ANGIODROID
Carbon Dioxide
Interventional Peripheral Angiography
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Angiodroid: The CO² Injector

Is a **CO2 Contrast Media Injector** dedicated to **Interventional and Diagnostic Angiographic Peripheral Procedures**
Angiodroid: Main Fields of Application

has 3 main Fields of Application

- Interventional Radiology
- Vascular Surgery
- Interventional Cardiology
Angiodroid: conclusion

Carbon Dioxide (CO²) is the only Safe Contrast Agent for patient with

- Hyper sensibility to Iodinated Contrast Material
- Renal Failure
- Diabetic Diseases
Angiodroid: conclusion

- 100% DIGITAL
- 100% AUTOMATIC
- 100% SAFE
- 100% USER FRIENDLY

Is the only Device Worldwide on Market
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.
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

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) 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.
Carbon Dioxide: Gas Properties

Gas Properties:

- Highly compressible
- 20 times more soluble than O²
- Non Viscous and Buoyant
- Invisible, Colourless and Odourless
- Radiopacity
- Rapidly dissolving in Blood
- Lacks both Allergic Potential & Renal Toxicity

Next:

- CO² doesn’t mix with Blood
- It has extreme diffusibility
- None Total Maximum dosage
CO2 angiography: critical issues

Basically there are 3 critical issues in the use of CO2 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.
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
• interauricular or interventricular communication

Possible side effects
• nausea
• pain
• dizziness
• tachycardia
CO₂ 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

- Borderline Renal Failure
- Chronic Nephropathy
- Allergic Potential
- Riduzione carico rene

Iodinated Contrast Agent

- Thoracic Angiography Procedures
- Coronary Angiography
- Neurovascular Studies
- Non cooperative patients
- Rear vessels

Peripheral Angiography
PTCA
Endoprosthesys
The Market: Overview

ANGIOFLUSH III fluid collection system

- manual injection kit

- operator-dependent: no procedural repeatability
CO2 ANGIOSET

- manual injection kit
- difficulty of achieving the desired injection volume
The Market: Overview

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 CO² Injector

100% DIGITAL

100% AUTOMATIC

100% SAFETY

100% USER FRIENDLY
# Market Overview Comparison

<table>
<thead>
<tr>
<th>Products</th>
<th>Automatic System</th>
<th>Digital System</th>
<th>Safety System</th>
<th>User Friendly System</th>
<th>CO2 Bottle included</th>
<th>Air Contamination Safety System</th>
<th>Volume Definition</th>
<th>Pressure Definition</th>
<th>Constant Pressure Injection System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiodynamics</td>
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<td>no</td>
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<tr>
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<td>yes</td>
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<tr>
<td>Angiodroid The CO2 Injector</td>
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<td>yes</td>
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<td>yes</td>
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<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
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 CO₂ 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 CO₂ injections. Phase A corresponds to line washing; phase B corresponds to gas injection – Corazza et al. 2013
Digital Automatic Injection

**Angiodroid The CO₂ Injector** has exceeded all those problems (Angiodroid®, Angiodroid SRL, Bologna, ITALIA)

P1 and P2 pressure recordings during automated line washout and CO₂ gas injection. (Corazza et. al 2013)
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

Results: 1 to 20 of 721

   PMID: 22288088 [PubMed - indexed for MEDLINE]
   Related citations

2. Rising PaCO(2) in the ICU: using a physiologic approach to avoid cognitive biases.
   PMID: 22147823 [PubMed - indexed for MEDLINE]
   Related citations

3. Mechanical aspects of CO(2) angiography.
   PMID: 22138139 [PubMed - as supplied by publisher]
   Related citations

4. Discontinuation of the plastic bag delivery system for carbon dioxide angiography will increase radiocontrast nephropathy and life-threatening complications.
   PMID: 22021546 [PubMed - indexed for MEDLINE]
   Related citations
Clinical Validation

Original Paper

**Mechanical aspects of CO₂ angiography**

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**Abstract**

The aim of this paper is to clarify some physical-mechanical aspects involved in the carbon dioxide angiography procedure (CO₂ angiography), with a particular attention to a possible damage of the vascular wall.

