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# **ORIGINAL ARTICLE**

# Management of Pelvic Arterial Bleeding by Aortic Balloon Occlusion

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# Abstract

*Background*: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) has become a viable method for hemorrhagic shock patients to reduce bleeding. It was suggested that the balloon may be used as an option to stop pelvic bleeding when it is deployed in Zone 3. Numerous organizations and societies have advocated REBOA as a guideline for the immediate care of pelvic bleeding after severe trauma.

Aim and objectives: To evaluate balloon occlusion's viability, suitability, safety, and consequences in the treatment of patients with pelvic arterial bleeding.

Patients and methods: A prospective, randomized research including 50 individuals who had pelvic arterial hemorrhage was done. It took place in the Al-Azhar University Hospital's Vascular Surgery Department.

*Results*: Age range from 14 to 80 years. Most patients were in third and fourth decades of life. Only one patient was in the eighth decade. The procedure showed 86 % success in controlling the pelvic bleeding by balloon occlusion of the aorta. Balloon control was successful in 43 (86 %) patients. Access site complications: groin hematoma/bleeding, significant vasospasm, intimal damage or dissection, pseudo-aneurysm formation, arteriovenous fistula, and arterial embolization. Systemic complications: renal failure and allergic/anaphylactic responses.

*Conclusion*: We conclude that Pelvic arterial hemorrhage may be effectively controlled by aortic balloon occlusion. It makes the patient more stable and gives the surgeons more time, more stability, and more easy exploration. With aortic balloon occlusion; there is less blood loss and more safety but we should avoid acute kidney injury and access site complications.

Keywords: Balloon occlusion, Complications, Extra-peritoneal packing, Pelvic arterial bleeding

# 1. Introduction

**O** ne of the most difficult problems for surgeons to solve is the treatment of pelvic arterial bleeding. After an acute post-traumatic pelvic hemorrhage, the death rate is still significant in individuals who are hemodynamically unstable. Due to fast exsanguination, the death rate may exceed 40 %.<sup>1</sup>

The ideal course of therapy for pelvic trauma has been a multimodal one. When necessary, this entails early mechanical stabilization using a pelvic binder, followed by surgical management using Extra-Peritoneal Packing (EPP) and endovascular procedures like Angio-Embolization procedures (AE) or Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), both of which are placed in zone III. Depending on the stability and force direction of pelvic fractures, every sort of urgent care must be taken into account.<sup>2</sup>

German researchers initially discussed EPP in 1994. Extraperitoneal pelvic is a life-saving surgery that lowers mortality as compared with patients maintained with alternative damage control methods, according to more current research. Since venous bleeding accounts for roughly 75–80 % of pelvic hemorrhage, controlling significant venous

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bleeding with direct compression is one of the core ideas of EPP.<sup>3</sup>

REBOA has just come to light as a viable method for hemorrhagic shock patients to stop bleeding. It was suggested that the balloon may be used as an option to stop pelvic bleeding when it is deployed in Zone  $3.^4$ 

When REBOA is employed in Zone 3 as compared with Zone 1 for an efficient management of pelvic artery flow, certain studies have shown a survival advantage.<sup>5</sup>

The balloon is not widely accessible and is linked with serious side effects such ischemia-reperfusion syndrome, acute renal damage, amputation, and a rise in mortality which are disadvantages of REBOA.<sup>6</sup>

This study's objective was to evaluate the viability, sufficiency, safety, and side effects of using balloon occlusion to treat patients with pelvic artery bleeding.

## 2. Patients and methods

A 50 individuals with Pelvic Arterial Bleeding participated in this prospective, randomized research. It took place in the Al-Azhar University Hospitals' Vascular Surgery Department.

All patients met the aforementioned inclusion requirements. The consent of the ethical committee was received from each patient.

Inclusion criteria: patients with ages between 14 and 80 years, Pelvic bleeding due to arterial injury and Patients' relatives giving consent for the intervention. Pelvic bleeding is considerable and confirmed by CT abdomen and pelvis and not for all cases of pelvic arterial bleeding.

Exclusion criteria: Pelvic bleeding due to venous injury, patients' relatives refusing the intervention, failure or refusal to adhere to the follow-up schedule, and patients with creatinine greater than 1.7 mg/dl. And patient with occluded access artery or occluded iliac arteries.

