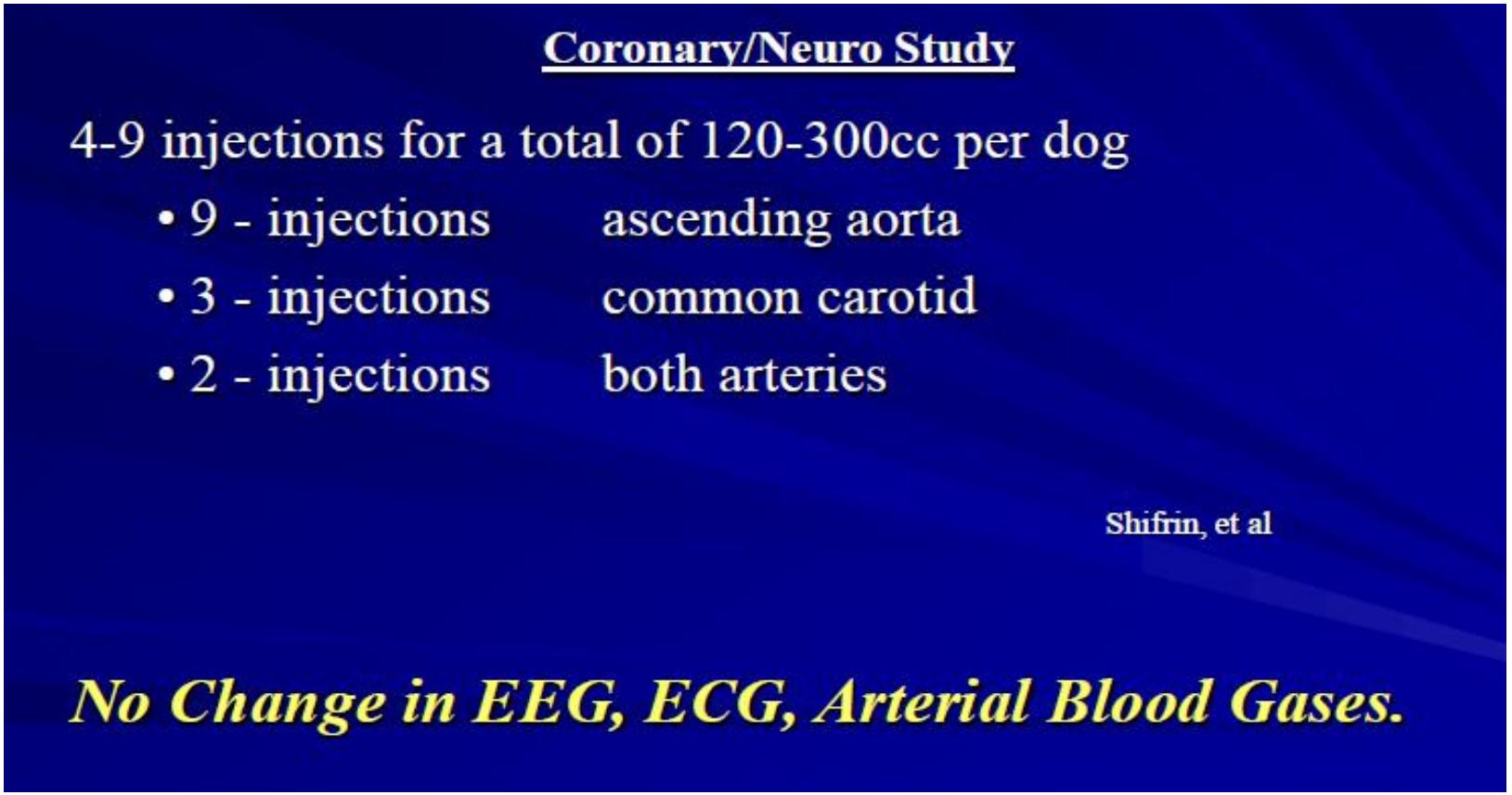
- CO_2 injected in three different positions :
  - Supine
  - Right decubitus
  - Left decubitus
- Parameters obtained pre-injection and 1, 3, 5 , 10 minutes after injection:
  - Pulmonary arterial pressure — *Transient increase*
  - Systemic arterial pressure — *No change*
  - Arterial blood gases(1,3,5,10min. Post inj.) — *No change*

