Endovascular balloon occlusion is associated with reduced intraoperative mortality of unstable patients with ruptured abdominal aortic aneurysm but fails to improve other outcomes

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Background: **Proximal aortic control by endovascular balloon occlusion (EBO) is an alternative to conventional aortic cross-clamping (CAC) in hemodynamically unstable patients presenting with a ruptured abdominal aortic aneurysm (rAAA). The aim of this study was to evaluate the potential clinical benefit of EBO over CAC.**

Methods: **Data from 72 patients with rAAA treated at our institution from 2001 to 2013 were retrospectively analyzed. All patients were hemodynamically unstable (mean arterial blood pressure at admission <65 mm Hg or associated unconsciousness, cardiac arrest, or emergency endotracheal intubation). Clinical end points of hemodynamic restoration, mortality rate, and major postoperative complications were assessed for CAC (group 1) and EBO (group 2).**

Results: **At admission, 72 patients were unstable. CAC was performed in 40 and EBO in 32. Intraoperative mortality was 43% in group 1 vs 19% in group 2 ($P = .031$). In group 1, the approach for CAC (thoracotomy [n = 23] vs laparotomy [n = 17]) did not influence intraoperative mortality (43% vs 41%). There was no significant difference in 30-day (75% vs 62%) and in-hospital (77% vs 69%) mortality rates between groups. After EBO, the treatment—open vs endovascular repair—did not influence the intraoperative mortality rate (31% vs 43%; $P = .5$). Eight surgical complications were secondary to CAC (1 vena cava injury, 3 left renal vein injuries, 1 left renal artery injury, 1 pancreaticoduodenal vein injury, and 2 splenectomies), but no EBO-related complication was noted ($P = .04$). Differences in colon ischemia (15% vs 28%) and renal failure (12% vs 9%) were not statistically significant. Abdominal compartment syndrome occurred in four patients in group 2 and in no patients in group 1.**

Conclusions: **Compared with CAC, EBO is a feasible and valuable strategy and is associated with reduced intraoperative mortality of unstable rAAA patients, but not in-hospital mortality, in this retrospective study. (J Vasc Surg 2015;61:304-8.)**

Proximal aortic control remains one of the challenges of the management of unstable patients with ruptured abdominal aortic aneurysms (rAAAs). Patients are usually treated by performing an expeditious midline incision with control of the infrarenal or upper abdominal aorta by direct aortic cross-clamping. Clamping of the descending thoracic aorta through a left thoracotomy is an alternative technique in unstable patients with previous upper abdominal surgery or an intraperitoneal rupture. These techniques require emergency general anesthesia, with a high risk of cardiac arrest. Perioperative mortality remains high (32%-80%) and has not improved significantly during the past two decades.[1-4]

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Proximal aortic control of an rAAA by endovascular balloon occlusion (EBO) was first described through a brachial approach by Heimbecker[5] in 1964. Transaxillary EBO was proposed by Smith[6] in 1972. More recently, percutaneous EBO has been proposed through a brachial[7] or a femoral[8] approach. Advantages of EBO over conventional techniques include ability to perform the technique under local anesthesia, speed and effectiveness in achieving hemodynamic stability, and use with conventional open or endovascular repair.[9] The aim our study was to determine the benefit of EBO over conventional aortic cross-clamping (CAC) in hemodynamically unstable rAAA patients secondarily receiving endovascular aortic repair (EVAR) or open surgical repair (OSR).

METHODS

Consecutive rAAA patients treated in our Vascular Surgery Unit from January 2001 to December 2013 were retrospectively reviewed from a prospective database. The Institutional Review Board approved the study, and waived patient consent for this retrospective record review.

We only collected data of hemodynamically unstable patients with at least one of the following criteria: mean blood pressure (MBP), calculated as [(systolic pressure + {2 × diastolic pressure})/3] upon admission of <65 mm Hg, unconsciousness, cardiac arrest, or need for emergency endotracheal intubation. Patients deemed unfit for surgical intervention or who were hemodynamically stable (stable MBP >65 mm Hg) after initial fluid resuscitation using <500 mL/30 min intravenous crystalloid fluid load were excluded. Patients referred for thoracoabdominal aneurysms were also excluded.

