Carbon Dioxide Guided Angiography in Endovascular Abdominal Aortic Aneurysm Repair

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Abstract:

Background: The contrast materials are considered vital factors for successful EVAR. However, they have their demerits as allergy and contrast-induced nephropathy. **Methods:** 20 cases underwent CO2-DSA assisted EVAR for infra-renal AAA. All procedures were performed using two angiographic methods in each procedure: automated iodinated contrast material digital subtraction angiography (DSA) and CO2 automated DSA. Upper and lower sealing zone are evaluated before and after deployment of the graft, as regard their visualization, by CO2 and ICM. Also, endoleaks had been assessed after angiography. **Results:** 45 % of cases presented with abdominal pain, 30 % of cases with abdominal mass, and 10 % of cases with limb ischemia. While 15 % of cases accidentally discovered AAA. 95 % technical success. Adequate Visualization of the upper zone in 11 cases and all cases had a clear image of lower sealing zones with CO2 as the ICM. Endoleak was detected in ten cases by CO2 while ICM was uncovered in three cases. There was neither change in renal status nor side effects of CO2. **Conclusion:** CO2-DSA-assisted EVAR for infra-renal AAA is safe and effective in reducing the dose of ICM and avoiding overload. It is more sensitive to detect endoleak especially type II.

Keywords: EVAR; CO2 angiography and endoleak.

INTRODUCTION:

Endovascular aneurysm repair (EVAR) has lower short-term morbidity and mortality than open surgery.[1,2] Intra-arterial contrast agents are an important component of successful EVAR as their usage for precise preoperative sizing and evaluation of aortic aneurysm morphology. Also, for intraoperative visualization of the Ostia of the hypogastric and renal arteries. Although iodinated contrast (IC) is overwhelmingly the most common agent used, the use of IC agents is not recommended in patients with renal dysfunction or to IC.[3,4] The allergic response of IC; (3.1- 12%) in the form of the release of bradykinins, histamine, and prostaglandins mediators systematically; this response ranges from mild, moderate, and severe urticaria to anaphylaxis. [5] 25 % of EVAR patients had a chronic kidney disease that could affect the morbidity and mortality; contrast-induced nephropathy might be permanent and induce cumulative effect [6] Many strategies have been suggested for reducing IC usages, such as the intravascular ultrasound,[7] fusion of preoperative and intraoperative imaging and high-quality 3-dimensional imaging techniques.[8-9] However, despite reports of various methods of renal protection, including the use of acetylcysteine, dopamine, mannitol, fenoldopam, and perioperative hydration but the effects of these methods are controversial.[10-12]

Carbon dioxide (CO2)-guided angiography is an alternative contrast approach first presented for diagnostic purposes by Hawkins.[13] In this study, we will compare Carbon Dioxide Guided Angiography with Iodinated Contrast Angiography during EVAR. This study aimed to evaluate the feasibility, efficacy, and safety of carbon dioxide (CO2) digital subtraction angiography (DSA) to guide endovascular aneurysm repair (EVAR) in a cohort of patients with abdominal aortic aneurysms.

PATIENTS AND METHODS:

Prospective interventional cohort study, with all cases, signed informed written consent and underwent CO2-DSA assisted EVAR for infra-renal AAA, during the period December 2019 to October 2022. Approved by Mansoura Faculty of Medicine Institutional Research Board; IDMD.19.11.248 - 2019/11/01 and registered at clinicaltrials.gov at ID NCT04444999. Inclusion criteria patients who were diagnosed with infrarenal abdominal aortic aneurysm and candidates for endovascular repair; diameter of infrarenal abdominal aortic aneurysm of 5.0 cm in female and 5.5 in male or common iliac artery aneurysms of 3.0 cm with favorable endovascular neck anatomy and iliac configuration. [14] Twenty patients had been evaluated. The primary outcome was the validity of CO_2 in Visualizing the neck of the aneurysm, origin of renal, hypogastric arteries, and Endoleak. The secondary outcome was the safety of CO_2 as a substitute for the contrast. The demographics, symptoms, and preoperative clinical data had been collected. Preoperative imaging was performed by contrast-enhanced computed tomography (CTA); Abdominal aortic aneurysm diameters and other variables had been calculated using a dedicated software of volumetric CTA analysis (3MensioTM). The patient's preparation toprevent gases-bowel artifacts and peristalsis artifacts in the form of following a low residue diet (to reduce visceral gases as well as bowel activity) and antiperistalsis drugs such as Buscopan (to reduce bowel peristalsis during the procedure) because the CO2 and the air have similar radiopacity.

