

Research Article

Placement of a Mobile Fluoroscopic System in an Obstetric Operating Room: A Pilot Study

Daniel Raskin^{1*}, Shmuel Balan¹, Boris Khaitovich¹, Gil Golan¹, Alexei Cherniavsky¹, Oshry Mozes¹, Eyal Sivan², and Uri Rimon¹

¹Department of Diagnostic and Interventional Imaging, Tel-Aviv University, Israel

²Department of Obstetrics and Gynecology, Tel-Aviv University, Israel

***Corresponding authors**

Daniel Raskin, Diagnostic and Interventional Imaging Department, Sheba Medical Center, Tel-Hashomer 52621, Israel, Tel: 97235302530; Fax: 97235357315; Email: Daniel.Raskin@sheba.health.gov.il

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Abstract

Objective: This pilot was performed to evaluate the benefits of placement of a mobile angiographic C-arm system in an Obstetric operating room to be used for embolization in both preventive and emergency occasions.

Study Design: A retrospective evaluation using mobile C-arm fluoroscopy in the obstetric operating room for transarterial embolization to prevent hysterectomy.

Results: During a period of 3 years, 10 patients with peripartum hemorrhage were treated with transarterial embolization by Interventional Radiologists in the Obstetric operating room. In two patients hysterectomy was performed due to continuous bleeding post embolization. In eight patients the uterus was preserved.

Conclusion: Integration of a mobile C-arm digital angiographic system into Obstetric operating room has produced opportunities for treatments in both planned and urgent hemorrhages without the requirement of patient transportation.

INTRODUCTION

The combination of advanced imaging and interventional capabilities in a full Operating Room (OR) is increasingly common in tertiary care centers. This combination is referred to as hybrid OR [1]. Integration of such facility has been described for endovascular treatments, especially in cardiovascular patients. These patients were also treated in an OR using C-arm fluoroscopy [2,3]. Performance of preventative trans-arterial embolization (TAE) in the obstetric setting has been described in a hybrid room, Interventional Radiology (IR) suite, regular and obstetric OR and in various combinations of these locations [4-9].

Abnormal placentation is a known obstetric condition describing fetal trophoblast invasion of the myometrium. Previous reports have shown increased maternal and fetal mortality and morbidity linked to this pathology [10-13]. Undesirable outcome of such pregnancies is hysterectomy due to uncontrolled hemorrhage in the setting of either planned or emergency Cesarean section (C- section) [14-17]. Incorporation of TAE, in cases of both C- section in the setting of abnormal placentation and post partum hemorrhage (PPH), has been shown to ensure low morbidity and mortality and maintained high chance of uterus conservation [6,18-25].

Since first reported [26], literature regarding integrated embolization in acute PPH describes transportation between the IR suite and the Obstetric ward as a complicating factor [27]. In many medical centers, the Gynecological and Obstetric ward and OR are located at a separate building complex from the general surgery rooms, IR suite and hybrid rooms. This is a significant factor when considering transportation of haemodynamically unstable patients in emergency conditions [28]. Few authors described conduction of the procedure in the Obstetric OR [7] or staged procedure with transport of patients from IR suite to Obstetric OR [9].

We present our pilot study of introducing a mobile fluoroscope C-arm into the Obstetric OR for integrated treatment of obstetric hemorrhages in both planned and emergency setting.

MATERIALS AND METHODS

This retrospective study was approved by the institutional review board. Between the years 2000 and 2013, there were 62 patients with abnormal placentation which were treated by TAE in the general surgery OR with a c arm or in a hybrid room. In 2013 we have decided to shift this procedure to the obstetric OR due to its better obstetrics and gynecology facilities. Here we report on the outcome of this shift.

For this pilot a OEC 9900 Elite VAS 8 Digital Mobile Fluoroscopic C-arm (General Electric healthcare, Salt Lake City, UT, USA), 12" tri-mode image intensifier with DSA program was placed in an obstetric OR. A new multifunctional obstetric table made of carbon fibers, suitable for fluoroscopy was placed instead of the original table. All the embolization required equipment was set up in the obstetric OR.

All procedures were carried out in the obstetric OR between August 2013 and August 2016 for all patients with abnormal placentation, as diagnosed pre-operatively by Ultrasound or MRI with expected severe bleeding during C- section. These patients group was further divided into planned embolization, which occurs during the planned C- section on a scheduled basis (Group A) and embolization on emergency basis, once rupture of membranes, bleeding or fetal distress occurred (Group B). The former enabled scheduled preparation of the patient for a planned surgery. In case of the later, the procedure was planned but the time is uncertain and depends on the patients' state and the maturity of the fetus. Alongside those two groups, patients with PPH were treated as in any acute lifesaving procedure.