Patients were allocated to two groups according to the technique of aortic control: CAC, followed by OSR (group 1), or EBO, followed by OSR or EVAR, depending on anatomic criteria and feasibility (group 2).

EBO was initially attempted through a percutaneous femoral approach using a specific kit including an introducer sheath 9F (Terumo, Heverlee, Belgium), a 0.035-inch heavy-duty guidewire (Terumo), a 5F Van Schie catheter (Cook Medical, Bloomington, Ind), a 260-cm-long extra-stiff Lunderquist guidewire (Cook Medical), a 45-cm-long 14F sheath (Cook Medical), and a 46-mm-diameter reliant aortic balloon (Medtronic, Brussels, Belgium).

If the percutaneous approach failed, we performed a femoral cutdown under local anesthesia (0.5% bupivacaine) and puncture of the common femoral artery under direct vision. A 0.035-inch heavy-duty guidewire (Terumo) was inserted under fluoroscopic guidance (OEC 9800; GE-OEC Medical Systems, Salt Lake City, Utah), up to the level of the descending aorta, and then exchanged for an extra-stiff guidewire. A 14F sheath was inserted over the guidewire up to the level of the celiac axis, allowing placement of the aortic balloon. The balloon was inflated proximal to the rAAA, at the level of the distal descending thoracic aorta, just above the diaphragmatic crus. The sheath was advanced so that it abutted the inflated balloon and was secured to patient's skin at the groin to prevent distal migration. A pigtail catheter was inserted through the contralateral femoral artery to just below the occlusion balloon, allowing an angiogram to assess the feasibility of EVAR treatment.

EVAR was performed whenever feasible (aortic neck ≥15 mm, angulation <90°, neck diameter <32 mm, adequate iliac sealing zone, good iliac access). The main body of the stent graft was inserted through the contralateral approach. In this case, lateral puncture with a 5F sheath of the valve of the ipsilateral 14F sheath allowed insertion of a pigtail up to the aneurysm neck to monitor the procedure. When hemodynamic stability was achieved, the EBO was deflated and withdrawn from the aneurysm sac to allow successful stent graft deployment.

In case of persisting hemodynamic instability, the balloon was kept inflated during graft deployment, providing that the distal end of the sheath supporting the balloon was above the proximal edge of the stent graft, to allow balloon retrieval through the sheath once the stent graft had been deployed. Alternatively, in case of recurring hemodynamic instability after occlusion balloon retrieval, the occlusion balloon could be inserted again through main body of the stent graft and inflated to restore hemodynamic stability.

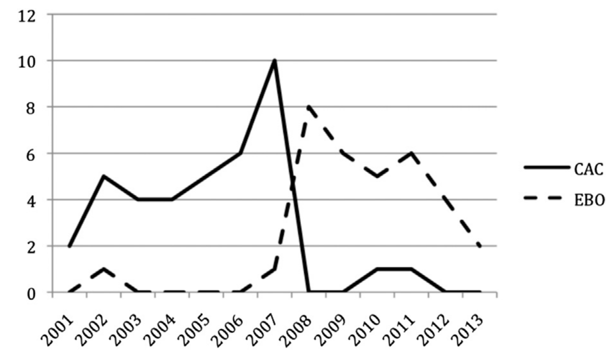

Fig. Evolution of our practice from 2001 to 2013. Endovascular balloon occlusion (*EBO*) was first used in 2002. A specific "endoclamping" kit has been available since 2007. *CAC,* Conventional aortic cross-clamping.

When EVAR was not deemed feasible, the balloon was kept inflated to avoid hemodynamic variations during anesthesia and the first steps of OSR until aortic control allowed proximal cross-clamping.

Clinical outcomes. The main outcome variable was restoration of hemodynamic stability defined by stable MBP >65 mm Hg associated with a reduction of ≥50% of vasopressive drugs mass flow. Secondary outcomes were intraoperative, 30-day, and in-hospital mortality rates, and morbidity directly related to EBO or CAC.

