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Editor's Choice – Feasibility and Safety of Using Carbon Dioxide Exclusively in Regular Endovascular Aortic Aneurysm Repair: Results of a Multicentre, Prospective, Zero Iodine Contrast Endovascular Aneurysm Repair Study☆

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WHAT THIS PAPER ADDS

This study has demonstrated that a standardised zero iodine contrast endovascular aneurysm repair protocol was safe and feasible in 82% of consecutive non-selected patients. Limitations primarily arose from anatomical factors. However, by employing adjunctive standardised manoeuvres (five separate steps are described), such as modifying the injection site, selectively cannulating the target vessel, or using a tilt table, many of these limitations can effectively be overcome. In cases of large aneurysm sac or a lowermost renal artery position between 3 and 9 o'clock, the use of iodinated contrast medium (ICM) may be considered. The findings of this study are promising, but they need to be validated in independent cohorts at various centres with long term data before they can be recommended for application. This validation should ideally involve a randomised comparison with ICM.

Objective: Carbon dioxide (CO_2) angiography has emerged as a viable alternative to regular iodinated contrast medium (ICM) for guiding endovascular aneurysm repair (EVAR) procedures. This study aimed to evaluate the feasibility and safety of a standardised EVAR procedure using only CO_2 angiography.

Methods: A prospective, multicentre, national study enrolled consecutive patients between January 2023 and January 2024 with asymptomatic abdominal aortic aneurysms measuring $\geq$55 mm and for whom a standard endovascular graft (instructions for use) was anatomically feasible. The study involved the use of an automatic CO_2 injector to standardise intra-operative imaging. A strategy comprising five standardised steps was devised to visualise a target vessel (TV) that could not be seen during the first CO_2 angiogram. The five steps were: (A) place the introducer closer to the TV; (B) tilt the table by 5 — 10° in the direction opposite to the TV; (C) selectively cannulate the TV; (D) cannulate the contralateral gate (only for repositionable devices); CO_2 angiography was repeated in steps 1 — 2; and (E) use ICM.

Results: Two hundred and ninety-three patients were enrolled (10 centres), with a median age of 78 (interquartile range [IQR] 72, 83) years; 256 (87.4%) were male. The overall procedure time, fluoroscopy time, and injected CO_2 volume were 90 (IQR 65, 125) minutes, 15 (IQR 10, 22) minutes, and 600 (IQR 400, 800) mL, respectively. The 30 day mortality, complication, and re-intervention rates were 0.3% (n = 1), 6.8% (n = 20), and 2.4% (n = 7), respectively. CO_2 related adverse events were rare (1%; n = 3) and minor. A zero iodine contrast EVAR procedure was feasible in 240 (patients 81.9%). The five standardised steps were used extensively: step A, 170 procedures (58.0%); step B, 109 procedures (37.2%); step C, 21 procedures (7.2%); step D, 14 procedures (4.8%); and step E, 53 procedures (18.1%), with a median volume of 20 (IQR 10, 35) mL. Significant predictors for ICM use were aneurysm diameter >70 mm and a lowermost renal artery positioned between 3 and 9 o'clock.

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Conclusion: This study demonstrated that the standardised zero iodine contrast EVAR protocol reported here is both safe and feasible and is applicable in 82% of consecutive non-selected patients. Limitations primarily arose from anatomical factors, and adjunctive standardised manoeuvres can effectively address these challenges in most cases.

Keywords: CO_2 angiography, EVAR, Multicentre, Prospective
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INTRODUCTION

Use of iodinated contrast medium (ICM) is the standard method for imaging in endovascular surgery but has several disadvantages, such as contrast nephropathy and the possibility of an allergic reaction.[1–5] Carbon dioxide (CO_2) angiography was originally introduced as an alternative agent for the visualisation of visceral, abdominal aortic, and lower extremity vascular structures in patients with contraindications to ICM.[1–3] CO_2 is an agent with completely different physical characteristics, such as high intravascular clearance with rapid dissolution time, buoyancy, extremely low viscosity, reflux, and the ability to displace fluids when injected intravascularly.[2,3] CO_2 angiography has been introduced in many vascular centres in their daily practice for treating aortic aneurysm pathology using endovascular aneurysm repair (EVAR) procedures. Studies are increasingly documenting the use of CO_2 as a contrast medium in EVAR procedures.[5–22] The 2019 and 2024 European Society for Vascular Surgery (ESVS) guidelines have already acknowledged CO_2 angiography as an effective alternative to ICM without the associated risk of worsening renal function.[23,24] The safety of using CO_2 during EVAR has been validated previosuly.[5,7,16–20,22] However, there is a lack of prospective studies with large sample sizes that focus on a standardised procedure with the aim of performing the procedure using only CO_2 as a contrast medium. This study aimed to evaluate the feasibility and safety of using only CO_2 angiography in daily practice for standardised EVAR in a prospective multicentre study of consecutive non-selected patients.

MATERIALS AND METHODS

Study design

This was a prospective, multicentre, national, non-randomised, investigator initiated observational study on CO_2 use as an exclusive contrast medium for EVAR. An automatic CO_2 injector (Angiodroid SpA, San Lazzaro di Savena, Italy) was essential for standardised imaging. All vascular surgeons and radiology technicians in the participating centres had received training in CO_2 angiography and CO_2 use for at least two years. The inclusion criteria were: consecutive, asymptomatic patients with abdominal aortic aneurysm (AAA) measuring $\geq$55 mm intended to be treated with a zero iodine contrast strategy; anatomical feasibility for a standard endovascular graft (instructions for use); and ability to give voluntary, written informed consent to participate in this clinical investigation.

Exclusion criteria were: age $<$18 years; urgent or symptomatic aneurysm rupture; major iliac aortic stent obstructive pathology requiring additional planned procedures; congenital aortic anomalies with abnormal arteries (i.e., accessory polar renal artery arising from the sac); and contraindication to the use of CO_2 as a contrast agent (supradiaphragmatic arterial studies, pulmonary insufficiency, presence of interatrial or interventricular communication, pulmonary arteriovenous malformation, or the need for nitric oxide anaesthesia). The local Ethics Committees approved the study (ID 23085, 20 December 2022) and patients gave informed consent before the procedure and during follow up. Inclusion in the computerised database required the patient's consent. A flow diagram of all patients treated for infrarenal elective AAA during the study period is provided in Supplementary Figure S1.

