



Bilateral internal iliac artery embolization for pelvic trauma: Effectiveness and safety

Alexander Bonde^{a, b}, Andriana Velmahos^a, Sanjeeva P. Kalva^c, April E. Mendoza^a, Haytham M.A. Kaafarani^a, Charlie J. Nederpelt^{a, 1, *}

^a Division of Trauma, Emergency Surgery and Surgical Critical Care, Massachusetts General Hospital, Harvard Medical School, Boston, United States

^b Department of Anesthesia, Center of Head and Orthopedics, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark

^c Division of Interventional Radiology, Massachusetts General Hospital, Harvard Medical School, Boston, United States



ARTICLE INFO

Article history:

Received 12 September 2019

Received in revised form

1 December 2019

Accepted 9 December 2019

Keywords:

Pelvic trauma: angio-embolization

Damage control

ABSTRACT

Introduction: Bilateral internal iliac artery embolization (BIIAE) with temporary embolic materials epitomizes damage-control principles in the treatment of exsanguinating hemorrhage from pelvic trauma. However, instances of ischemic complications have been reported. The aim of our study was to assess safety and effectiveness of BIIAE.

Methods: All patients who received BIIAE for pelvic trauma at a Level I Trauma Center between 1998 and 2018 were reviewed. Effectiveness was assessed by radiographic bleeding control and clinical bleeding control, i.e. stabilization of vital signs and reduction in blood transfusion. Safety was assessed by any evidence for ischemic damage of pelvic organs or tissues.

Results: Of 61 patients undergoing BIIAE, bleeding control was confirmed radiographically in 60 (98%) and clinically in 55 (90%), including 4 (7%) patients who required repeat embolization. Six (10%) patients died due to insufficient pelvic bleeding control. No BIIAE-related complications were identified.

Conclusion: The overall clinical effectiveness and safety rates of BIIAE for pelvic bleeding control, when combined with other methods of hemostasis, were 90% and 100% respectively.

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Introduction

Major pelvic fractures have been reported in 4–9% of blunt trauma patients and is commonly associated with shock and with mortality rates as high as 46%, predominantly owing to retroperitoneal hemorrhage.^{1–8} The EAST guidelines suggest pelvic binding, external fixation, preperitoneal pelvic packing, intraoperative vascular control, and angiographic embolization as effective methods to control pelvic bleeding.⁹ The sequence, timing, effectiveness, and safety of each method are hard to assess. Angiographic embolization offers a method of direct bleeding control, which is hard to achieve by the other methods. However, sub-selective cannulation of the numerous bleeding pelvic vessels is technically challenging and time consuming.^{10,11} Exsanguination in

critically injured patients calls for damage control methods that can achieve rapid control of bleeding, even if the effect is not definitive or completely risk-free.

Bilateral internal iliac artery embolization (BIIAE) with temporary embolic materials has been proposed as a favorable technique to control pelvic exsanguination.¹² However, widespread adoption of the technique has not occurred, as BIIAE was not reported in a recent American Association for the Surgery of Trauma multicenter study, despite positive level III recommendations in the 2011 management guidelines for managing hemorrhagic pelvic trauma.^{1,9} Selective catheterization of internal iliac arteries is relatively easy and can be achieved quickly. In theory, embolizing both the anterior and posterior divisions of internal iliac arteries with thrombogenic particles reduces the arterial pressure in the pelvic circulation, allowing hemostasis, while collateral blood supply ensures the viability of pelvic organs and tissues. Subsequent recanalization of the vessels will restore normal blood flow to the tissues. However, ischemic complications of pelvic organs following embolization have been reported despite the use of temporary embolic materials.⁴

* Corresponding author. Division of Trauma, Emergency Surgery and Surgical Critical Care, Suite 810, 165 Cambridge Street, Boston, MA, 02114.

E-mail address: c.j.nederpelt@lumc.nl (C.J. Nederpelt).

¹ Permanent address: Afdeling Heelkunde, Leids Universitair Medisch Centrum, Albinusdreef 2, 2333 ZA Leiden, The Netherlands. c.j.nederpelt@lumc.nl

The aim of this study is to assess the safety and effectiveness of BIIAE in patients with major pelvic trauma and life-threatening hemorrhage in the largest cohort to date. Our hypothesis is that BIIAE is associated with high rates of clinical bleeding control, and acceptably low ischemic complication rates.