Careful history taken, complete clinical examination (General examination and Local examination) and investigations (Laboratory investigations, Radiological investigations and Angiographic investigations) were performed in all patients.

# 3. Methods

#### 3.1. Preprocedural assessment

After taking written consent from all (50) patients' relatives on intervention procedure not the approach, they were subjected to the following:

history and examination, assessment of patient hemodynamics, complete blood picture, blood grouping, and coagulation profile, resuscitative fluids (in hemodynamic unstable patients). To evaluate blood leakage from the pelvic artery system and define the lesion, duplex scanning, and CTA were performed.

Equipment: duplex ultrasound, C-arm (angiographic apparatus) and materials (Micropuncture needle, Hydrophilic coated Terumo guidewire, 0.035 French 'J tipped' of 180 cm, 8 French caliber sheaths and their dilators, 4 or 5 French straight or vertebral multipurpose catheter, aortic balloon catheters, inflation device, and drugs such as xylocaine 2 %, nonionic contrast material, heparin, papaverine HCl, and nitroglycerine).

Technique: Before needle access, we employed duplex ultrasonography to determine where the contra-lateral common femoral artery (CFA) bifurcation was in reference to the superior edge of the femoral head. According to US recommendations, a 21 G micropuncture needle has been used to reach a 'high' CFA puncture site. We frequently introduced the CFA at the level of the uppermost limit of the femoral head on sonography (most often with a  $60^{\circ}$  entry angle), It has been selectively implanted using a 0.035-inch microwire into the CFA. 8Fr sheath insertion comes next. The 8Fr sheath in CFA has been punctured with a guidewire measuring 0.035, Then, the catheter has been introduced into the sheath which located in CFA, The wire has been removed leaving the catheter inside the artery, Fluoroscopy with 'road-map' has been done and On successful entry into the CFA, retrograde intervention has been performed by balloon insertion and occlusion of the infra-renal abdominal aorta.

Follow-up and assessments: this study evaluated the results of aortic balloon occlusion in management of pelvic arterial bleeding. Patients had been followed-up immediately post-operatively then daily for a week after the procedure. Patients had been followed-up by clinical examination, Doppler, duplex scan, and CT angiography in selected cases. The results obtained had statistically evaluated and the main parameters, which had been analyzed, are patient hemodynamics, complications, and mortality.

Complications were classified into two categories: access site complications: Groin hematoma/ bleeding, significant vasospasm, intimal damage or dissection, pseudo-aneurysm formation, arteriovenous fistula, and arterial embolization and Systemic complications: renal failure and allergic/anaphylactic responses. Postoperatively: dual antiplatelet therapy (81 mg aspirin plus 75 mg clopidogrel) administered daily for 1 month. Then continued with a single antiplatelet (81 mg aspirin) daily for 1 year after that.

# 4. Results

#### Table 1.

Age range from 14 to 80 years. Most patients were in third and fourth decades of life. Only one patient was in the eighth decade Fig. 1, Table 2.

All 50 patients were subjected to aortic balloon occlusion. The procedure showed 86 % success in controlling of pelvic bleeding by balloon occlusion of the aorta. It saved time and blood loss which lowered the patient risk and surgeon stress Table 3.

Table 1. Age of the patients at the onset of the complaint.

Ag (years)	Number (Percentage)
14-20	0
21-30	17 (34 %)
31-40	15 (30 %)
41-50	10 (20 %)
51-60	4 (8 %)
61-70	3 (6 %)
71-80	1 (2 %)

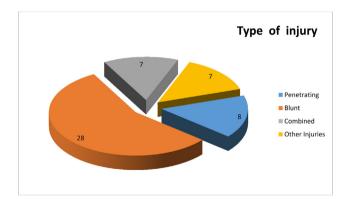


Fig. 1. Type of injury.

Table 2. Duration and success.

Type of injury	Duration (min)	Success (N)	Percentage
Penetrating		6	75 %
Blunt		25	89.28 %
Combined	$25.5 \pm 10.4$ (15-35)	5	71.43 %
Other Injuries		7	100 %
Total		43	86 %

Table 3. Postoperative follow-up.