Operative technique and carbon dioxide protocol

All procedures were performed in an angio suite or hybrid room equipped with a C arm. After gaining bilateral 11 F (11 cm) femoral percutaneous or surgical access, the automatic CO_2 injector was connected to the femoral sheath sidearm where the main body of the graft was to be deployed. On the other side, a long sheath $\geq$6 F (55 cm) was placed between the L1 and L2 vertebrae. The first injection was made to evaluate the iliac field (hypogastric bifurcation of both sides, iliac bifurcation) generally with the caudal C arm positioned at 10° (Fig. 1A). This angiogram was performed with a CO_2 volume of 100 mL and a pressure of 650 mmHg. After immediate post-processing of the angiogram, including the use of re-masking and stacking software, and the creation of a reference imaging overlay or drawing markers for the target vessels (Supplementary Video S1), the main body was introduced by placing the distal part of the graft above the ipsilateral hypogastric artery and the gate above the iliac bifurcation. With the main body of the graft in the aorta, a second CO_2 angiogram was performed, generally with a 10° cranial C arm position (Fig. 1B). A second injection was performed to evaluate the renal blood supply. This angiogram was performed using a CO_2 volume of 100 mL and a pressure of 650 mmHg. After immediately post-processing the angiogram, an overlay reference was created or markers were drawn for the target vessels of the lowest renal artery, and the graft was delivered. After complete delivery of the graft, the final angiogram was performed through one of the 11 F femoral sheaths with

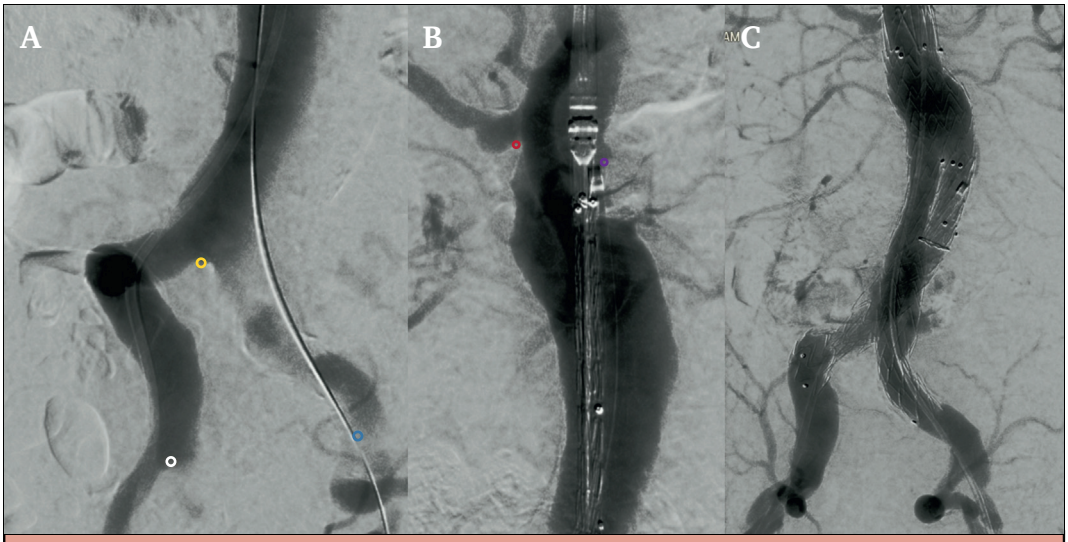

Figure 1. Visualisation of target vessels during a zero contrast endovascular aneurysm repair procedure and completion angiography. (A) The iliac field (including the hypogastric bifurcation on both sides and the iliac bifurcation) was visualised by means of angiography using 100 mL of carbon dioxide (CO_2) at a pressure of 650 mmHg through an 11 F femoral sheath. Re-masking and stacking software were used, along with the creation of markers for the target iliac vessels (the yellow dot represents the aortic carrefour, the white dot indicates the right iliac bifurcation, and the blue dot corresponds to the left iliac bifurcation). (B) The renal field was visualised using a CO_2 volume of 100 mL at a pressure of 650 mmHg through a long 7 F sheath placed between the L1 and L2 vertebrae. Re-masking and stacking software were employed, along with the creation of markers for the target renal vessels (the red and purple dots represent the origins of the right and left renal arteries, respectively). (C) Completion angiography was conducted through one of the 11 F femoral sheaths using the same volume and pressure of CO_2. This angiogram assessed graft, iliac, and renal patency, as well as the absence of high flow endoleaks (re-masking and stacking software were employed).

the same volume and pressure of CO_2. This angiogram was aimed at evaluating graft, iliac, and renal patency, and the absence of high flow endoleaks (Fig. 1C). To avoid gas fragmentation, the catheter was flushed each time it was connected to a sheath, and an interval of 120 seconds was observed between two injections to avoid excessive CO_2 administration into the aorta, which could cause possible complications (abdominal pain, nausea, vapor lock).[1–3]

Strategy for visualising a target vessel that could not be seen during the first carbon dioxide angiogram

In cases where a target vessel (hypogastric or renal artery) was not visible during the first CO_2 angiogram, the following manoeuvres were performed until unambiguous visualisation of the target vessel (Supplementary Video S2) was obtained. This strategy was implemented by all ten centres. The steps are not intended to be used sequentially; each step provides a specific solution based on the circumstances:

Step A: solution for misplacement of the introducer sheath. Bring the introducer closer to the target vessel and repeat the angiogram (using a CO_2 volume of 100 mL and a pressure of 750 mmHg) (Fig. 2).

Step B: solution for renal arteries with a position between 3 and 9 o'clock. Tilt the table 5 — 10° in the direction opposite to the target vessel and repeat the angiogram (using a CO_2 volume of 100 mL and a pressure of 750 mmHg). This manoeuvre takes advantage of the buoyancy property of CO_2 (Fig. 3).

Step C: possible solution if steps A and or B fail. Selectively cannulate the target vessel and repeat the angiogram directly from the catheter using a CO_2 volume of 40 mL and a pressure of 250 mmHg. This manoeuvre takes advantage of the reflux property of CO_2 (Fig. 4).