Methods

All adult trauma patients admitted to our Level 1 Trauma Center between January 1, 1998 and December 31, 2018, who received BIIAE following pelvic fractures, were identified retrospectively. Three databases were interrogated to identify eligible patients: our hospital-wide patient research registry, the Trauma Center's trauma registry, and the interventional radiology database. Patients who received angiography without embolization or embolization of only one internal iliac artery were excluded. Our indications to use BIIAE included pelvic fractures with significant bleeding and labile hemodynamics. Typically, the bleeding was confirmed by the presence of a large pelvic hematoma on CT, often with active extravasation of intravenous contrast. Our protocol for the majority of patients with major pelvic fractures and evidence of significant bleeding is to stabilize the pelvis with a binder and then make a decision between preperitoneal pelvic packing versus angiographic embolization. Patients who are hemodynamically unstable and in need of emergent bleeding control are taken to the OR for preperitoneal pelvic packing. Nearly all of these patients receive angiographic embolization after packing. Those patients who are deemed to respond to resuscitative efforts and can tolerate a short period of time until bleeding control, are offered angiographic embolization first. For all these patients, those who receive packing first and those who receive embolization first, the principal method of angiographic bleeding control is BIIAE with temporary embolizing agents. When appropriate, we place patients with complex pelvic fractures in one of our hybrid Operating Rooms. These rooms are equipped to accommodate any type of open or minimally invasive surgery and radiologic intervention. In this way, we do not transfer critical patients to different areas of care (from the OR to the IR suite and vice versa) but rather offer all operations and interventional radiology procedures in the same room. Absorbable gelatin slurry (Gelfoam [Upjohn, Kalamazoo, MO]) was used for BIIAE in all patients; additionally, coils were used in specific vessels of selected patients. All angiograms and angioembolizations were performed by interventional radiologists.

Our primary outcomes were effectiveness and safety of BIIAE. Effectiveness of BIIAE was assessed by a combination of radiographic and clinical bleeding control criteria. Radiographic bleeding control was defined as the complete cessation of intravenous contrast material extravasation on post-embolization angiography (Fig. 1). Clinical bleeding control was defined as the stabilization of vital signs, at least 50% reduction or cessation of blood product requirements (as is available through the institutional blood bank data), and absence of signs of continuous bleeding (e.g. continued hemodynamic instability noted by attending physician, high volume blood transfusion and multiple vasopressor support, unplanned return to the operating room for bleeding control). Safety was assessed by the presence of any clinical, laboratory, or imaging findings consistent with significant ischemia of pelvic organs and soft tissues, including muscles and skin. Because retrospective judgments were required to establish the above criteria, all cases were reviewed independently by two of the authors. An experienced trauma surgery attending was invited as third reviewer in the presence of disagreement, and potential complications or failure of BIIAE. All notes, imaging and laboratory results during the admission and subsequent encounters were examined for the presence of hematuria in the absence of urogenital injury, blood per

rectum in the absence of colorectal injury, gluteal and perineal muscle or skin necrosis, creatine phosphokinase elevations after embolization, rectal mucosal sloughing on colonoscopy, imaging of ischemic pelvic organs, etc. An exhaustive search of the records was performed to that effect and, recognizing the need for retrospective judgments in these complex patients, we maintained the same concept of two independent reviews and a third one in cases of disagreement.

All continuous variables were expressed as median values with interquartile ranges and/or mean values with standard deviations, depending on the distribution of the data. Categorical variables were expressed as direct values and incidences. The study received approval by our Institutional Review Board.

Results

Out of 9656 patients admitted for a pelvic fracture, 61 patients (0.63%) received BIIAE during the study period. Baseline demographics and emergency department (ED) information is presented in Table 1. They were predominantly men (65%), with a median age of 50 years (33–67), and a median Injury Severity Score of 27 (21–34). Twenty-one (34%) patients were pedestrians or bicyclists struck by motor vehicle, 21 (34%) patients were involved in a MVC, the remaining 19 (31%) patients suffered a fall from a height. Isolated pelvic injuries were found in 15 (25%) patients. Laparotomy was performed in 37 (61%) patients, in 33 patients before BIIAE and in 4 after BIIAE. In 19 (51%) it was therapeutic, as significant intraperitoneal injuries were addressed, mostly splenic or liver lacerations. Preperitoneal packing was performed in 31 patients before BIIAE and in 3 after BIIAE, a total of 34 (56%) patients. External pelvic fixation was performed in 19 patients before BIIAE and 6 after BIIAE, a total of 25 (41%) patients. One patient (2%) underwent zone 3 REBOA before BIIAE, and none after. Overall, 100% of the patients had at least one additional intervention besides BIIAE and 25 (41%) patients had all four, exploratory laparotomy, preperitoneal pelvic packing, external fixation, and angiographic embolization.