Dr. Cho - Univ. of Michigan

- 2 Expired (1IC 3.2cc/kg, 1CO_2 6.4cc/kg rd)
- ***Conclusion: Diagnostic doses have no significant effect on cardiopulmonary function.***

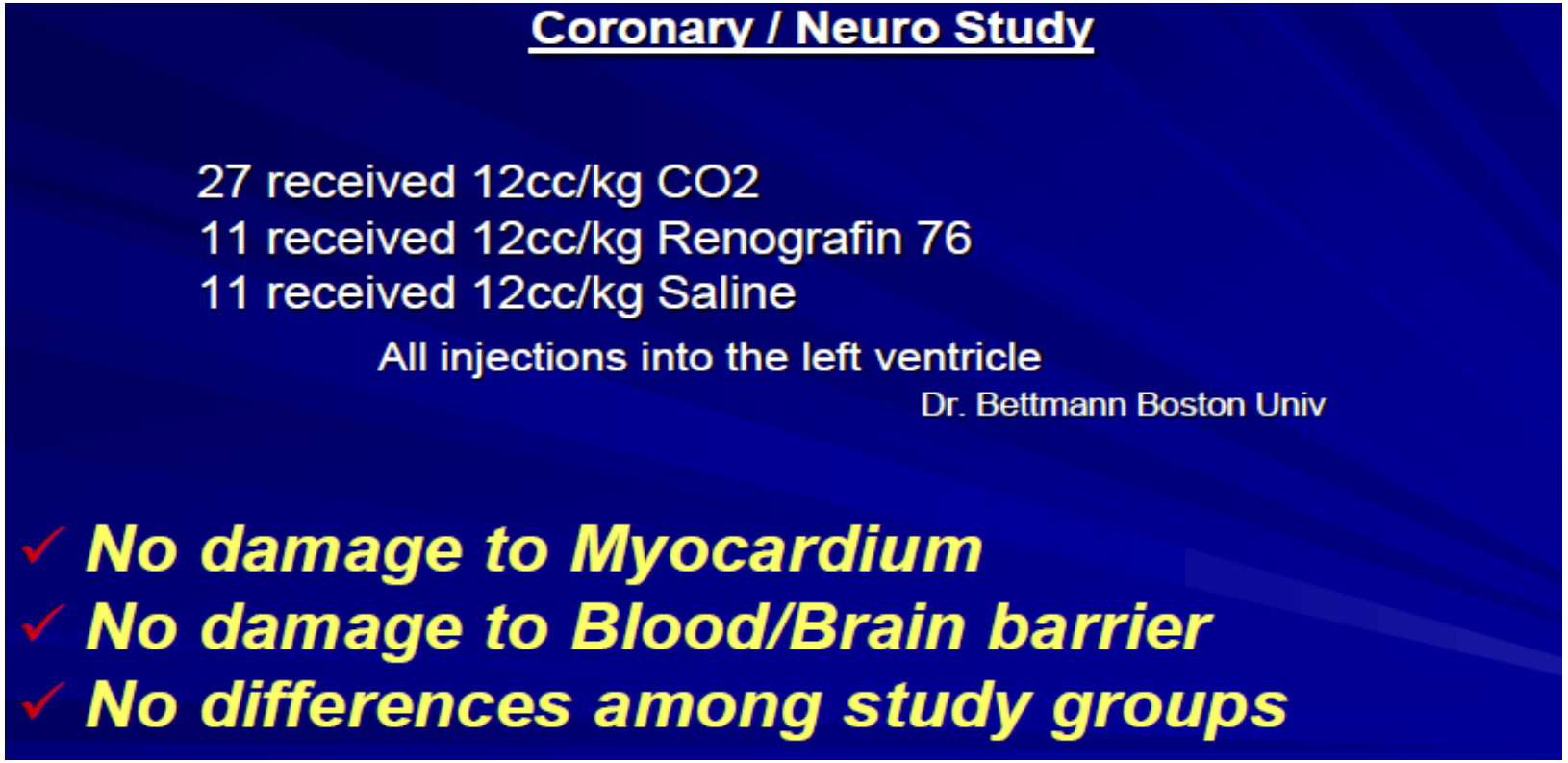
Carbon Dioxide Toxicity Analysis