Days	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Patient hemodynamics							
Stable	23	27	30	37	37	39	39
Unstable	20	14	11	4	3	0	0
Mortality	7	2	0	0	1	1	0

Technical success: Balloon control was successful in 43 (86 %) patients.

The hospital stay was evaluated in 50 patients who either passed smooth postoperatively or associated with complications. Patients had been followed-up immediately postoperatively then daily for a week after the procedure. Patients had been followed-up by: clinical examination, Doppler, duplex scan and CT angiography in selected cases Table 4.

Access site complications: Groin hematoma/ bleeding, significant vasospasm, intimal damage or dissection, pseudo-aneurysm formation, arteriovenous fistula, and arterial embolization and Systemic complications: renal failure and allergic/anaphylactic responses.

During the procedure, 5000 IU of heparin were given to each of the patients listed above.

During and during the procedure, there were a few minor problems. None of these issues result in significant morbidity. Ecchymosis and serroma development may also coexist with other mild problems in the same patient.

Major complications occurred in 3 (6 %) patients of 50 patients. However, postoperative bleeding occurred in one of them in which a large hematoma in the groin was developed, another patient developed infection at the fourth postoperative day and the third developed acute renal failure Figs. 2 and 3.

Tabl	e 4.	The	incide	ence oj	f posi	toperative	comp	lications.
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Complications	PTA	
Minor complications:		
Ecchymosis	3	
Seroma formation	1	020
Mild allergic reactions	2	
Major complications:		
Postoperative bleeding	1	
Acute arterial thrombosis	0	
Infection	1	11000000000
Pseudo-aneurysm	0	
formation		
Arterial dissection	0	
Distal embolization	0	
Perforation of the artery	0	
Retro-peritoneal hematoma	0	
Acute renal failure	1	
Anaphylaxis	0	

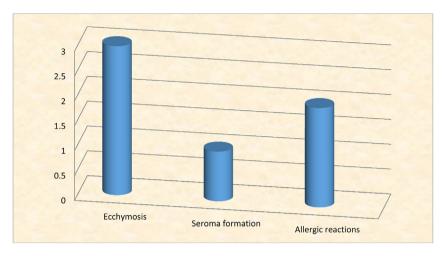


Fig. 2. Minor postoperative complications.

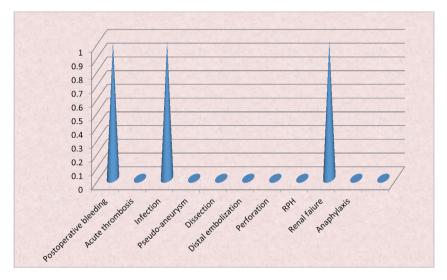


Fig. 3. Major postoperative complications.

# 5. Discussion

A potential method for hemostasis in individuals with severe trauma injuries is REBOA. It has been shown that balloon occlusion of the aorta may be an effective hemostatic strategy that boosts blood pressure, promotes survival, and enhances brain oxygenation and carotid artery blood flow.<sup>7</sup>

This discovery was followed by Brenner et al.<sup>8</sup> This included the insertion of REBOA in 6 trauma victims. They came to the conclusion that REBOA is practical and successful in stopping bleeding in patients with end-stage shock. Following these conclusions, prospective observational research by DuBose et al.<sup>9</sup> 114 individuals were examined, 46 of whom had REBOA implantation. They came to the conclusion that at centers with the capacity to undertake REBOA placement, REBOA has become a feasible solution to open aortic occlusion.