Active evidence of bleeding, either on computed tomography or operation was noted on all patients. However, active extravasation was detected during angiography in 34 patients (56%) with 17 (28%) showing bilateral bleeding sources; the remaining 27 (44%) patients had only indirect signs of angiographic bleeding, including pseudoaneurysms, abrupt cutoff of vessels, intimal irregularities, arteriovenous fistulas, and vascular spasm. A total of 26 patients (43%) had other significant bleeding site in addition to the identified pelvic bleeding.

BIIAE was performed in a hybrid Operating Room in 26 patients (43%) and in the angiography suite in the remaining 35 (57%). The median time to embolization was 156 min [IQR 102–311] with a longer time (250 min [145–476]) in those who received it in the angiography suite compared to those who received it in the hybrid setting (126 min [98–182]). Six patients (10%) underwent subselective coil embolization following injection of gelatin slurry. The following vessels were coiled: unilateral internal iliac artery ($n = 3$), inferior/superior gluteal artery ($n = 2$), and inferior epigastric artery ($n = 1$).

Results are presented in Table 2. Initially, BIIAE achieved radiographic bleeding control in 60 patients (98%), and clinical bleeding control in 51 (84%). Subsequently, 4 (7%) patients who showed signs of ongoing pelvic bleeding received a repeat embolization which successfully controlled the bleeding. Of the remaining 6 patients, who continued to bleed, 4 expired shortly after embolization without an opportunity to consider additional interventions, 1 patient acutely compensated on the 3rd day, and 1 patient expired on the 5th day due to ongoing coagulopathy, and. Thus, the clinical

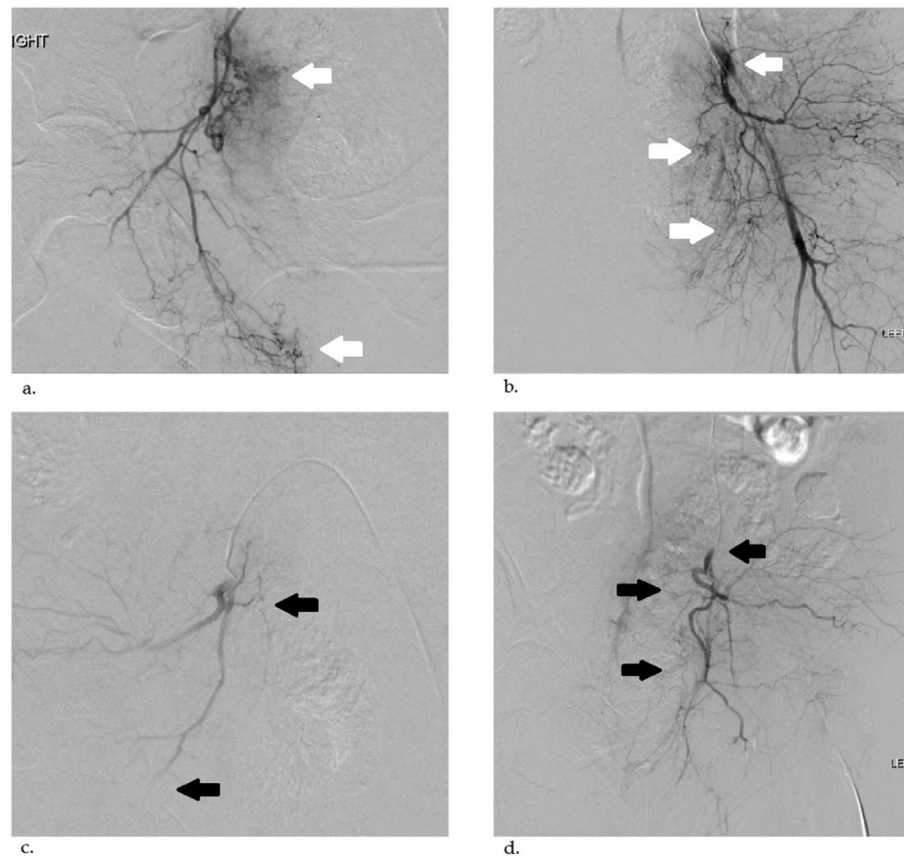


Fig. 1. Successful bilateral internal iliac artery embolization. 1a. Right internal iliac artery angiogram. 1 b. Left internal iliac artery angiogram. 1c. Right Gelfoam embolization. 1 d. Left Gelfoam embolization. White arrows indicate active bleeding sites. Black arrows indicate post-embolization occluded vessels.