Dogs accomplished Studies



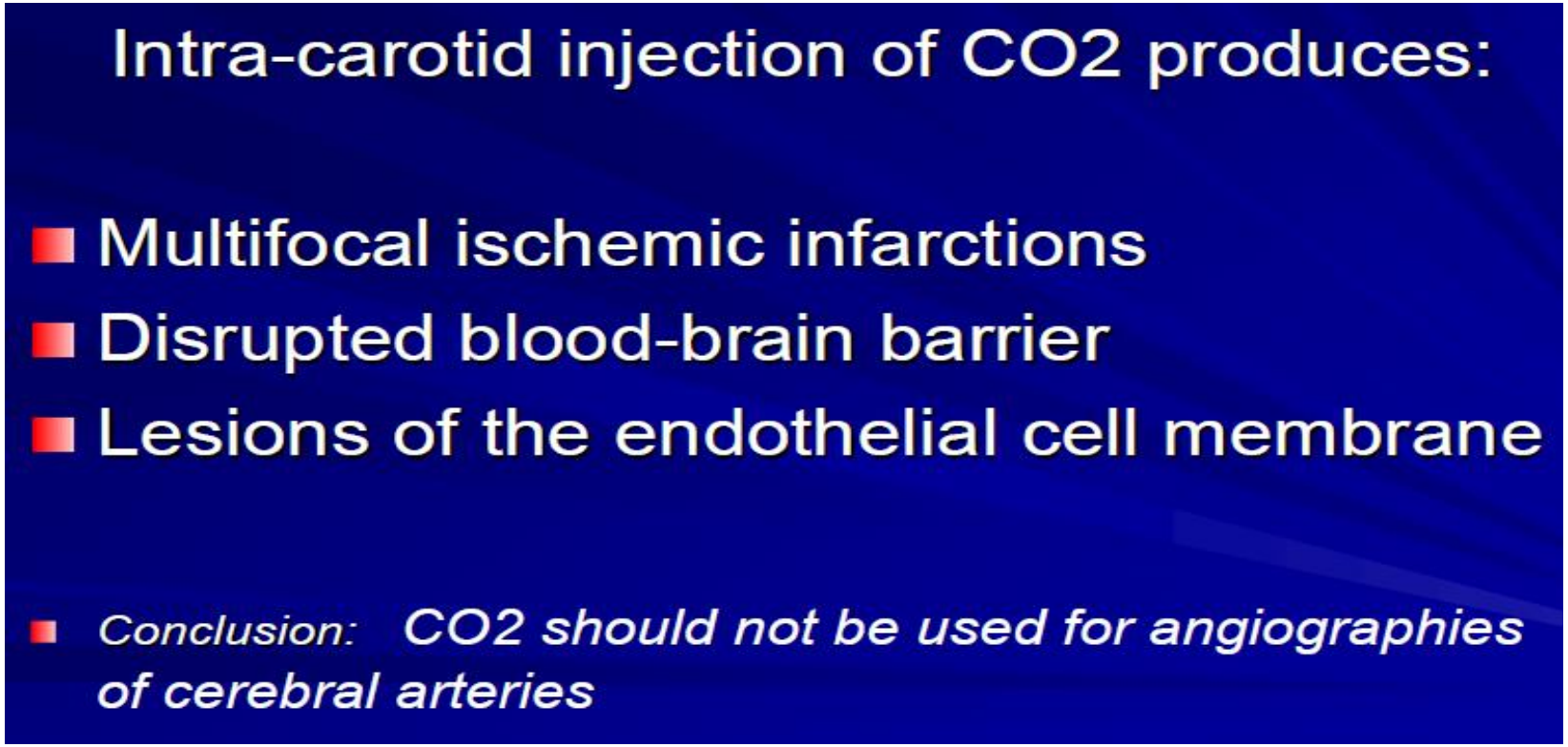
Carbon Dioxide Toxicity Analysis

Rabbits accomplished Studies



Carbon Dioxide Toxicity Analysis

Rats accomplished Studies



Carbon Dioxide Toxicity Analysis

Human accomplished Studies