A team of two to three Obstetricians, two Anesthesiologists, one or two IR physicians, a Pediatrician, Hematologist, nurses and an IR technician were present for all procedures. The procedures were performed by Interventional Radiologists with 13 - 23 years of experience (B.H., U.R. and G.G.) and one case performed by a fellow with 3 years of experience (A.C.).

The angiographic procedure for both group A and B involved two IR physicians and began with bilateral common femoral artery access using 5-F Micro-Introducer Kit (Angiodynamics, Amsterdam, Netherlands) and 5-F introducer sheath (Terumo, Leuven, Belgium) according to common angiography practice. Preparation of multiple 10cc syringes containing sterile re-absorbable hemostatic gelatin sludge (Cutanplast, Milano, Italy) with contrast media was performed concurrently [29,30]. Both uterine arteries were catheterized simultaneously contralaterally with a 4-F Glidecath catheter (Terumo, Leuven, Belgium) according to As Low As Reasonably Achievable (ALARA) concept [31]. The patient was then prepared for C-section according to standard approach.

Once the neonate was delivered, manual extraction of the placenta took place. Once most or the entire placenta was extracted, hemostasis was attempted with surgical packing, followed by vigorous bilateral embolization.

First embolization endpoint was bilateral complete stasis as shown by fluoroscopy. Second step operation was performed with remnant hemostasis, packing and ligation of bleeding vessels by the Obstetric surgeons. Second embolization, in case of further bleeding, took place thereafter until hemostasis was gained. This second embolization took less time in comparison with the first and major one. Care was taken throughout the procedure to avoid reflux of embolization material to non- target vessels. After achieving bleeding control, completion of C-section was performed. If bleeding continued, in spite all measures, surgical, hematological and radiological, the uterus was removed. After that, the sheaths were removed and hemostasis was achieved with Exoseal (Cordis Corporation, Miami lakes, FL).

In cases of PPH after all means of surgical and hemostatic resources could not stop the hemorrhage, the IR team on- call (a physician and technician) was called. One femoral artery was accessed. Angiographic search was performed for the bleeding vessel in both uterine arteries or on the anterior hypogastric divisions, based on the discretion of the attending IR physician. Targeted TAE was performed to the demonstrated bleeding artery. The embolization was followed by visual and manual examination of the bleeding cessation by the surgeon. The equipment for this type of procedures was the same as for the abnormal placentation.

Procedural success was considered if hysterectomy was avoided.

Total radiation emission dose and exposure time were recorded.

RESULTS

During the length of this pilot, 10 procedures took place: eight prior to the C- sections with abnormal placentation and two emergency PPH procedures. The patients median age was 31 years. Group A had 5 planned procedures; group B had 3 anticipated procedures, which took place in an emergency setting due to amniorrhexis or bleeding. Out of the two emergency PPH procedures one was due to post early spontaneous delivery of a deceased newborn and one due to uncontrolled post routine C- section hemorrhage.

Eight of uteri were preserved, two of the PPH, three of group A and all of group B. Two hysterectomies were performed in group A. For one patient, this was her 4th pregnancy with placenta previa and accreta. For the other, it was the 7th pregnancy with placenta accreta.

There were no complications neither during nor following the endovascular procedures. All patients were discharged after a mean of 6.8 days.

For the IR physicians undertaking the individual procedure, the imaging method was sufficient to facilitate safe embolization in all patients.

Mean maternal radiation dose during procedures was 122 mGy (± 187 mGy) and radiation time 328 s (± 253 s). In one procedure radiation time was prolonged to 997 s with the dose of 650 mGy. This procedure was performed by the fellow in IR. In the rest of the patients, which were performed by more experienced radiologists, the median radiation dose was 72 mGy with the mean time of 286 s. Continuous, rather than pulsed, fluoroscopy was used in order to achieve better graphics. The digital subtraction images were done in 2 frames per second. Fluoroscopy was used as little as possible to decrease maternal and fetal radiation. We have attempted in keeping the image intensifier at a level of 5 cm from maternal abdomen.

Dose area product (DAP) was measured with a median of 16318 mGy cm².