Step D: this is only possible with a repositionable device (e.g., Excluder, Gore; or Anaconda, Terumo Aortic) for the main body deployment. After releasing the graft in the intended position, cannulate the contralateral gate, place the introducer sheath inside the main graft, and repeat the angiogram using a CO_2 volume of 100 mL and a pressure of 750 mmHg (Fig. 5). If the main body needs to be re-positioned, it can be safely performed after this angiogram. This manoeuvre takes advantage of the reduction in the total volume to be visualised, which is particularly useful in cases of large aneurysms, and has previously been investigated by Vacirca *et al.*[18]

Step E: the solution when the target vessel is not visible after attempting at least one of the previous steps, or when the operator requires a comparative image (e.g., due to diagnostic uncertainty or complications), is to use ICM.

Definitions and endpoints

Primary endpoints were procedural technical success, clinical success at 30 days,[25] and zero iodine contrast EVAR procedure feasibility, which was defined as the ability to deploy the endoprosthesis without using ICM, ensuring the patency of the endoprosthesis and the renal and visceral vessels, in the absence of surgical conversion or death, and type I or III endoleaks. Clinical success at 30 days was defined as the absence of major adverse events (death, major bleeding complications, cardiology, respiratory,

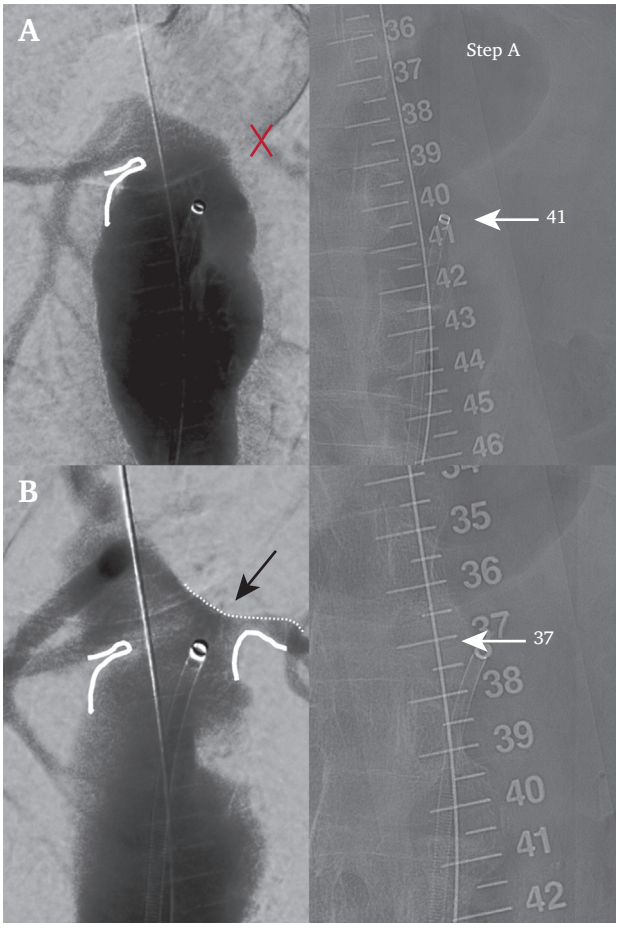

Figure 2. Step A, solution for misplacement of the introducer sheath. Step A involved bringing the introducer closer to the target vessel (from 41 to 37 cm: the white arrows indicate the positions of the introducer sheath tips), followed by repeating the angiogram (using a carbon dioxide [CO_2] volume of 100 mL and a pressure of 750 mmHg), with images captured (A) before and (B) after. The left (lowermost) renal artery was then visible (black arrow).

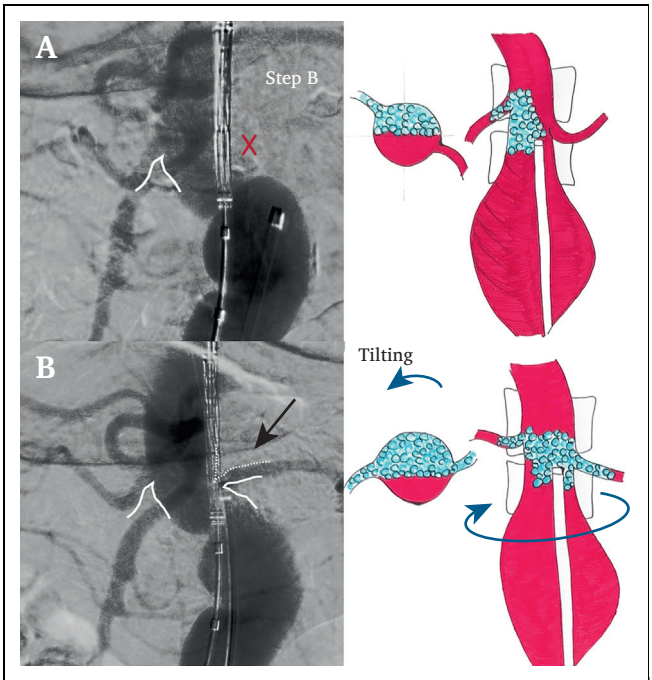

Figure 3. Step B, solution for renal arteries with a position between 3 and 9 o'clock. Step B involved tilting the table by 5 – 10° in the direction opposite to the target vessel, followed by repeating the angiogram using a carbon dioxide (CO_2) volume of 100 mL and a pressure of 750 mmHg, with images captured (A; The red cross marks the location of the left renal artery, which is present but not visible with the first CO_2 angiography) before and (B) after. The left renal artery was then visible (black arrow). This manoeuvre leverages the buoyancy property of CO_2.

intestinal ischaemia), aneurysm related re-intervention, type I or III endoleaks, graft infection or thrombosis, aneurysm expansion (diameter > 5 mm), aneurysm rupture, or conversion to open repair.

Secondary endpoints were 30 day and twelve month outcomes in terms of AAA related death, overall mortality, patency of renal and visceral vessels, patency of iliac arteries, EVAR related re-interventions, and assessment of renal function (serum creatinine and estimated glomerular filtration rate [eGFR] values). Acute kidney injury (AKI) was defined according to the RIFLE classification.[26] CO_2 specific adverse events were recorded either as minor adverse events (non-serious adverse events) such as nausea, vomiting, and transient abdominal pain, or major adverse events (serious adverse events) such as gas contamination (gas embolism), vapour lock (defined as severe abdominal pain that persists beyond three minutes, necessitating further angiographic investigation), athero-embolism, spinal cord ischaemia, and neurotoxicity.