Retrospective Study

208 procedures /189 patients (138 males / 70 female, 9 to 86 yrs.)

- CO_2 injected in all 208 procedures
- CO_2 and iodinated contrast 175 procedures
- CO_2 alone 33 procedures.

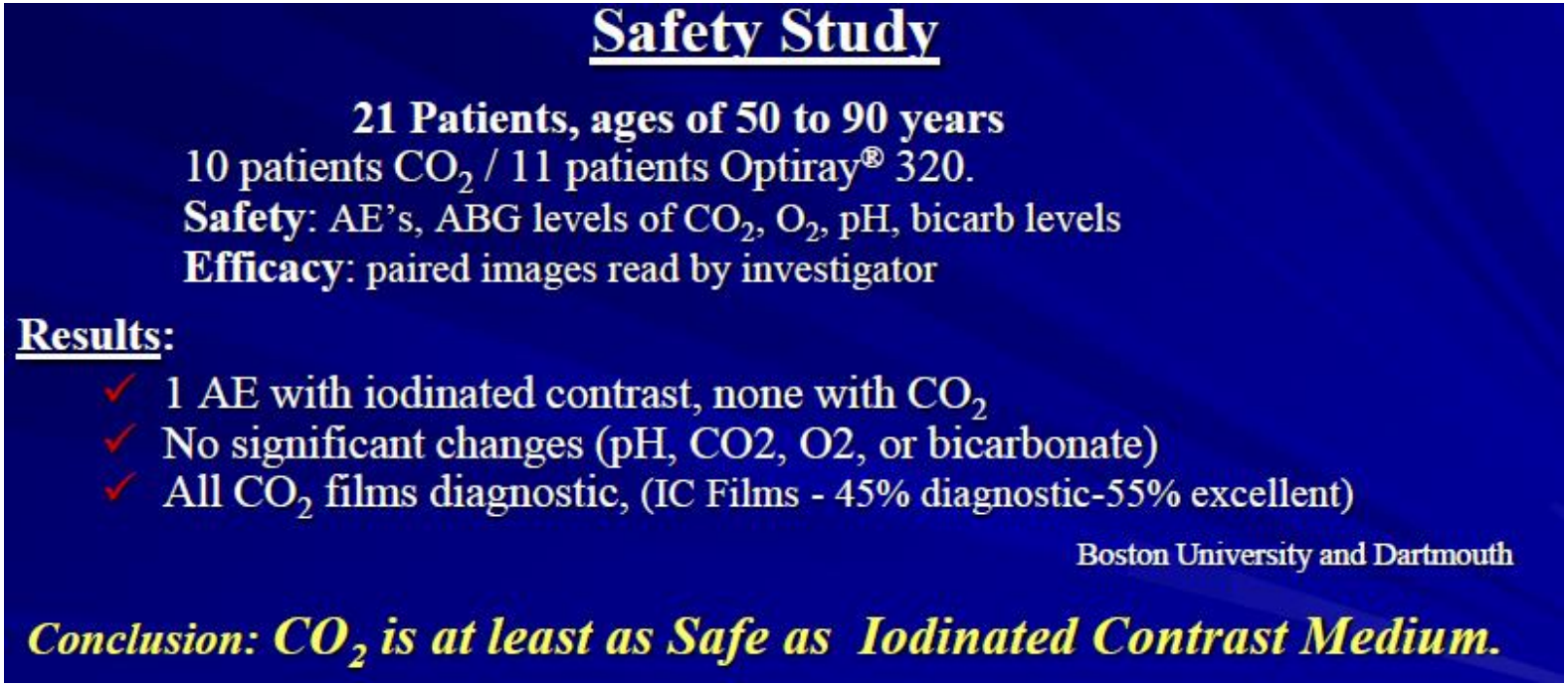
Results:

- 32 AE with CO_2, 6 with iodinated contrast
- Most common CO_2 AE: GI related (nausea)
- Most common with iodinated AE: Allergic reaction

University of Florida

Carbon Dioxide Toxicity Analysis

Human accomplished Studies



Carbon Dioxide Toxicity Analysis

Retrospective Study

Human accomplished

- **1997 – 2007 - 8 years**
- **Individual Operator**
- **654 procedures**
  - **245 angiographies**
    - **64 CO2 alone**
    - **181 Combined approach (CO2 e Iodine)**
  - **409 PTCA**
    - **185 CO2 alone**
    - **224 Combined approach (CO2 e Iodine)**

Dr. Calabrese – Italy -

Carbon Dioxide Toxicity Analysis

Retrospective Study

Human accomplished

Results

- 119 pain and annoyance attacks within 7290 injections
  - 75 on the first 180 injections per a total of 12 procedures
  - 44 on the followind 7110 injection, within 642 procedures

- 482 100% positive results (No IODINE)
  - Alone CO2 use
  - Relevant Imaging

- 157 Partialy positive results (IODINE < 50 ml)
  - Good Imaging Quality of some Arterial Region
  - Combined approch required (with IODINE)

- 15 failure results (IODINE > 50 ml)
  - Non cooperative Patients
  - Exagerate Interference with Bowel movement
  - Low Imaging Quality

Dr. Calabrese – Italy -

Carbon Dioxide Toxicity Analysis

Carbon Dioxide and Iodine Combines Study

- 82 patients
- Random Prospective Study
- Renal Angiographt and PTRA
- Combined Approach vs IODIO alone

The quantity of delivered Iodinated Contrats Agent is strickly related to Creatinine increase within 2 days post procedure. (p=0.011)

Higher is the use of Iodine, Higher is CIN Risk

Procedures	Creatinine before Procedures	Creatinine Afetr 3 days	Creatinina Significance
IODINE 100% failure	1,8 ± 0,4	2,9 ± 0,9	P < 0.05
IODINE partial failure	1,9 ± 0,6	2.0± 0,8	ns
NO IODINE 100% success	1,7 ± 0,8	1,8 ± 0,4	ns

Liss, Berqvist, Olsson, Nillson: J Vasc Interv Rad;16(1): 57-65 2005

Carbon Dioxide Toxicity Analysis

Carbon Dioxide Angiography Effective Analysis

- **50 cases – Retrospective Study** **PTA-PTRA**
  - **88% with CO2**
  - **12% combined approach with a small Iodine quantity** *Kessel DO et al: Cardiovasc Interv Rad 25(6):476-83 2002*

- **Renal Transplantation Analysis**
  - **17 patients – Retrospective Study**
  - **None false information**
  - **100% correct diagnosys**

Chao, Major, Weaver et al. :J Vascular Surgery 45(3);451-60 2007

- **100 cases . Retrospective Study** **EVAR**
  - **CO2 vs IODIO**
    - **None Cretinine changement**
    - **Most part of sucessfully procedures**

Lorsch et al.: CO2 angio in transplant Rontegnpraxis 55(1) 26-32 2003

Carbon Dioxide Toxicity Analysis

Animal accomplished studies

✓No Renal Toxicity

✓No Epatic Toxicity

✓No significant effect on Cardiopulmonary function

✖ Possible neurotoxicity on rats. None evidence on dogs and rubbits

Human accomplished studies (more than 300 pubblications)

✓Retrospective study: 208 procedures/ 189 pat → 32 (**16%**) AE (Bowel movement)

✓Safety evaluation: 61 pat → **none changements**
ph, CO2, O2, HCO3

CE mark: medical device

Notified body: IMQ

Applicant: SIAS Spa

CERTIFICATO CE

Certificato n. 1497/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

S.I.A.S. S.r.l.