DISCUSSION

TAE in Obstetric bleeding is a viable option for uterine preservation. In a non-emergent setting, the multidisciplinary

approach involving IR and Obstetric surgery, have been well deployed. Integration of either hybrid operation rooms or combination of IR suite for catheter position followed by transfer to operation suite for the C- section were described in an effort to decrease morbidity and mortality due to severe un-controlled bleeding in women with known abnormal placentation [4-9,18-20,30,32-35].

In acute life threatening obstetric hemorrhages, after all surgical and conservative measures have failed, where a swiftly performed embolization is not a feasible option, life-saving hysterectomy is performed [4,14-16,22].

In our medical center, much like many other facilities, the Obstetric ward is located in a different building complex from the IR suite. While the transfer of patients for a prophylactic embolization is reasonable and safe, transferring hemodynamically unstable patients is more complicated and incorporates risks. We sought to combine the fertility preserving conservative method of TAE with the safety and care of a fully functional, fully staffed and equipped OR without any need of patient transfer. In order to have the capability of performing TAE in these situations, we installed a C-arm fluoroscopy system in the Obstetric OR with all the relevant equipment. We used this facility in planned, anticipated and acute settings.

While Rebonato et al. [9], described placement of catheters in the IR suite followed by transfer to the obstetric suite for delivery and embolization. Li q et al. [7], described conducting the procedure in a general surgery room. Niola et al. [8], like us, depicted conduction of the whole procedure in the obstetric OR with a C-arm system. The operating table was not adapted to facilitate best imaging.

In our pilot, we describe our preliminary results with a dedicated obstetric OR to perform TAE.

We have had two patients with PPH which TAE controlled their hemorrhage and the uterus preserved. Of the eight patients with known abnormal placentation, six uteri were preserved due to TAE and in two other patients all attempts to control hemorrhage were unsuccessful and hysterectomy performed.

One of our initial concerns was whether C-arm fluoroscopy was sufficient enough to avoid non target embolization. In all ten patients we experienced no complications resulting from embolization of non-target vessels, so we concluded that C-arm fluoroscopy is probably good enough to perform safe TAE.

Maternal and fetal radiation dose is a significant consideration [7,36,37]. Vinas et al. [24], had a mean maternal radiation dose of 132 mGy (± 97.1 mGy) and mean fetal radiation of 4.4 mGy (± 3.5 mGy) with the total fluoroscopy time of 456s (± 212 s), with procedures performed in an IR suite considered to be with less radiation than C-arm fluoroscopy. Niola et al. [8], performed the procedure in the obstetric operation suite using C-arm (GE OEM 9800). The radiation dose was measured by dosimeters, which were attached to the patients back, with entry surface dose of 70 mGy (range 18-234 mGy) and uterine radiation dose of 15 mGy (range 8.15-38.18 mGy). Mean radiation time of 222 s (range 81 s- 418 s) was measured. Li O et al. [7], who performed the procedure with a mobile C-arm as well, had a measured mean

absorbed fluoroscopy dose (air kerma) of 91 mGy (range 30-171) and mean radiation time of 580 s (275-924 s). The average fetal fluoroscopy time was 102 s (41-196 s) with an average X-ray dose of 17 mGy (range 6-23).

In our pilot, the assessment of radiation was measured as a total emitted by continuous fluoroscopy of the C-arm. We have measure total emitted radiation and did not divide it into maternal and fetal absorbed measurements. While difficult embolizations naturally take more time and required greater amount of exposure, experience of the IR physician contributes greatly to procedure length and radiation needed.

In this study we have attempted to evaluate the technical aspect of the benefits of placement of a mobile fluoroscopic system in an obstetric operating room. This intervention isn't unique and its wide variation in practice has been described. As such, we have wished to assess the safety of the set-up in relation with maternal radiation dose and avoidance of hysterectomy.

This study has a few limitations:

(1) This was a pilot study and as such contained a small number of patients. This makes it hard to extrapolate from these patients

(2) Averages in radiation dose and time greatly influenced by small number of patients and were measured as was emitted by the C-arm fluoroscopy.

(3) The financial costs of purchasing the fluoroscopic C-arm and carbon operating table and its upkeep were not considered.

To conclude, we are aware of the different interventional approaches and locations to prevent unnecessary hysterectomies. Alongside that, we have created a pilot study in which the benefits of placement a C-arm in an Obstetric OR to facilitate TAE are assessed. Our main goal was describing this arrangement. Our preliminary results are optimistic but further studies have to be performed in order to better assess this set-up.

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