All patients included in the study were intended to be treated with a zero iodine contrast approach. To facilitate the evaluation of results, patients who received ICM were grouped separately from those who received only CO_2 as the contrast medium. A comparative analysis of both pre-operative characteristics and outcomes was then conducted between the two groups. As the twelve month outcomes are still being collected, they will be evaluated and discussed in a future study.

Follow up

Follow up was based on clinical evaluation, duplex ultrasound performed at one and 30 days, and computed tomography (CT) angiography at 30 days, or contrast enhanced ultrasound (CEUS) + CT in cases of serum creatinine > 2 mg/dL. A one year clinical duplex ultrasound and renal function evaluation was conducted as an end of study evaluation. If a new endoleak occurred, a CEUS evaluation was performed, and if a high flow endoleak or any EVAR related complication was detected, a CT or CT angiography was required.

Statistical analysis

The ARGOS - Dedalus Digital Medical Record System (Dedalus, Florence, Italy) was used for patient data collection. Normal distribution and homogeneity of variance were confirmed by

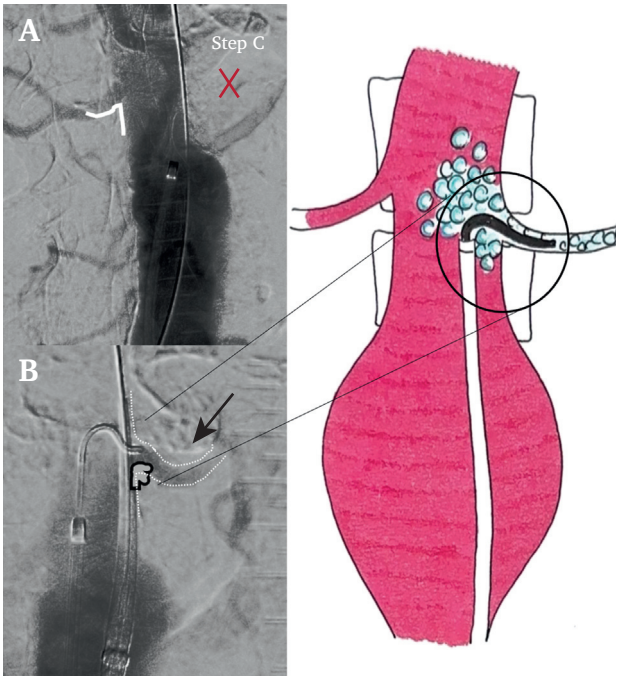

Figure 4. Step C, possible solution if steps A and or B fail. Step C involved selectively cannulating the target vessel (in this example, a shepherd hook type catheter SHK 0.8) followed by repeating the angiogram directly from the catheter using a carbon dioxide (CO_2) volume of 40 mL and a pressure of 250 mmHg, with images captured (A; The red cross marks the location of the left renal artery, which is present but not visible with the first CO_2 angiography) before and (B) after. The left renal artery was then visible (black arrow). This manoeuvre capitalises on the reflux property of CO_2.

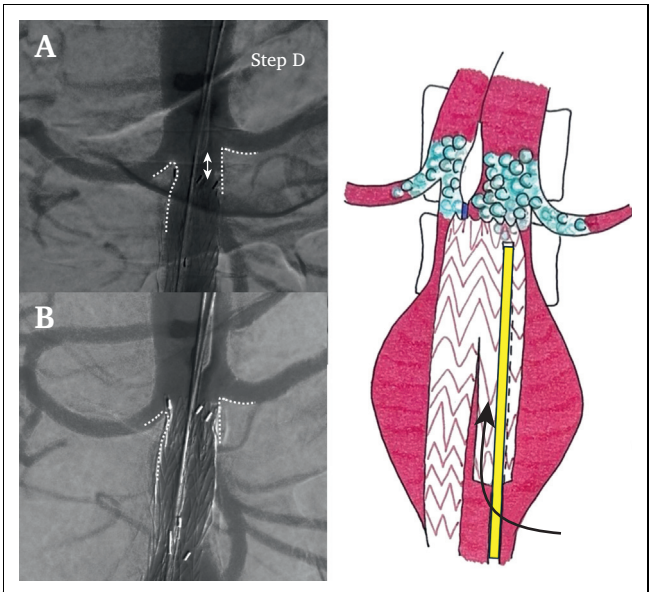

Figure 5. Step D, possible only with a repositionable device. Step D involved a manoeuvre possible only with repositionable devices such as Excluder (Gore) or Anaconda (Terumo Aortic) for main body deployment. After releasing the graft in the intended position, the contralateral gate was cannulated and the introducer sheath was placed inside the main graft. Angiography was then repeated using a carbon dioxide (CO_2) volume of 100 mL and a pressure of 750 mmHg, with images captured (A; the double-ended white arrow indicates the space into which the graft should be advanced during repositioning) before and (B) after. This manoeuvre capitalised on the possibility of reducing the total volume to be visualised, particularly advantageous in the case of large aneurysms. If necessary, the main body could be safely repositioned after this angiogram.

the Kolmogorov–Smirnov and Levene's tests, respectively. Data were expressed as median and interquartile range (IQR), or absolute frequency (%), depending on their distribution. The χ^2 or Fisher's exact tests were used for comparison of proportions. Continuous variables were compared using Student's *t* test, while non-parametric data were analysed using the Mann–Whitney *U* test. Multivariable analyses adopted a forward stepwise approach. Variables from the univariable analysis with a *p* value of $<.20$ were included in the multivariable model. Following forward multivariable logistic regression, odds ratios (ORs) were calculated to assess the significant risk of ICM use. The goodness of the logistic model was assessed by evaluating the absence of multicollinearity, which was checked using the variance inflation factor. A *p* value $<.050$ (two tailed) was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics Version 24.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Study cohort and pre-operative characteristics

A total of 293 patients were enrolled at ten centres between January 2023 and January 2024, with a median age of 78 (IQR 72, 83) years. Of these, 53 patients (18.1%) required an intra-operative injection of ICM during the EVAR procedure, forming the ICM comparison group against the zero iodine contrast group. Overall demographic characteristics, risk factors, comorbidities, and intra-operative data are presented in Table 1, whereas procedural details and 30 day results are provided in Table 2. Figure 6 depicts the clock positions of the lowermost renal artery in all patients. A position of the lowermost renal artery between 3 and 9 o'clock was more frequent in the ICM group (zero contrast *vs*. ICM group: $n = 94$, 39.2% *vs*. $n = 42$, 79%; $p < .001$). Additionally, specific positions at5 and 7 o'clock were significantly more common in the ICM group.