Procedure: All procedures were performed using two angiographic methods in each procedure: automated conventional ICM digital subtraction angiography (DSA) and CO2 automated DSA, in a Philips hybrid operating theatre. Upper and lower sealing zone are evaluated before and after deployment of the graft, as regard their visualization, by CO2 and ICM. Also, endoleaks had been assessed after angiography. Comparing the images obtained by both CO2 and ICM. A bilateral inguinal incision was done with bilateral common femoral artery access obtained through surgical cut down under spinal or general anesthesia followed by two sheaths 6 French then a pigtail catheter (5F/65 mm length) was passed through the sheath.

Conventional contrast media angiography (gold standard): isotonic ICM has injected through the pigtail catheter (5F/65 mm length) positioned at the renal arteries level, using an automated injector. During each procedure two automated ICM DSA, 20 mL volume at a rate of 15 mL/s: one injection before endograft deployment, to assess the upper sealing zone, the bifurcation of the aorta and the lower sealing zone, and a completion angiography to document the technical success and to evaluate the presence of endoleaks.

Automated carbon dioxide angiography: by digital Angiodroid injection system (Angiodroid SRL, San Lazzaro, Bologna, Italy), the position adjusted in the Trendelenburg position with the feet elevated; connecting them to the pigtail. We maintained apnea, during the x-ray acquisition to reduce motion artifacts. The flush of the sheath was 15 ml to fill the tubing system and eradicate the air and the pressure was 500 mmHg and the volume was 90. the catheter was purged before each injection. In each procedure, an image was taken before endograft deployment, another angiogram was to assess the internal iliac arteries' origin and a completion angiography, is performed after the deployment. **Figure 1**

Endpoints and definition

- The primary endpoints are to determine the efficacy of CO2 automated DSA in upper/lower sealing zone evaluation and endoleaks detection, in comparison with ICM.
- The secondary endpoint is to evaluate the safety of CO2 standardized automated injection (any side effects).
- The intraoperative upper sealing zone evaluation is defined as effective when the lower renal artery and the proximal aortic neck just below it, are correctly visualized.
- The intraoperative lower sealing zone evaluation is defined as effective if the origin of the hypogastric artery and the distal segment of the common iliac artery just above it, are visualized.
- Technical success (TS) is defined as the complete endograft deployment with patency of renal and hypogastric arteries, absence of type I/III endoleaks and iliac leg kinking or stenosis, and no conversion to OR(open repair), 24-hour mortality. Endoleaks are defined according to White and May classification .[15]
- CO2 side effects (CO2 narcosis) are defined as any adverse events correlate to CO2 automated injection. As reported in the literature, abdominal pain, transient hypotension, nausea, and ischemic colitis occurring intraoperatively or within 30 minutes of the procedure, are considered adverse events correlate to CO2. [16]

Follow up

- Every patient will be followed the first week and month, then every 3 months For at least 6 months, by CTA or duplex ultrasonography.
- Evaluation of renal affection through eGFR and serum creatinine on the third day and second month.