40057 CADRIANO DI GRANAROLO EMILIA (BO) - VIA MINGHETTI 9/11 (ITA) - Italy

mantiene negli stabilimenti di:

40050 FUNO DI ARGELATO (BO) - VIA ZANOTTI 4 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Iniettore per mezzo di contrasto
Mod. ANGIODROID
Marca SIAS

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale).

Riferimento pratiche IMQ: 10AL00102.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2012-01-16

IMQ

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".
Esso non è comunque valida dopo il 2017-01-15 (articolo 11, comma 11 della direttiva).

IMQ

CE mark: single-use connection line

Notified body: TUV

Applicant: Bioengineering Laboratories Spa

ZERTIFIKAT ◆ CERTIFICATE ◆ 证书 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

CERTIFICATO CE

Garanzia di qualità della produzione

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N° G2 12 02 44964 028

Fabbricante: **Bioengineering Laboratories S.p.A.**
Via Isonzo 9/B
20036 Meda (MI)
ITALIA

Categoria(e) di prodotto: **Cateteri per gastromanometria, rettali, uretrali, urologici e loro accessori; ago per blocco paracervicale uterino, circuiti per l'aferesi del sangue; Clamp vascolari; linee di estensione per angiografia**

Con il presente certificato, l'organismo notificato di TÜV SÜD Product Service GmbH certifica che il fabbricante sopra menzionato ha implementato un sistema di qualità per la fabbricazione ed il controllo finale dei dispositivi / categorie di dispositivi in questione secondo quanto stabilito nella direttiva DDM, allegato V. Questo sistema di qualità risponde ai requisiti della presente direttiva ed è soggetto a sorveglianze regolari. Per l'immissione sul mercato di dispositivi delle classi IIb e III, è richiesto un certificato addizionale, di cui all'allegato III.
Osservare le note riportate sul retro.

N° del rapporto: ITA 2071251S

Valido da: 2012-02-21
Valido fino al: 2016-03-02

Data: 2012-02-22

Hans-Heiner Junker

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TÜV®

Practical applications of the advanced Angiodroid anallergic, nontoxic CO_2 contrast media system

CO_2 is used in various types of peripheral vascular interventions, such as:

- Angioplasty
- Stent placement
- Transcatheter embolization
- Treatment of abdominal aortic endovascular aneurysm
- Renal ablation

CO_2 is also used as a contrast media in cases of:

- Cholangiography
- Nephrostomy
- Gastrostomy
- Visualization of abscesses and cysts

In the vascular field CO_2 is the ideal contrast media in the following cases:

- Pelvic arteries
- Lower leg arteries
- Renal arteries
- Visceral Arteries
- Visualization of arteriovenous fistulas for hemodialysis
- Venous Studies
- Retrograde Portography

References:

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CE

angiodroid

CO_2

Angiodroid Innovative CO_2 System

Resolving the critical limitations of peripheral angiography with clearly visible benefits for patients

Angiodroid carbon dioxide peripheral interventional angiography: Eliminating critical issues for improved patient safety

Peripheral interventional angiography overview.

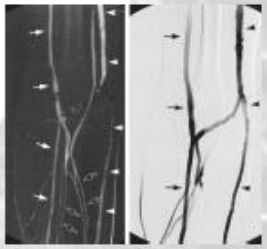
The rise in life expectancy, the increase in vascular disease and the development of increasingly sophisticated interventional radiological techniques is leading to a progressive increase in investigative procedures in cardiac angiography (coronary angiography and PTCA) in the brain and peripheral areas.