Intra-operative and post-operative results

Technical success was achieved in 99.7% of cases (one limb occlusion). The overall procedure time, fluoroscopy time, and injected CO_2 volume was 90 (IQR 65, 125) minutes, 15 (IQR 10, 22) minutes, and 600 (IQR 400, 800) mL, respectively. Procedure and fluoroscopy times were significantly longer in the ICM group. The types of stent grafts implanted are shown in Supplementary Figure S2. Infrarenal stent grafts were implanted more often (64%), without statistically significant differences between the two groups. Major complications related to pre-existing patient comorbidities occurred in six patients (2.0%), including two myocardial infarctions, one stroke, one bowel ischaemia, and two acute respiratory distress cases. Specifically, bowel ischaemia was not related to a vapor lock issue but rather resulted from a

Table 1. Patient and anatomical abdominal aortic aneurysm characteristics (n = 293).

Characteristic	Overall (n = 293)	Zero contrast (n = 240)	ICM (n = 53)	p value
Patient characteristics				
Age − y	78 (72, 83)	77 (72, 82)	80 (74, 84)	.10
Age >80 y	106 (36.2)	80 (33)	26 (49)	.090
Male sex	256 (87.4)	209 (87)	47 (88)	.090
Smoker	101 (34.5)	79 (33)	22 (42)	.97
Hypertension	258 (88.1)	205 (85)	53 (100)	.33
Hypercholesterolaemia	230 (78.5)	178 (74)	52 (98)	.050
Coronary artery disease	105 (35.8)	87 (36)	18 (34)	.42
COPD	66 (22.5)	49 (20)	17 (32)	.13
Peripheral arterial disease	32 (10.9)	29 (12)	3 (6)	.37
CKD stage 3–5	90 (30.7)	66 (27)	24 (45)	.12
Dialysis	2 (0.7)	1 (0.4)	1 (2)	.32
Creatinine − mg/dL	1.1 (0.8, 1.45) (0.5–7.7)	1.1 (0.9, 1.5) (0.5–7.7)	1 (0.8, 1.2) (0.5–5.2)	.40
eGFR − mL/min/1.73m^2	68 (52, 87)	70 (54, 88)	63 (42, 82)	.54
Diabetes mellitus	56 (19.1)	43 (18)	13 (24)	.33
Congestive heart failure	16 (5.5)	10 (4)	6 (11)	.79
Stroke or transient ischaemic attack	25 (8.5)	23 (10)	2 (4)	.57
Antiplatelet therapy	98 (33.4)	84 (35)	14 (26)	.68
Statin	218 (74.4)	174 (72)	44 (83)	.45
Warfarin	20 (6.8)	12 (5)	8 (15)	.26
DOACs	36 (12.3)	29 (12)	7 (13)	.44
BMI − kg/m^2	26 (24, 29)	26.1 (24, 29)	26 (25, 28.6)	.60
Anatomic characteristics				
Aortic sac diameter − mm	57 (55, 61) (55–101)	57 (55, 60) (55–100)	57 (55, 66) (55–101)	.55
>70 mm	24 (8.2)	13 (5)	11 (21)	.001
Neck length − mm	22 (17, 33) (7–70)	22 (17, 33) (7–70)	22 (15, 31) (10–46)	.42
<15 mm	43 (14.7)	31 (13)	12 (23)	.18
Neck diameter − mm	23 (20, 25) (18–33)	22 (20, 25) (18–33)	24 (20, 25) (17–33)	.12
>28 mm	22 (7.5)	15 (6)	7 (19)	.15
Proximal neck angulation > 60°	21 (7.2)	14 (6)	7 (13)	.84
Target renal artery stenosis	10 (3.4)	8 (3)	2 (4)	.77

Data are presented as n (%) or median (interquartile range) (range). ICM = iodinated contrast medium; COPD = chronic obstructive pulmonary disease; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; DOACs = direct oral anticoagulants; BMI = body mass index.

technical error involving thrombus dislodgement during embolisation of a large inferior mesenteric artery. Procedure related complications occurred in seven patients (2.4%), all requiring re-interventions: one iliac occlusion, endovascular relining; two femoral occlusions, one stenting, one surgery; and four treated surgically for femoral haemorrhage. CO_2 specific adverse events were minor, with transient nausea and abdominal pain in three cases (1.0%); this was associated with vomiting in one case (0.3%). Neither type I nor III endoleaks were detected at the 30 day follow up, while type II endoleaks were observed in 32 cases (10.9%) . The zero iodine contrast EVAR procedure was feasible in 240 patients (81.9%). Adjunctive CO_2 angiography was repeated in 170 procedures (58.0%) to gain better visualisation of a target vessel (renal, n = 153, 90%; hypogastric n = 17, 10%). Specifically, main body release required a median of two CO_2 angiography procedures (range one to six), while a median of one CO_2 angiography procedure (range one to four) was needed for limb release. As reported in Table 2, of all the adjunctive angiograms performed, 156 (53.2%) were categorised as step A, 109 (37.2%) as step B, 21 (7.2%) as step C, and the remaining 14 (4.8%) as step D. Table tilting was required for renal and hypogastric visualisation in 55 (18.8%) and 54 (18.4%) cases, respectively (step B, 37.2%), while selective target vessel cannulation was needed for imaging in seven renal (2.4%) and 14 hypogastric arteries (4.8%) (step C, 7.2%). The frequency of use is reported for each step in both the zero contrast and ICM groups in Table 2. Iodinated contract was required (step E) in 53 procedures (18.1%), with a median volume of 20 mL (IQR 10, 35; range 1 − 100 mL) injected. The reasons for ICM use were as follows: failure to visualise the target renal artery (n = 30, 58%); failure to visualise the target hypogastric artery (n = 13, 25%); inconclusive findings from the final angiogram (unclear endoleak evaluation that could not distinguish between a type I or II endoleak: n = 8, 15%); and the occurrence of a complication (limb occlusion and access complication: n = 2, 2%). Significant predictors for ICM use were aneurysm sac with a diameter > 70 mm (OR 3.75, 95% confidence interval [CI] 1.18 − 11.92; p = .025) and a position of the lowermost renal artery between 3 and 9 o'clock (OR 34.76, 95% CI 11.52 − 78.49; p = .034) (for more details see Supplementary Tables S3 and S4).