CO₂ 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.

CO₂ 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.

CO₂ angiography is a powerful and safe procedure which diffusion will certainly increase, although some aspects related to gas injection and chamber filling are not yet well known. The use of an automatic system permits better results, shorter training period and limitation of vascular wall damage risk.

**Keywords:** Angiography, CO₂ angiography; Interventional radiology
Carbon Dioxide Toxicity Analysis

Dogs accomplished Studies

**Renal Study**

7cc/kg of CO\textsubscript{2} were injected into the renal artery in lateral decubitus

- **Radioisotope infusion**, to determine renal function, was done:
  - 24 hours pre-injection
  - Immediately after injection
  - 24 hours after injection
- Immediate Post CO\textsubscript{2} injection - Transient change in blood flow
- 24 hours Post CO\textsubscript{2} injection - Resumed normal flow and function
- SEM showed no changes to endothelial lining, renal parenchyma

*Conclusion: CO\textsubscript{2} has no renal toxicity*
Carbon Dioxide Toxicity Analysis

Rubbits accomplished Studies

**Hepatic Study**

CO₂ was injected into the hepatic artery

• Blood samples to determine ALT (Alanine Transferase)
  • Pre injection (Baseline – Normal)
  • Immediately post-injection (Transient elevation)
  • 7 days post-injection (Return to baseline normal)

• Liver pathology study 7 day post-injection:
  • No significant abnormalities in histopathology

Dr. Mladinich, Univ. of Florida

**Conclusion:** CO₂ has no long term hepatic toxicity.
Carbon Dioxide Toxicity Analysis

Pigs accomplished Studies

**Venous Study**

15 CO₂ / 5 IC, (0.2cc/kg - 6.4cc/kg) IVC

- CO₂ 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, 10 min. Post inj.): No change

- 2 Expired (1IC 3.2cc/kg, 1CO₂ 6.4cc/kg rd)

- **Conclusion:** Diagnostic doses have no significant effect on cardiopulmonary function.
Carbon Dioxide Toxicity Analysis

Dogs accomplished Studies

Coronary/Neuro Study

4-9 injections for a total of 120-300cc per dog

- 9 - injections ascending aorta
- 3 - injections common carotid
- 2 - injections both arteries

Shifrin, et al

No Change in EEG, ECG, Arterial Blood Gases.
Carbon Dioxide Toxicity Analysis

Rabbits accomplished Studies

**Coronary / Neuro Study**

- 27 received 12cc/kg CO₂
- 11 received 12cc/kg Renografin 76
- 11 received 12cc/kg Saline
  
  All injections into the left ventricle
  
  Dr. Bettmann Boston Univ

- No damage to **Myocardium**
- No damage to **Blood/Brain barrier**
- No differences among study groups
Intra-carotid injection of CO2 produces:

- Multifocal ischemic infarctions
- Disrupted blood-brain barrier
- Lesions of the endothelial cell membrane

Conclusion: CO2 should not be used for angiographies of cerebral arteries
Carbon Dioxide Toxicity Analysis

Human accomplished Studies

Retrospective Study

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

• CO₂ injected in all 208 procedures
• CO₂ and iodinated contrast 175 procedures
• CO₂ alone 33 procedures.

Results:
• 32 AE with CO₂, 6 with iodinated contrast
• Most common CO₂ AE: GI related (nausea)
• Most common with iodinated AE: Allergic reaction

University of Florida
Carbon Dioxide Toxicity Analysis

Human accomplished Studies

Safety Study

21 Patients, ages of 50 to 90 years
10 patients CO₂ / 11 patients Optiray® 320.
Safety: AE’s, ABG levels of CO₂, O₂, pH, bicarb levels
Efficacy: paired images read by investigator