Statistical analysis and data interpretation:

Data analysis was performed by SPSS software, version 18 (SPSS Inc., PASW statistics for windows version 18. Chicago: SPSS Inc.). Quantitative data were described using median (minimum and maximum) for non-normally distributed data and mean, and standard deviation for normally distributed data after testing normality using the Kolmogrov-Smirnov test. The significance of the obtained results was judged at the (0.05) level. Validity is detected using cross-tabulation for categorical variables. Chi-Square and Monte Carlo, Marginal homogeneity test for pared comparison of more than 2 categories used to qualitative variables. The interclass correlation was used to assess the reliability between continuous variables.

RESULTS:

Twenty male patients had been included in the study. Mean 68.40±7.52 (54-79) Mean±SD (min-max), 13 cases were smokers, and seven were diabetic. 90.8% of patients had hypertension and 75 % had coronary artery diseases. Thirteen patients had dyslipidemia. Four patients with COPD while two patients were on Hemodialysis and also four patients presented with peripheral arterial diseases.

According to presenting symptoms, 45% (n=9 cases) presented with abdominal pain; 30 % (n=6 cases) with Abdominal mass; 10 % (n=2 cases) with limb ischemia, and 15 % (n=3 cases) were accidentally discovered. 10 % (n=2 cases) had a peripheral aneurysm in the form of a popliteal aneurysm.

15 % (n=3 cases) documented a history of vascular operation (bypass in two cases and one case of angioplasty) but two cases reported cholecystectomy and appendicectomy. 8 cases (50 %) had a CABG surgery.

Three cases (18.8%) had a common Iliac artery aneurysm(two cases bilateral and one case unilateral), and two cases (12.5 %) had a bilateral internal iliac aneurysm. **Table 1**

For the parameters of preoperative planning; AAA diameter (Mean ±SD) was 63.73±13 (38.8-85.7) mm, For the operative details variables, the total median volume of ICM; was 55.40±18.1 (25-96) ml, and total median volume of CO2; 472.75±126.98 (270-700) ml, procedure time 130.05±33.11 (69-210) minutes, fluoroscopy time 69.85±18.60 minutes. As regard type of anesthesia; Spinal 17 (85 %), General 3 (15 %). The devices used were Endurant "Medtronic " 30% (n=6) and Zenith alpha "cook" 70 % (n=14).

Upper sealing zone visualization (p-value 0.014) was well visualized as both renal arteries in 11 cases (55) but 7 cases (35 %) reported inadequate visualization; renal arteries appeared but were not clear as the ostia or both arteries. Only two cases were difficult to visualize the upper zone; 55 % Sensitivity, 100 % positive predictive value, 100 % negative predictive value, and 55 % accuracy while specificity could not be assessed because there were no false positive or negative studies. Lower zone visualization was well visualized in all 20 cases as the origin of the internal iliac as the ICM with 100 % Sensitivity, 100 %Specificity, 100 % positive predictive

value, 100 % negative predictive value, and 100 % accuracy. **Table 2 Figure 2.**

Carbon Dioxide Guided Angiography reveals Type I endoleak in one case as the ICM report. However, Type II was documented in nine Cases (45%) that ICM uncovered in two cases only (10%) with 100 % Sensitivity, 58.9 %Specificity, 30 % positive predictive value, 100 % negative predictive value, and 65 % accuracy (p-value .008). **Table 3 Figure 3**

Coiling of the internal iliac was done in three cases and Extension cuff in one case. There was a technical success in 19 cases (95 %) with no conversion to open surgery in all cases though one case reported Type Iaendoleak; no complication in 17 cases (85 %) while two cases (10 %) reported leg thrombosis and one case showed one endoleak Type I a. Postoperative mortality within 72 hrs. documented in one case during follow up that was related to COVID 19.

Renal function evaluation documented the same results before and after the procedure through serum creatinine and eGFR at day 3 and 2nd-month post-operative. CTA post-operative showed endoleak only in one case that was managed with a cuff later.