Table 1
Demographics, emergency department presentation and treatment choices.

| Variable | BIIAE (n = 61) |
|---|----------------|
| Age (Mean (SD)) | 52 (22) |
| Sex | 40/61 (66%) |
| Charlson Comorbidity (Median [IQR]) | 1 [0–3] |
| ISS (Median [IQR]) | 27 [21–34] |
| SBP (Median [IQR]) | 124 [94–144] |
| HR (Median [IQR]) | 108 [85–128] |
| GCS (Median [IQR]) | 14 [3–15] |
| Mechanism of Injury | |
| Fall | 19/61 (31%) |
| Pedestrian/cyclist struck | 21/61 (34%) |
| MVC | 21/61 (34%) |
| Concomitant TBI | 17/61 (28%) |
| Concomitant Extracranial Hemorrhage | 26/61 (43%) |
| Intrathoracic | 19/61 (31%) |
| Intra-abdominal | 6/61 (10%) |
| External (e.g. thigh, vaginal) | 10/61 (16%) |
| Minutes in the ED (Median [IQR]) | 70 [39–91] |
| Minutes to BIIAE (Median [IQR]) | 160 [106–312] |
| Hybrid OR | 26/61 (43%) |
| Pre-BIIAE CT-Scan | 51/61 (84%) |
| Positive for Pelvic Hematoma | 45/61 (74%) |
| Exploratory Laparotomy with Packing | 34/61 (56%) |
| Positive for Pelvic Hematoma | 28/61 (46%) |
| Pre-BIIAE Pelvic Fixation | 29/61 (48%) |
| External Fixation | 18/61 (30%) |
| ORIF | 11/61 (18%) |
| Angiography | 61/61 (100%) |
| No Contrast Extravasation ('Empirical') | 26/61 (43%) |
| Unilateral Contrast Extravasation | 18/61 (30%) |
| Bilateral Contrast Extravasation | 17/61 (28%) |

bleeding control rate after initial BIIAE was 84% (51 of 61 patients) and 90% (55 of 61 patients) after repeat embolization.

No complications were detected in relationship to BIIAE. There were no instances of pelvic organ ischemia or pelvic/gluteal/perineal soft tissue necrosis. One patient reported urine and fecal incontinence 5 weeks after the injury; he had a devastating pelvic fracture with direct injury to the bladder, rectum, and perineal floor muscles. The electromyography showed significant nerve damage attributable to the direct injury.

A total of 18 patients (30%) died. Besides the 6 patients who died of uncontrolled pelvic bleeding, 2 more patients died of other

Table 2
Bleeding control and complications.

| Variable | BIIAE (n = 61) |
|--|----------------|
| Angiographic Bleeding Control | 60/61 (98%) |
| Initial Clinical Bleeding Control | 51/61 (84%) |
| Insufficient Bleeding Control | 10/61 (16%) |
| Re-embolization | 4/61 (7%) |
| Uncontrolled Pelvic Bleeding | 6/61 (10%) |
| Ultimate Clinical Bleeding Control | 55/61 (90%) |
| Total In-Hospital Mortality | 18/61 (30%) |
| Uncontrolled Pelvic Bleeding | 6/61 (10%) |
| Non-Pelvic Bleeding (Liver, Lumbar Vessel) | 2/61 (3%) |
| Devastating Head Injuries | 6/61 (10%) |
| Pulmonary Embolism | 2/61 (3%) |
| Sepsis/Fungaemia | 2/61 (3%) |
| Complications | 1/61 (2%) |
| Urine Incontinence | 1/61 (2%) |

bleeding (liver and lumbar vessels respectively), 6 due to devastating head injuries, 2 due to pulmonary embolism, and 2 due to sepsis. The median hospital stay of all patients was 12 days (6–28); for survivors it was 15 days (9–32) and for non-survivors 3 days.^{1–7}

Discussion

In this study, BIIAE has shown a 90% effectiveness and 100% safety to control bleeding from pelvic injuries. Patients with life-threatening trauma require damage control procedures. BIIAE follows all the principles of damage control: it is rapid, temporary, and highly effective. In contrast to regular angiographic embolization, which typically requires time and skill to define the exact anatomy, cannulate specific branches, and ensure blood flow cessation proximal and distal to a bleeding point, BIIAE calls for proximal cannulation of the internal iliac arteries and non-selective embolization of all pelvic arterial branches by use of temporarily-occluding, thrombosis-inducing, embolic materials.