Each angiographic procedure requires the injection of iodinated contrast medium which features clear contraindications or quantitative limitations: especially in the case of conditions associated with impaired renal function or diabetic vascular disease. Patients who present these chronic conditions (more than 20% of cases treated) are particularly susceptible to the toxic effects of contrast agents and to developing Contrast-Induced Nephropathy (CIN) - a form of Acute Renal Failure.

It is, therefore, necessary to find alternative methods that address the risk of intolerance for the patient and reduce the economic impact to the medical community.

CO_2: the easier, safer and established alternative system.

An alternative, "CIN-FREE", media is represented by carbon dioxide (CO_2), a gas injected into the vessels that results in a clear contrast effect and is easily removed from the circulation via the lungs.



(a) (b)

Anteroposterior venograms of the elbow region in a 57-year-old man with renal insufficiency and a failed hemodialysis AVF in the contralateral wrist and elbow.
(a) CO2 venogram shows the cephalic (white arrows), basilic (arrowheads), and deep (black arrows) veins.
(b) Conventional venogram depicts only the cephalic (arrows) and basilic (arrowheads) veins.[1]

Angiodroid is the new, patented system for CO_2 injection that resolves the critical limitations associated to most devices currently on the market.

- Angiodroid is 100% safe and eliminates the risk of CIN.
- Angiodroid allows the interventionalist to define and precisely control the amount of gas to be injected into the vessel.
- Angiodroid guarantees complete removal of the air contained in the injection catheter, providing total patient safety.
- Angiodroid ensures a constant injection pressure of the gas during the procedure with extreme ease and precision, allowing the repeatability of the procedure to obtain quality images while eliminating the risk of vessel rupture in the presence of obstructive aneurysms.
- Angiodroid uses a very thin catheter (CO_2 is about 400 times less viscous than iodine)[1] allowing more selective catheterization.
- Over 100 clinical reviews and publications demonstrate the effectiveness of CO_2 angiography.

Example of image quality as seen on modern based digital technologies.

Compatible with most modern digital imaging systems

The Angiodroid injection technique has been optimized for use with modern, currently available, angiographic systems that implement algorithms for digital image acquisition.