In trauma patients, we discovered that REBOA installation was linked to greater mortality and worse outcomes. Our findings conflict with two American prospective observational studies that were previously published.<sup>10</sup>

Numerous limitations in those 2 studies may be used to account for these disparities. First off, the criteria for resuscitative thoracotomy are different from those for REBOA, although each of those trials compared REBOA with open aortic occlusion or resuscitative thoracotomy. Patients who are having cardiac arrest are given a thoracotomy in the emergency room, while trauma patients who are hypotensive and have a pelvic fracture or abdominal fluid seen on an initial ultrasonographic scan in the trauma bay are given a REBOA. Additionally, those trials lacked a real control group of patients (those who did not get a resuscitative thoracotomy or REBOA implantation). In order to compare patients who received REBOA with similarly damaged trauma patients who did not get REBOA, we had to exclude patients who had thoracotomies in the ED. Second, the patient cohorts in both trials were small (DuBose et al.<sup>9</sup>; 46 patients; and Brenner et al.<sup>11</sup>; 83 patients), This can be a small sample size with insufficient power to determine if REBOA is useful. The biggest patient cohort for REBOA in the United States, to our knowledge, was comprised of 140 patients in the REBOA group paired with 280 patients in the no-REBOA group. Third, the investigations by Brenner et al.<sup>11</sup> and DuBose et al.<sup>9</sup> found substantial variations in damage patterns and vital signs between the two patient groups.

The patient cohorts in our analysis were matched according to patient demographics, prehospital vital signs, emergency department vitals, overall injury severity, the degree of injury in each body region, mechanism of injury, solid organ injuries, vascular injuries, pelvic fractures, and lower extremity fractures to get around this limitation. The outcomes of our investigation are in agreement with those of a prior study by Norii et al.<sup>12</sup> who examined the safety and effectiveness of REBOA in patients with severe trauma from the Japanese National Trauma Registry, and after adjusting for the chance of REBOA therapy, observed an increased mortality rate in the REBOA group. The research by Norii et al.<sup>12</sup> had certain restrictions. They lacked information on blood product transfusions or the vital signs at the presentation. These data points were included in our analysis, and there was no distinction in these characteristics between the 2 patient groups. Acute renal damage and lower limb amputation are two consequences of REBOA deployment that Norii et al.<sup>12</sup> did not examine.

A longer time to AE or laparotomy for the patients in the REBOA group in our research may be linked to a greater death rate. The delay in establishing final surgical control enhances mortality by 0.35 % each minute, according to well-established research in trauma literature.<sup>13</sup>

Once the patient makes it out of the ED period, the length of the aortic blockage is crucial. Organs far from the site of occlusion may suffer ischemia damage as a result of decreased blood flow from a prolonged aortic occlusion. Furthermore, aortic dissection or rupture as well as thrombus embolization may result from mechanical injury to the aorta. According to our data, patients who had REBOA implantation had greater risks of acute renal damage and lower limb amputation. Similar to what we found, Brenner et al.<sup>11</sup> found that patients who received REBOA experienced distal embolism and the necessity for an amputation.

In addition, Wasicek et al.<sup>14</sup> investigated lowerlimb issues in 31 patients and discovered that a longer duration of aortic occlusion at zone I is associated with a greater incidence of calf and thigh fasciotomies. Of the 20 patients who got REBOA at zone I, 15 % established lower extremity compartment syndrome.<sup>14</sup>

In either group of seriously wounded trauma patients, our research found no change in the need for blood products 4 h or 24 h after injury. The REBOA group's average PRBC and plasma needs over the first 24 h are comparable with those described in previously published research.<sup>10</sup>

The American College of Emergency Physicians and the ACS Committee on Trauma have released clinical recommendations for the safe utilization of REBOA.<sup>11</sup>

Two studies from 11 American facilities have already been published by the American Association for the Surgery of Trauma, Aortic Occlusion in Resuscitation for Trauma, and Acute Care Surgery (AORTA) group. However, they lack a proper control group and a standardized technique for REBOA installation. The majority of REBOA placements are made at the trauma surgeon's discretion rather than in line with a predetermined procedure. 149 level 1 trauma hospitals now have access to a REBOA device; however, each facility has a different approach based on funding and other reasons.<sup>15</sup>

#### 5.1. Conclusion

We conclude that Aortic balloon occlusion is efficient in controlling pelvic arterial bleeding. It makes the patient more stable and gives the surgeons more time, more stability and more easy exploration. With aortic balloon occlusion; there is less blood loss and more safety but we should avoid acute kidney injury and access site complications.

#### Disclosure

The authors have no financial interest to declare in relation to the content of this article.

## Authorship

All authors have a substantial contribution to the article.

# **Conflicts of interest**

The authors declared that there were NO conflicts of Interest.

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