Thirty day outcomes

No patient was lost by the 30 day follow up. The 30 day mortality rate was 0.3% (n = 1), which was not related to AAA but rather to cancer progression with an unexpected complication due to infection. The overall clinical success at 30 days was 96.6% (96.2% in the ICM group and 96.6% in

Table 2. Procedural details and 30 day results.

Variable	Overall (n = 293)	Zero contrast (n = 240)	ICM (n = 53)	p value
Procedure details				
General anaesthesia	143 (48.8)	103 (43)	40 (75)	.010
Infrarenal stent graft	189 (64.5)	159 (66)	30 (56)	.28
Percutaneous EVAR	223 (76.1)	176 (73)	47 (89)	.021
CO_2 volume − mL	600 (400, 800)	600 (400, 785)	700 (500, 835)	.11
Total operating time − min	90 (65, 125)	86 (60, 120)	108 (86, 165)	<.001
Total fluoroscopy time − min	15 (10, 22)	14 (10, 20)	20 (11, 29)	.002
Estimate blood loss >200 mL	16 (5.5)	13 (5)	3 (6)	.88
Procedural complications	12 (4.1)	9 (4)	3 (6)	.47
Step A	156 (53.2)	103 (43)	53 (100)	<.001
Step B	109 (37.2)	65 (27)	44 (83)	<.001
Step C	21 (7.2)	14 (6)	7 (13)	.070
Step D	15 (5)	13 (5)	2 (2)	.48
Limb occlusion	1 (0.3)	0 (0)	1 (2)	.18
Access complication	6 (2.0)	5 (2)	1 (2)	.46
Unplanned procedure	18 (6.1)	13 (5)	5 (9)	.28
30 day results				
Death	1 (0.3)	1 (0.4)	0 (0)	.62
AAA related death	0 (0)	0 (0)	0 (0)	–
Endoleak	30 (10.2)	23 (10)	7 (13)	.29
Type II	30 (10.2)	23 (10)	7 (13)	.29
Type I–III	0 (0)	0 (0)	0 (0)	–
Myocardial infarction	2 (0.7)	2 (0.8)	0 (0)	.48
Stroke	1 (0.3)	1 (0.4)	0 (0)	.62
Spinal cord ischaemia	0 (0)	0 (0)	0 (0)	–
ARDS	2 (0.7)	2 (0.8)	0 (0)	.48
Creatinine − mg/dL	1 (0.9, 1.5) (0.5–4.8)	1 (0.8, 1.4) (0.5–4.1)	1.3 (1, 1.6) (0.7–4.8)	.047
eGFR − mL/min/1.73 m^2	66 (48, 85)	70 (54, 88)	57 (37, 78)	.041
Acute kidney injury	7 (2.4)	2 (0.8)	5 (9)	.003
Bowel ischaemia	1 (0.3)	1 (0.4)	0 (0)	.62
30 day complications	20 (6.8)	13 (5)	7 (13)	.060
30 day re-interventions	7 (2.4)	5 (2)	2 (4)	.77
30 day clinical success	283 (96.6)	232 (96.6)	51 (96.2)	1.0

Data are presented as n (%) or median (interquartile range) (range). ICM = iodinated contrast medium; EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; ARDS = acute respiratory distress syndrome; eGFR = estimated glomerular filtration rate.

the zero iodine contrast group; $p = 1.0$). The reasons for the ten cases of 30 day clinical failure were: two in the ICM group (major bleeding and limb occlusion) and eight in the zero iodine contrast group (one death, two major bleeding, two cardiological complications, two respiratory complications, and one case of intestinal ischaemia). AKI occurred in two patients (0.8%) in the zero iodine contrast EVAR group and five (9%) in the ICM group ($p = .003$). Additionally, 30 day serum creatinine values were lower and eGFR values higher for the zero iodine contrast EVAR group (Table 2). All AKI events occurred in patients with pre-existing compromised renal function. Notably, the two patients who experienced AKI in the zero iodine contrast group had pre-operative serum creatinine levels that were >6 mg/dL. These two patients had a history of continuous oscillations in serum creatinine levels due to their kidney disease; however, at the time of writing, both patients (with eight and fourteen months of follow up) are still free of the need for dialysis.

DISCUSSION

This study is the most extensive prospective, multicentre investigation to date into the feasibility and safety of EVAR using CO_2 as the exclusive contrast medium and involved a cohort of 293 patients. A comprehensive literature review encompassing a total of 642 patients, primarily drawn from smaller scale retrospective studies, underscores the significance of the findings (Supplementary Table S3).[5–22] In contrast to the median feasibility rate of zero iodine contrast EVAR reported in the literature of 24% (IQR 17, 42; range 0 − 100%), this study achieved a feasibility rate three times that figure (82%). This substantial improvement is attributed to the implementation of a standardised procedure, meticulous procedure planning, and the adoption of standardised protocols to address challenges related to the visualisation of target vessels. This advance has profound implications for patient safety and procedural success in endovascular interventions. The advantages of CO_2 angiography are that it has no renal or systemic toxicity, it is not allergenic, it is widely available in the hospital environment at an extremely low cost, and, when used with adequate knowledge and the proper technique, it is an extremely safe negative contrast agent.[27] In the last decade, the technical suitability of CO_2 angiography for EVAR and its beneficial effect on the preservation of renal function have been suggested in several studies.[4,10,15,16,19–21,23] The current study reports an increased