Statistical analysis. Nonparametric continuous variables are described using means and minimum and maximum values and were compared using a Mann-Whitney test. Categoric variables are described using numbers and percentages and were compared using χ^2 or Fisher exact tests. Continuous values are given as mean with the standard deviation or range. $P < .05$ was considered significant.

RESULTS

Over 13 years, 159 consecutive patients (mean age, 75 years; range, 49-96 years) presenting with an rAAA underwent operations in our institution. Initial hemodynamic instability was present in 72 patients, who were analyzed in this study. In early 2001, we only performed CAC, and our experience with EBO started in 2002. The Fig shows the evolution of our practice over time.

We performed CAC (group 1) in 40 of the 72 patients, using a thoracotomy in 23 and laparotomy in 17. Cross-clamping in these 17 patients was infrarenal in 12 and suprarenal in five. EBO (group 2) was performed in 32 patients, followed by OSR (n = 24) or EVAR (n = 8; one died before graft insertion). The proportion of complex AAAs (aneurysm without infrarenal neck or clamp site, with renal or visceral arteries involvement) was identical in both groups (15% in group 1 vs 12% in group 2; $P = 1$). The mean time for proper balloon placement was 9 minutes (range, 5-13 minutes) after arrival in the operating room. Unfortunately, the time taken to achieve aortic cross-clamping through an open approach was not recorded in most patients.

Regaining intraoperative hemodynamic stability, as defined by criteria detailed above, was achieved in only 57% of group 1 patients vs 85% of group 2 patients ($P =$ .014). Intraoperative mortality was 43% in group 1 and 19% in group 2 ($P =$ .031). Table I summarizes the intraoperative, 30-day, and in-hospital mortality rates of the 72 unstable patients. There was no significant difference in the total 30-day (75% vs 62%; $P =$ .25) and in-hospital (77% vs 69%; $P =$ .40) mortality rates between groups. An analysis of the patient subgroup that regained hemodynamic stability found no significant difference in 30-day (56% in group 1 vs 54% for group 2; $P =$ .85) and in-hospital mortality (61% vs 62%; $P =$ .96). Furthermore, we compared 30-day mortality between two periods—2001 and 2006 (only one EBO case) and between 2007 and 2013—and found no significant difference (67% vs 70%; $P =$ .81).

The rate of colonic ischemia and of acute renal failure was not significantly different between groups 1 and 2 (15% and 12% vs 28% and 9%, respectively). In group 2, seven patients had EVAR and 25 had OSR. Among them, colonic ischemia occurred in one in the rEVAR group and in eight in the OSR group (32%; $P =$ .64). Although not significant, there is a trend in favor of rEVAR to reduce colonic ischemia. In group 1, there was no significant difference between those with thoracic and abdominal cross-clamping in these secondary outcomes or in intraoperative mortality (43% vs 41%; $P =$ .894). In group 2, postoperative compartment syndrome developed in four patients that required decompressive laparotomy. These data are summarized in Table II.

In group 1, eight patients sustained an injury as a direct result of aortic cross-clamping: 1 vena cava injury, 3 left renal vein injuries, 1 left renal artery injury, 1 pancreaticoduodenal vein injury, and 2 splenectomies. All complications were immediately treated, and there was no negative effect on patient outcome. In group 2, there were no complications related to EBO ($P =$ .04). In particular, there were no cardiac complications related to balloon inflation, and the only death before treatment was related to a hypovolemic cardiac arrest that occurred despite all resuscitation maneuvers, including successful aortic occlusion.

Table I. Intraoperative, 30-day, and in-hospital mortality rates in unstable patients operated on for ruptured abdominal aortic aneurysms (rAAAs)

		Mortality		
Variable	*No.*	*Intraoperative, No. (%)*	*30-day, No. (%)*	*In-hospital, No. (%)*
CAC				
Overall	40			
Thoracotomy	23	10 (43)	17 (74)	17 (74)
Laparotomy	17	7 (41)	13 (76)	14 (82)
Stabilized	23	0	13 (56)	14 (61)
EBO				
Overall	32	6 (19)	20 (62)	22 (69)
Stabilized	26	0	14 (54)	16 (61)
Treatment				
OSR	65	20 (31)	47 (72)	50 (77)
EVAR	7	3 (43)	3 (43)	3 (43)
Total	72	23 (32)	50 (69)	53 (74)

CAC, Conventional aortic cross-clamping; *EBO,* endovascular balloon occlusion; *EVAR,* endovascular aortic repair; *OSR,* open surgical repair.