Table (1): socio-demographic, history and clinical presentation characteristics of the studied cases:

	n=20	**%**
Age/yearsMean±SD (min-max)	68.40±7.52 (54-79)	
Sex: male	20	100
Smoking status	13	65
DM	7	35
Hypertension	18	90.8
COPD	4	20
CAD	15	75
Dyslipidemia	13	65
Obesity	7	35
Peripheral Arterial Disease	4	20
Hemodialysis	2	10
Presenting complaint		
Accidently discovered	3	15
Abdominal Pain	9	45
Abdominal Mass	6	30
Limb Ischemia	2	10
Peripheral Aneurysm		
NO other peripheral aneurysm	18	90
Popliteal	2	10
Past Surgical History		
NO Past History of Any Surgical Operation	14	70
Vascular Operation (Bypass or Angioplasty)	3	15
Non-Vascular Operation	2	10
CIA Aneurysm	4	20
IIA Aneurysm	3	15

Table (2): Abdominal Aortic Aneurysm diameters and total volume of ICM, CO2 among studied cases

AAA diameter	63.73±13 (38.8-85.7 mm)	
Distance Between Lowest RA and AB	135.45±1754 (117-168)	
RT CIA Diameter	24.7± 12.8(14.3-50.9)	
LT CIA Diameter	19.98± 7.04(15.2-44.7)	
RT IIA Diameter	10.3 ± 9.2(4-38.4)	
LT IIA Diameter	10.8 ± 9.8(4-47.2)	
Total Volume of ICM	55.40±18.1 (25-96)	
Total Volume of CO2	472.75±126.98 (270-700)	
Operative Details		
Procedure Time	130.05±33.11 (69-210)	
Fluoroscopy Time	69.85±18.60	
Type of Anesthesia		
Spinal	17	85 %
General	3	15 %
Device Type		
Medtronic System	6	30 %
Cook System	14	70 %
Upper Sealing Zone Visualization		
Not Visualized	2	10 %
Adequate Visualization	11	55 %
Inadequate Visualization	7	35 %
Lower Sealing Zone Visualization		
(Adequate Visualization)	20	100%
Endoleak Type of CO_2		
NO Endoleak	10	50
Type I	1	5
Type II	9	45
Additional Procedure		
No added Procedure	16	80 %
Coiling Of Internal Iliac	3	15 %
Extension Cuff	1	5 %
Technical Success	19	95 %
Complications		
NO Complications	17	85 %
Endoleak	1	5 %
Leg thrombosis	2	10 %
Intraoperative Morality	0	0.0
Post-operative Mortality		
No Morality	19	95 %
Post Operative Morality within 72 hrs.	1	5 %
CTA 6 Weeks Postoperative		
NO Endoleak	19	95 %
Type I	1	5 %

parameters described as Mean ±SD or median (min-max)

Table (3): Validity of CO2 in visualization in relation to ICM intraoperative

	CO2	ICM	Sensitivity	specificity	PPV	NPV	Accuracy
Upper sealing zone Adequate Inadequate/not visualized	n=20(%) 11(55%) 9(45%)	n=20(%) 20(100%) 0 (0 %)	55%	--	100	100	55 %
Lower sealing zone Adequate	20(100 %)	20(100%)	100	100	100	100	100
Endoleak No endoleak Type I Type II	10(50%) 1(5%) 9(45%)	17(85%) 1(5%) 2(10%)	100	58.9	30	100	65 %

PPV: positive predictive value,**NPV:**Negative predictive value

Table (4): Validity of CO2 DSA at endoleak visualization:

		ICM DSA Gold Standard		
		Positive	**Negative**	
CO2 DSA Endoleak	**Positive**	True += 3	False += 7	PPV =TP/(TP+FP) =3/10 =30%
	Negative	False -= 0	True - = 10	NPV =TN/(FN+TN) =10/10 =100%
		Sensitivity =TP/(TP+FV) =3/3 =100%	Specificity =TN/(FP+TN) =10/17 =58.9%	Accuracy =(TP+TN)/ALL =13/20 =65%