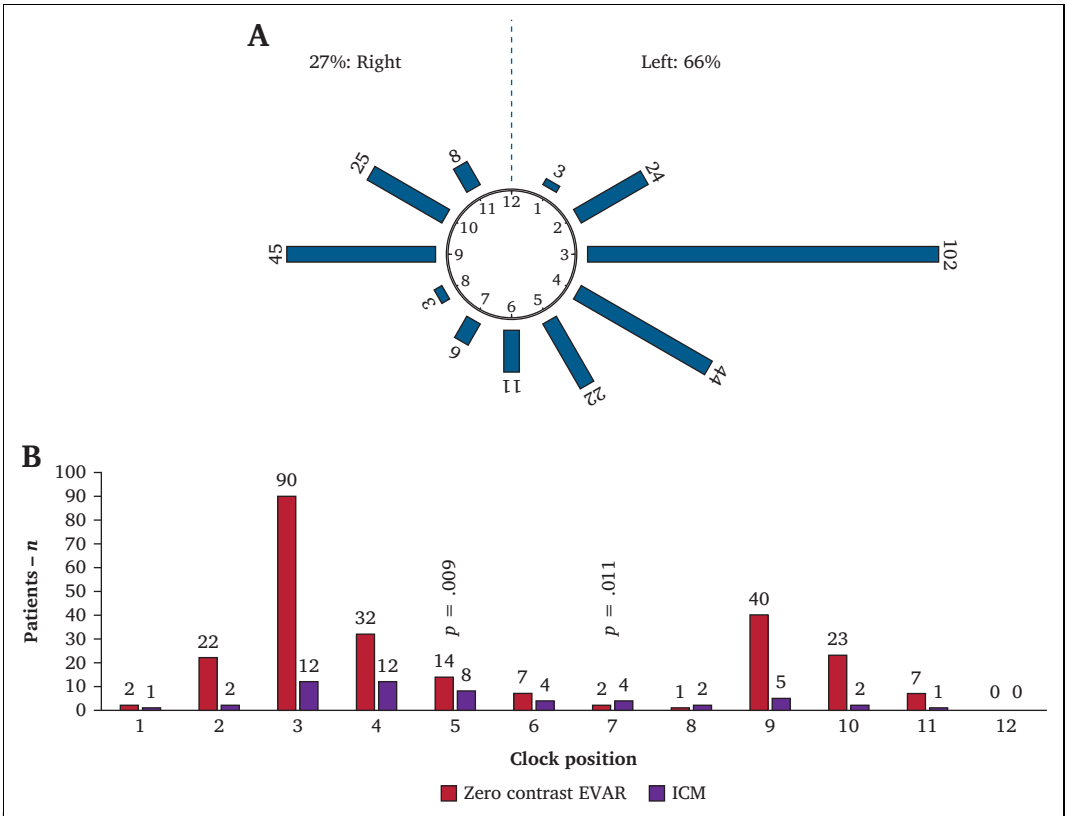

Figure 6. Clock face positions of the lowermost renal artery in the standardised zero iodine contrast endovascular aneurysm repair (EVAR) group and the iodinated contrast medium (ICM) group. (A) Clock face positions of the lowermost renal artery for all patients are depicted, indicating the axial distribution of the lowermost renal artery originating from the aorta. (B) Bar graph illustrating the distribution of clock face positions for each hour. Notably, 5 and 7 o'clock were significantly more frequent in the ICM group.

frequency of 30 day AKI occurrence among patients receiving adjunctive ICM, all of whom had pre-existing compromised renal function. This finding is in line with recent literature indicating that the risk of AKI is higher in patients with pre-existing renal impairment.[28] Additionally, these patients may benefit the most from an ICM free EVAR protocol.[19,29] These findings could be further elucidated through a direct comparison of EVAR exclusively performed with ICM *vs*. CO_2 in a large prospective comparison study. Furthermore, there is a growing body of literature indicating that CO_2 angiography can reduce the volume of ICM used and post-operative creatinine levels.[4,10,15,16,19–21,23] It is an additional tool to be used selectively in complex EVAR,[30] it can accurately detect endoleaks,[31] and it helps reduce the cost of the procedure.[9]

However, wider use of CO_2 angiography remains limited, primarily due to the lack of standardisation in procedural protocols adopted by operators in different centres, as well as significant variations in the devices used.[2,11,18] While CO_2 angiography requires specialised equipment for precise delivery and control of the CO_2 in the vascular system for imaging, the lack of uniformity in procedural approaches and device specifications contributes to constraining its adoption. There are multiple options for CO_2 delivery from its source, including injection with the purged syringe method, the plastic bag system, dedicated computerised and automated CO_2 injectors, and portable closed system platforms.[2] Interest in automated CO_2 injection has recently resurfaced with the introduction in Europe of the Angiodroid Injector (Angiodroid SpA).[2,11,13,16,30] This latest generation computerised CO_2 injector was chosen for evaluation in this study since it is reliable, versatile, and user friendly. This device calculates the amount of gas to be injected in the vessel, and accordingly automatically purges air out, verifies CO_2 purity, and determines the delivered volume and injection pressure. Preliminary reports of this system's clinical performance and safety have been encouraging.[2,11,13,16,30] Other automated CO_2 injectors (INSPECT 3005R and the more compact 2005R, Malek Medical GmbH, Wismar, Germany; and INX—1000A, VIMAP Technologies, Málaga, Spain) recently came onto the European market but there has been little experience with these systems. Furthermore, due to the implementation of this standardised protocol, this study can be replicated using any automated CO_2 injector system. Real time CO_2 pressure and volume monitoring are fundamental because imaging relies on them rather than radiopacity for visualisation. Without these characteristics, a procedure could not be standardised. Standardisation of the procedural steps among operators and centres is fundamental, as highlighted by this prospective study. Reports have exaggerated the

fear of complications and the unfounded assumption that the procedure is time consuming and produces inferior quality imaging.[1–3] In terms of safety, the literature indicates a 30 day mortality rate of 0 — 7%. The study by Criado *et al.*[5] (114 patients) is considered to be particularly reliable since it has the highest published sample size, reporting a mortality rate of 1.7%, whereas the current study recorded a rate of 0.3%. Complication rates varied between 0 — 15%; the study by Criado *et al.*[5] reported a low rate of 1%, whereas this study observed a slightly higher rate of 5%. For 30 day re-intervention, rates ranged from 0 — 19%, with Criado *et al.*[5] reporting 3.5% and this study 2%.