Table II. Mortality and complications of conventional aortic cross-clamping (*CAC*) vs endovascular balloon occlusion (*EBO*) in 72 unstable patients

Variable	*CAC (n = 40), No. (%)*	*EBO (n = 32), No. (%)*	P
Intraoperative mortality	17 (43)	6 (19)	.031
OSR (n = 65)	17 (43)	13 (41)	.57
EVAR (n = 7)	0	3 (–)	–
Complications			
Colonic ischemia	6 (15)	9 (28)	.17
Renal failure	5 (12)	3 (9)	.67
Compartment syndrome	0	4 (12)	–
30-day mortality	30 (75)	20 (62)	.25
In-hospital mortality	31 (77)	22 (69)	.40

DISCUSSION

The benefit of EBO over CAC has been suggested by several recent publications,[10,11] claimed by animal experimentation,[12] but never established by a comparative study. To our knowledge, this report is the first to compare both techniques. Patients in this series were not randomized to EBO or CAC treatment. Management was left to the surgeon's discretion. Moreover the strategy has evolved over time. The skill of the surgeons has certainly affected the choice of the treatment: less experienced vascular surgeons were initially more likely to use EBO as the primary procedure for hemodynamic stabilization compared with skilled physicians comfortable with CAC. These limitations may have affected our comparative outcome variables. However, given the intuitive superiority of EBO over CAC, obtaining an ethical approval for a randomized trial would have been impossible.

In the present analysis, we observed that EBO was feasible in rAAA patients. We have shown that EBO restored hemodynamic stability in 85% of patients. Of utmost importance, we have demonstrated that EBO, compared with CAC, significantly reduced intraoperative mortality of rAAA patients. Despite a trend of improved survival for patients treated with EBO and receiving EVAR, we failed to demonstrate that EBO affected 30-day and in-hospital mortality rates. The small size of the cohort could account for these conclusions, and probably, conclusions would have been different with a larger cohort. Unfortunately, we could not evaluate the effect of both the level and the type of aortic occlusion on the secondary outcome variables we have monitored.

In our series, we report a relatively high proportion (45%) of unstable patients admitted with rAAA. This may be due to the French national care system for two reasons:

1. In France, the diagnosis of rAAA is often made by secondary care hospitals with no on-site vascular units. Transfer to a specialized vascular unit accounts for delays in treatment.
2. France has not adopted a "scope and run policy" but rather a "stay and treat" policy, which is deleterious in some patients who require rescue surgery. Usually, the PHEMD (Pre-Hospital Emergency Medicine Department) uses an ambulance equipped for resuscitation at patient's home, with a medical team comprising an intensive care medicine physician and a specialized nurse. This medical team starts on-the-scene initial fluid resuscitation, inotropic, and respiratory support, attempting to improve hemodynamics before transfer to the tertiary care hospital. This management, which combines diagnosis and treatment, favors optimal triage strategy and may improve the outcome in situations such as acute coronary syndromes but may delay referral of surgical emergencies such as rAAA.

We performed the first EBO case in 2002. EBO was not always feasible due to lack of availability of an endovascular suite or permanent staff skilled in endovascular interventions, or both. Owing these factors, no EBO was performed between 2002 and 2007. But in 2007, our team designed a disposable "endoclamping kit," usable by all surgeons, resulting in an increase in EBO use and a reduction of primary CAC in unstable rAAA patients (Table I). Today, all vascular surgeons managing rAAA use first-line EBO in unstable patients because of its simplicity of placement and efficiency at restoring hemodynamic stability.[13]