Results:
✓ 1 AE with iodinated contrast, none with CO₂
✓ No significant changes (pH, CO₂, O₂, or bicarbonate)
✓ All CO₂ films diagnostic, (IC Films - 45% diagnostic-55% excellent)

Boston University and Dartmouth

Conclusion: CO₂ is at least as Safe as Iodinated Contrast Medium.
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 following 7110 injection, within 642 procedures

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

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

- 15 failure results (IODINE > 50 ml)
  - Non cooperative Patients
  - Exaggerate 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 Angiography and PTRA
- Combined Approach vs IODIO alone

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

Higher is the use of Iodine, Higher is CIN Risk

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Creatinine before Procedures</th>
<th>Creatinine After 3 days</th>
<th>Creatinine Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IODINE 100% failure</td>
<td>1.8 ± 0.4</td>
<td>2.9 ± 0.9</td>
<td>P &lt; 0.05</td>
</tr>
<tr>
<td>IODINE partial failure</td>
<td>1.9 ± 0.6</td>
<td>2.0 ± 0.8</td>
<td>ns</td>
</tr>
<tr>
<td>NO IODINE 100% success</td>
<td>1.7 ± 0.8</td>
<td>1.8 ± 0.4</td>
<td>ns</td>
</tr>
</tbody>
</table>

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

- 50 cases – Retrospective Study
  - 88% with CO2
  - 12% combined approach with a small Iodine quantity

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

- 100 cases. Retrospective Study
  - CO2 vs IODIO
    - None Creatinine changement
    - Most part of sucessfully procedures
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 rabbits

Human accomplished studies (more than 300 publications)
✓ 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
CE mark: single-use connection line

Notified body: TUV

Applicant: Bioengineering Laboratories Spa
Practical applications of the advanced Angiodroid analgesic, nontoxic CO₂ contrast media system

CO₂ is used in various types of peripheral vascular interventions, such as:
- Angioplasty
- Stent placement
- Transcatheter embolization
- Treatment of abdominal aortic endovascular aneurysm
- Renal ablation

CO₂ is also used as a contrast media in cases of:
- Cholangiography
- Nephroscopy
- Gastroscopy
- Visualization of abscesses and cysts

In the vascular field, CO₂ is the ideal contrast media in the following cases:
- Femoral arteries
- Lower leg arteries
- Renal arteries
- Visceral arteries
- Visualization of arteriovenous fistulas for hemodialysis
- Venous studies
- Retrospective perfugraphy

References:
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- Di board (editor), volume 160. London: Springer 2013
- Di board (editor), volume 161. London: Springer 2014

Angiodroid Innovative CO₂ 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 an intravenous contrast medium, which features clear contraindications or qualitative limitations, especially in the case of conditions associated with impaired renal function or diabetics vascular diseases. Patients who present these chronic conditions (more than 20% of cases) 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 non-safety for the patient and reduce the economic impact to the medical community.

- **CO₂: the safer, safer and established alternative system.**

  An alternative, “CIN-FREE”, media is represented by carbon dioxide (CO₂), a gas injected into the vessels that results in a clear contrast effect and is easily removed from the circulation via the lungs.

  - **Angiodroid is the new, patented system for CO₂ 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 anomalies.
    - Angiodroid uses a very thin catheter (CO₂ is about 400 times less viscous than saline) allowing more selective catheterization.
    - Over 100 clinical reviews and publications demonstrate the effectiveness of CO₂ angiography.

- **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

**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) 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.
Carbon Dioxide History

CO² has been in use in Radiology as an imaging agent since 1914 to evaluate the retroperitoneum and to image kidneys and tumors.

CO² 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 CO². 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, CO² is used not only in patients with contrast material allergies and renal failure, but also in patients undergoing routine angiography/c studies and many interventional procedures.
Carbon Dioxide (CO²) is the only Safe Contrast Agent for patient with

- Hypersensitivity 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

*Is the only Device Worldwide on Market*

- 100% DIGITAL
- 100% AUTOMATIC
- 100% SAFETY
- 100% USER FRIENDLY
Thanks for the attention