Table (5): Validity of CO2 DSA at endoleak visualization

	CO2	ICM	Test of significance
Upper sealing zone Not visualized Adequate Inadequate/	 2(10) 11(55) 7(35)	 0 20(100) 0	 MH=1.67 p=0.014*
Lower sealing zone adequate	20(100)	20(100)	MH=0.0 P=1.0

Endoleak			
No endoleak	10(50)	17(85)	MH=2.65
Type I	1(5.0)	1(5)	P=0.008*
Type II	9(45.0)	2(10)	

MH: Marginal Homogenity test

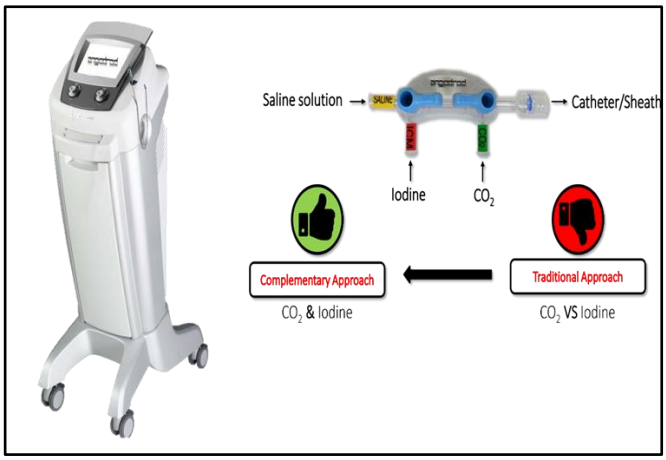

Figure 1: Angiodroid CO2 injector device with the method used as the complementary approach with double port system

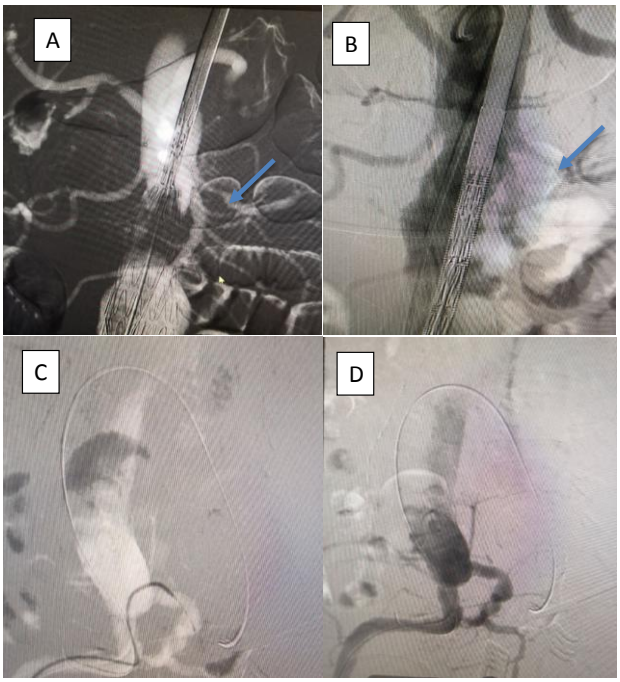

Figure 2: CO2 DSA image (A) showing both renal arteries equal to ICM DSA(B) image while CO2 DSA (C) of lower sealing zone similar to ICM DSA (D) during coiling of Rt IIA