Our results are in line with previously published studies. BIIAE, as an embolization technique, was first reported in 1987.¹⁰ The early outcomes in cohort studies were very encouraging with 97% effectiveness and 100% safety in a sample size of 30 patients, and 100% technical success in a sample size of 56 patients.^{11,12} Almost contemporaneously came the concern. In isolated case reports or small case series, complications were attributed to the acute ischemia of pelvic tissues.^{13–17} In most of these patients, BIIAE may have been implicated as the causative factor of tissue ischemia but in reality its effect could not be separated from the impact of the original injury and the multiple operations, which affected tissue viability. In a recent cohort study, gluteal necrosis was seen in 0/70 patients after BIIAE with gelatin sponge over 10-year period.¹⁸

In our study, all BIIAE were performed by using absorbable gelatin slurry. The temporary nature of absorbable gelatin allows for recanalization of the occluded vessels after several days or weeks, with evidence from tumor embolization, which also makes it especially suitable for trauma.^{19–21} In patients with post-traumatic coagulopathy, the occlusion period may be much shorter, in the order of hours, thus offering an acute drop in pelvic circulation pressures, allowing thrombosis of bleeding vessels, and returning blood flow to critical structures through recanalization shortly thereafter.²² In our study we did not identify a single ischemic complication that could be directly attributed to BIIAE. No gluteal necrosis or compartment syndrome, perineal skin necrosis, or critical pelvic organ ischemia was detected. Only 1 patient reported fecal and urinary incontinence but, as mentioned above, the nature of the injury could very well explain the complication.

On the other hand, the temporary effect of absorbable gelatin may be the reason for ineffective bleeding control in certain patients, particularly in the presence of severe trauma-induced coagulopathy. In accordance with previous studies, reporting the need for repeat embolization in 7%–11% of the patient,^{2,12} 4 (7%) of our patients required repeat embolization, resulting in effective bleeding control.

It is interesting that active extravasation on angiography was found only in 56% of our patients. One could argue that embolization is unnecessary under these circumstances, but opinions differ.^{23–26} Absence of contrast extravasation may relate to transient vasospasm, inadequate blood flow due to hypotension, temporary clotting, or suboptimal timing of contrast injection. We tend to believe that most patients who are hemodynamically labile and have had evidence of major pelvic bleeding on computed tomography or operation should be embolized regardless of angiographic evidence of contrast extravasation.

Limited by its retrospective design our study has several shortcomings. First, the assessment of clinical bleeding control was

challenging. Our patients were critically injured on multiple sites. It was rarely the case that full hemodynamic instability converted into full hemodynamic stability immediately upon completion of embolization. Patients improved gradually and a precise turning point was hard to detect. Second, the exact contribution of BIIAE to hemodynamic stability was unclear, when other bleeding-control interventions were performed around the same time. Pelvic bleeding control requires a multidisciplinary approach. It is unlikely that the effect of any single intervention will be isolated and measured independently of the others. In this population, all patients underwent at least one additional bleeding control intervention. Third, similarly to the previous argument, the contribution of embolization to complications cannot be easily isolated from the effect of the injury itself or the simultaneous interventions. Fourth, the optimal timing of BIIAE has not been determined. Exploratory laparotomy, external fixation, preperitoneal pelvic packing, and a multitude of other interventions may precede or follow BIIAE. It is ill-advised to protocolize the sequence of these interventions, as it may change according to patient clinical needs and institutional resources. Last, whereas we initially intended to compare patients with and without successful embolization in order to determine the risk factors of failure of BIIAE, we realized that such a comparison would be statistically meaningless due to the low number of failures.

Conclusions

The overall clinical effectiveness and safety rates of BIIAE for pelvic bleeding control, when combined with other methods of hemostasis, were 90% and 100% respectively. It should be considered early in the treatment of such patients, if institutional resources allow it.

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