Another major advantage of EBO over CAC relies on the fact that the balloon can be positioned under local anesthesia, thus sparing the patient's abdominal muscles tone. Induction of anesthesia required for CAC intensively reduces abdominal pressure, which is reputed to prevent blood loss. Moreover, the dramatic anesthetic agent-induced decrease in systemic vascular resistance worsens tissue perfusion, thus compromising already altered organ function. Of interest, general anesthesia can be more safely induced after hemodynamics have been restored by aortic occlusion performed under local anesthesia.[14,15] Moreover, EBO allows a rapid increase of cerebral and coronary perfusion, while decreasing hemorrhage and blood loss due to open repair.[6]

Nevertheless, our report presents several limitations. Its retrospective nature and the small size of our cohort are the most important. Furthermore, the learning curve of EBO and above all rEVAR may have affected on our results. The proportion of unstable rAAAs treated by EVAR is low (10%) compared with the number of EVARs performed on the entire series of rAAAs (34%). Young surgeons are not always comfortable with emergency EVAR, especially for unstable patients, which could explain why we report only seven rEVARs in our study.

Lastly, because these patients arrive in an extreme emergency context and are usually directly transferred to the operating room, recording of previous medical history and comorbidities is sometimes impossible. For this reason, it is possible that our two groups might not have been exactly identical in clinical characteristics and comorbidities.

Some authors have dismissed the use of EBO, stating that rapid placement of a stent graft is just as effective. This may be true in hemodynamically stable rAAAs, but even in highly specialized units, EVAR cannot challenge the 9-minute mean time it takes to perform EBO. EBO is particularly useful for less experienced surgeons who may not have the experience to make rapid intraoperative decisions. EBO is also advantageous in the patient with hostile anatomy who may not be suitable for an endovascular intervention. Furthermore, EBO allows "anesthetic catch up" and patient stabilization after balloon inflation before the definitive surgical procedure is performed.

If OSR is chosen after EBO, endovascular occlusion of the aorta has the potential benefits to enable careful dissection, avoids massive bleeding, and decreases the risk of damaging neighboring fragile anatomic structures. Because EBO allows EVAR of the rAAA, hemodynamic instability should no longer be a contraindication for EVAR. Only anatomic criteria should be taken into account. Even in the absence of a preoperative computed tomography scan,[10,13] an intraoperative angiogram can be achieved through the sheath used for EBO or by a contralateral pigtail.

Although a brachial[7] or axillary[6] approaches are feasible, we favored the femoral route for several reasons: (1) a left brachial approach interferes with the positioning of the C-arm, as a contralateral right side approach carries a risk of cerebral emboli[14]; (2) for both sides, the risk of peripheral emboli from the aortic arch or the descending aorta is higher than with the femoral approach[7]; (3) currently available EBO catheters require 10F to 14F introducer sheaths, which may damage the brachial artery or require an axillary cutdown. Among complications of EBO, ruptures of occlusion balloon have occasionally been reported,[7,16] but we did not experience such an event in our patients, probably because we use a dedicated inflator to monitor the inflation pressure.

Despite many technical advances, mortality for these patients remains high and not only linked to aortic repair modalities. The patient's medical history and clinical condition at arrival are crucial, with a direct effect on mortality. Although a recent randomized trial did not show a significant effect of the technique (EVAR vs OSR) on 30-day mortality[17] of rAAA, an increasing number of surgeons seem convinced that EVAR is more effective than OSR.[18] EBO, while restoring hemodynamic stability, increases the proportion of patients eligible for EVAR.

CONCLUSIONS

In this retrospective series, EBO of the aorta in unstable rAAAs compared with CAC may be associated with a marked reduction of intraoperative mortality and reduced collateral damage, such as surgical injuries, although it did not significantly influence in-hospital mortality. EBO, while restoring hemodynamic variables, could facilitate EVAR in unstable rAAA but does not preclude OSR. Further studies with larger cohorts are mandatory to evaluate benefits of EBO over CAC.

AUTHOR CONTRIBUTIONS

Conception and design: MR, JM, JB, PD
Analysis and interpretation: MR, JM, JB, PD
Data collection: MR, JM
Writing the article: MR, JM, PD
Critical revision of the article: MR, JM, HK, FC, JB, PD
Final approval of the article: MR, JM, HK, GD, EA, FC, JB, PD
Statistical analysis: MR, JM
Obtained funding: Not applicable
Overall responsibility: PD

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