Notably, serious adverse events related to CO_2 were not observed in any case apart from anecdotal case reports.[2] However, minor adverse events were reported, ranging from 0 — 12.3%. These mainly involved gastrointestinal issues such as abdominal pain, nausea, vomiting, diarrhoea, and, in rare instances, hypotension. Minor adverse events in this study were predominantly nausea (1%) and vomiting (0.3%), indicating a generally favourable safety profile associated with CO_2 angiography. The overall procedure time should be adjusted depending on factors such as the type of access, graft used, experience of the operators, and their proficiency in using CO_2. Criado *et al.*[5,7] have previously reported that CO_2 angiography has the potential to reduce operation and fluoroscopy time. This prospective study is in line with these findings, although a large comparative analysis of ICM only and CO_2 only EVAR could provide conclusive answers. However, the conviction that CO_2 angiography is time consuming warrants thorough investigation and scrutiny.

The disadvantage of CO_2 as a contrast medium is the lower imaging quality compared with ICM. The purpose of an intravascular contrast agent during EVAR is to localise the major branches of the aorta and iliac arteries to allow the precise deployment of the endograft, and, on completion, to identify significant endoleaks and ascertain the patency of the graft, renal arteries, and outflow vessels. CO_2 as a contrast agent provided all this information in 82% of the consecutive non-selected patients. However, training and experience are required to use CO_2 angiography proficiently. Post-processing the images is fundamental for better visualisation, especially the use of stacking software, which can summarise the information in the images and provide a more complete visualisation. It is also a powerful tool for visualising target vessels for stent graft deployment (i.e., the inferior renal artery for proximal sealing or the hypogastric bifurcation for iliac sealing). This study found that an aneurysm sac with a diameter of >70 mm and a lowermost renal artery position of between 3 and 9 o'clock were associated with the failure of zero iodine contrast EVAR. The manoeuvres to address the challenge of insufficient visualisation of a target vessel are now standardised and highly effective in this protocol. From current experience, step A was used most and was most effective. All steps benefit from the physical and chemical properties of CO_2, highlighting the importance of a thorough practical understanding of CO_2. In any scenario, ICM can be applied promptly if necessary. According to Criado's experience with elective EVAR,[5] a small amount of ICM was used in 47% of EVAR cases. In the current experience, the rate of ICM use was 18%. In any event, the literature reports alternative ways of avoiding the use of ICM, which could be desirable in patients with normal renal function if this alternative has the same diagnostic power.[32] The combination of 3D image fusion of a pre-operative CT with live fluoroscopy and CO_2 digital subtraction angiography verification,[33–35] intravascular ultrasound,[36] and Fibre Optic RealShape technology[37] have proven to be the most promising techniques for reducing radiation exposure, ICM volume, and operating time.

Study limitations

Although this study involved a relatively large cohort, it did not assess all the variables that may have influenced outcomes because the distribution of several additional variables occurred at low frequency in the study group and did not provide sufficient statistical power to adequately analyse their roles, potentially resulting in a type II statistical error. The limited generalisability, selection bias, and the lack of a direct comparison with an ICM EVAR group are additional limitations.

Conclusions

This study has demonstrated the safety and feasibility of the standardised zero iodine contrast EVAR protocol in 82% of consecutive non-selected patients. Limitations primarily arose from anatomical factors. However, by employing adjunctive manoeuvres, such as modifying the injection site, selectively cannulating the target vessel, or using table tilting, many of these limitations can be overcome. The findings of this study are promising, but they need to be validated in independent cohorts at various centres with long term data before they can be recommended for application. Ideally, this validation should involve a randomised comparison with ICM.

CONFLICT OF INTEREST

None.

FUNDING

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.11.011.

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Traumatic Tear of Inferior Vena Cava in Motor Vehicle Collision

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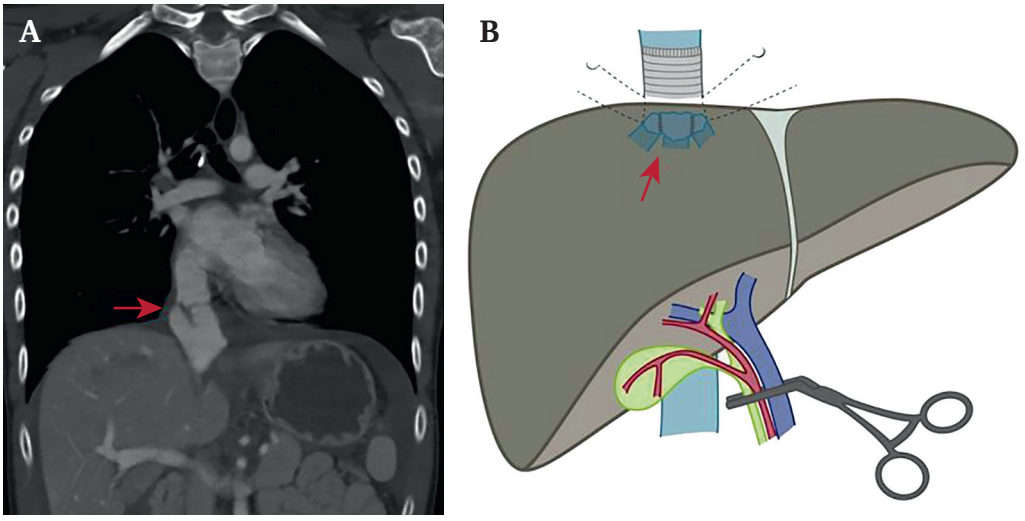

Following a motor collision, a 21 year old haemodynamically unstable woman with free intra-abdominal fluid on computed tomography was transferred with abdominal packing following laparotomy. After de-packing there was torrential venous bleeding along the diaphragmatic hiatus. The inferior vena cava (IVC) was torn along the hepatic vein confluence (A, red arrow). Inferior vena cava clamping at the atrium and the Pringle manoeuvre were performed. The hepatic veins and distal IVC were fused and sutured to a reinforced prosthesis re-inserted into the cranial part of the torn IVC (B, red arrow). The patient was stabilised and discharged with lifelong anticoagulation. The graft was patent at one year follow up.

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