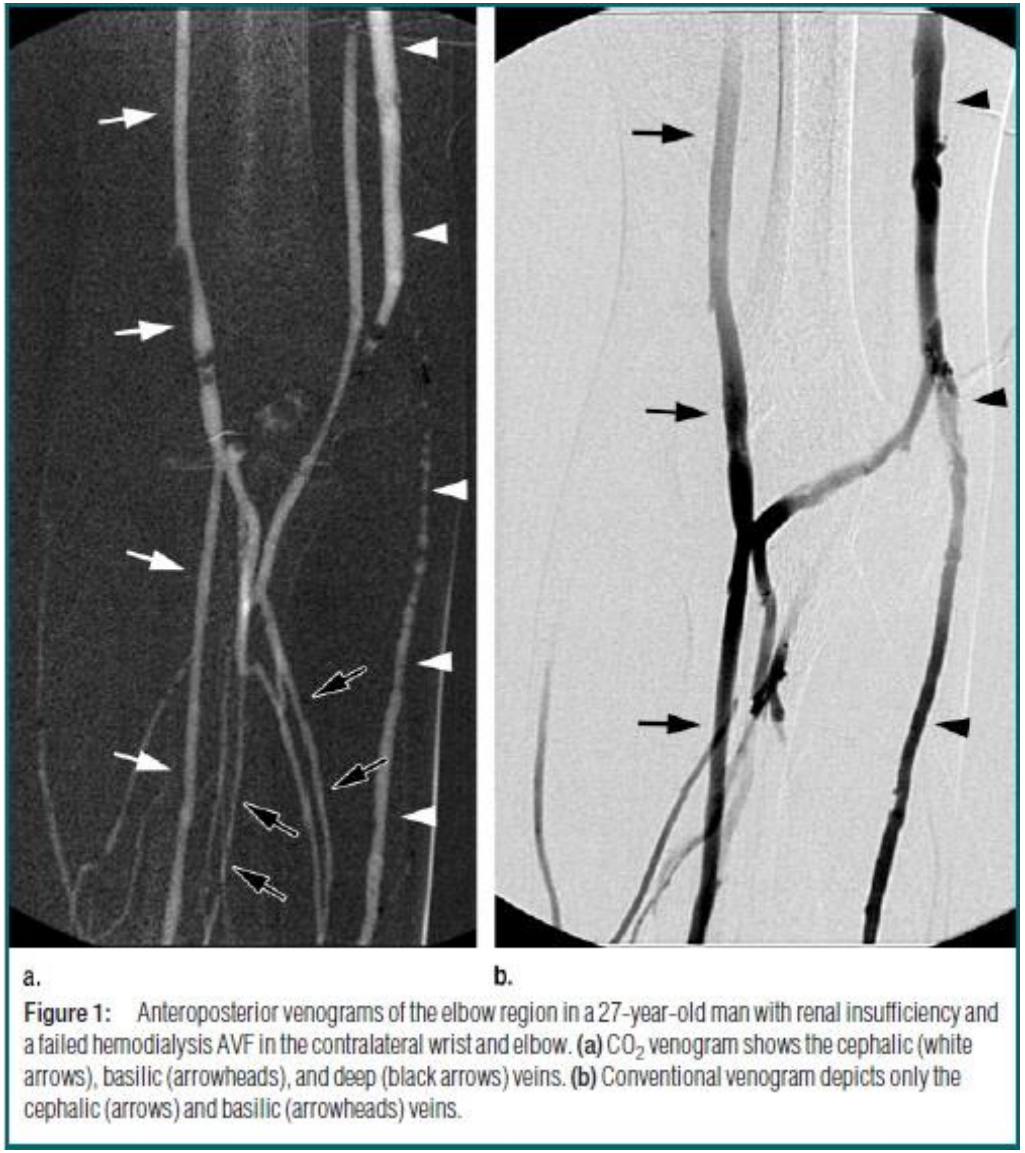
CO2 Imaging

CO2 Imaging

CO2 Imaging

CO2 and Iodine angiography venograms comparison

CO2



Iodium

a. b.

Figure 1: Anteroposterior venograms of the elbow region in a 27-year-old man with renal insufficiency and a failed hemodialysis AVF in the contralateral wrist and elbow. **(a)** CO_2 venogram shows the cephalic (white arrows), basilic (arrowheads), and deep (black arrows) veins. **(b)** Conventional venogram depicts only the cephalic (arrows) and basilic (arrowheads) veins.

Carbon Dioxide History

CO^2 has been in use in Radiology as an imaging agent since 1914 to evaluate the retroperitoneum and to image kidneys and tumors.

CO^2 was in the routinely in the early 1950s for detection of pericardial effusion.

In the 70s Dr. Hawkins and Dr. Cho pioneered the intraarterial use of CO^2 .
With the advent of Digital Substraction Angiography (DSA) in 1980, reliable imaging of "low density" contrast material became available.
With the addition of high-resolution DSA, Stacking SW, Tilting Tables, and reliable delivery systems, CO^2 is used not only in patients with contrast material allergies and renal failure, but also in patients undergoing routine angiographyc studies and many interventional procedures

Angiodroid: conclusion

Carbon Dioxide (CO^2) is the only *Safe Contrast Agent* for patient with

- ***Hypersensibility to Iodinated Contrast Material***
- ***Renal Failure***
- ***Diabetic Diseases***

Carbon Dioxide can be injected as Contrast Agent in any Luminal Structure (Peripheral Regions mandatory) except for thoracic aorta and its branches

Angiodroid: conclusion

angiodroid

Is the only Device Worldwide on Market

- 100% DIGITAL
- 100% AUTOMATIC
- 100% SAFETY
- 100% USER FIENDLY

angiodroid

ANGIODROID

Carbon Dioxide Interventional Peripheral Angiography

Thanks for the attention