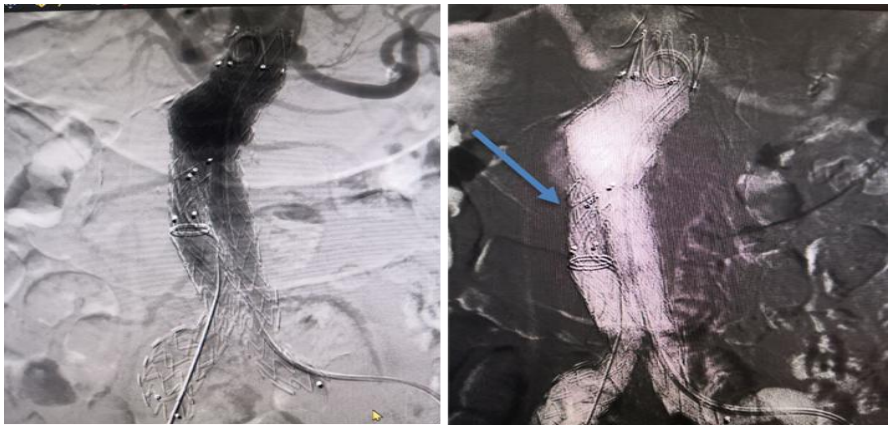

Figure 3: ICM DSA image (A) showed no type 2 endoleak while CO2 DSA image (B) showed this endoleak

Discussion

Endovascular aneurysm repair demanded the first line of management of abdominal aortic aneurysm in the current practice due to its lower morbidity and mortality than open surgical repair. However, ICM plays a vital role in the EVAR procedure that contradicts the patients with allergies to IC. Also, for patients with chronic kidney diseases; EVAR will increase morbidity.[17-18] CO_2 is a gas contrast that has the advantages of no Allergenic reaction, no toxicity, less viscous than iodinated contrast, and buoyant and radiolucent. CO_2 DSA is used for patients with borderline renal disease; Chronic renal failure on dialysis; renal transplant and in a patient with a previous allergic reaction to ICM. Not only to avoid fluid overload but also to avoid contrast-induced nephropathy. [19-20]

In this study; we evaluated the upper, and lower sealing zones and endoleak visualization by comparing images by both CO_2 DSA and ICM DSA in cases with AAA candidates for EVAR. The upper zone visualization was 55 % % (accuracy of 55 %) and the lower zones 100 % (accuracy of 100 %) these results were similar to that reported by Mascoli et al.[21]

Criado et al [22] reported that CO_2 DSA failed to detect endoleak in one case but others claimed that CO_2 DSA is highly sensitive in detecting endoleak.[23] Also, Huang et al [24] stated that CO2-DSA during EVAR could detect endoleak. In our study we noted that CO2 DSA revealed ten (50 %) cases of endoleak; one was a type I endoleak and nine were type II but the ICM uncovered three cases only (15 %) one case of type Ia and two cases of type II; the sensitivity discovered to be 100 % while 58.9% specificity, and 65 % accuracy. Thereby CO_2 is highly sensitive but less specific for type II endoleak in subgroup analysis; this could be explained as the CO2 has its buoyancy that augments the type II endoleak that results from aortic branches.

Preservation and protection of renal function during CO2-assisted EVAR was ascertained by a lot of studies [25-26] that was documented in this study that there was no deterioration or change in the renal condition of the patients before and after the procedure

The side effects of CO2 are mainly related to the vapor lock phenomenon wherein the gas is displacing blood and is trapped, obstructing the lumen that occurs when injecting large volumes multiple times with

insufficient time for blood to clear the gas.[27] In this study, we used the automated device (Angiodroid R- FAST) that takes from one to three minutes between the injections. So that the study showed that CO_2-assisted EVAR is safe with no complication or side effects related to CO_2 as Vacirca et al.[28] However, some studies showed some complications such as mesenteric and colonic ischemia that may be related to cholesterol embolism.[29]

CONCLUSION:

CO_2-DSA-assisted EVAR for infra-renal AAA is safe and readily effective in reducing the dose of ICM and avoiding overload in patients with allergy to iodinated contrast, and chronic kidney disease. It could overrate type II endoleak detection thereby the need for iodinated contrast is essential.

Limitation of the study:

A small number of cases as the study was carried out during the era of COVID-19. Absence of long-term results and cost-effectiveness which need future large randomized studies. Inability to use Intra-vascular ultrasound (IVUS) and contrast-enhanced ultrasonography (CEUS) due to non-availability.

- **Funding**: *No funding*
- **Conflict of Interest:***no conflict of interest*

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