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Interventional radiology in gynecology and obstetric practice: Safety issues

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Interventional radiology is continuing to reshape current practice in many specialties of clinical care and the fields of gynecology and obstetrics are no exception. Imaging skills, clinical knowledge as well as vascular and non-vascular interventional technical ability, are essential to practice interventional radiology effectively. Patient safety is of paramount importance in interventional radiology as in all branches of medicine. Potential failures occur throughout successful procedures and are attributed to a spectrum of errors, including equipment unavailability, planning errors, and communication errors. These are mainly preventable by improved preprocedural planning and teamwork. Of all the targeted and effective actions that can be undertaken to reduce adverse events, the use of safety checklists might have a prominent role. The advantage of a safety checklist for interventional radiology is that it guarantees that human error in terms of forgetting key steps in patient preparation, intraprocedural care, and postoperative care are not forgotten.
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Introduction

Despite being a relative new branch in the world of medicine, in the last 2 decades, interventional radiology (IR) has broadly extended its range of applications, mainly as a result of the technological progress.

IR procedures have become the main method of care of a multiplicity of pathological emergency and non-emergency conditions, offering less risk, less pain and less recovery time compared to open surgery.

Interventional radiologists use x-rays, computed tomography, magnetic resonance, or other imaging guidance to navigate small instruments, like catheters and needles, through blood vessels and organs to treat a variety of diseases.[1,2] Examples of treatments administered by interventional radiologists include angioplasty, biopsies, stenting, thrombolysis, embolization, and radiofrequency ablation.[1,3-6]

In recent years, the transcatheter and percutaneous techniques of IR have been applied for the treatment of diseases of various organs and systems, including the female pelvis.[7-10] Through improvement of new procedures and enhancement of standard techniques, the interventional radiologist can now offer many services to the obstetrician-gynecologist.[11-15]

Regarding gynecological and obstetric diseases, interventional radiologists are very familiar with the pelvic vascular anatomy based on previous experience with embolization for pelvic trauma in addition to the growing experience with uterine fibroid embolization.[7-16] Most of the interventional procedures are performed percutaneously with little associated patient discomfort and with conscious sedation instead of general anesthesia.[17]

In the gynecological field, transarterial embolization is used for treating uterine arterio-venous malformations (Fig. 1) and uterine myomas (Fig. 2). A modern approach of treating fibroids is also represented by image-guided thermal ablation with both percutaneous and no touch methods; transvenous embolization is instead an established therapy for pelvic congestion syndrome (Fig. 3).[3,8,12,16,18] In patients

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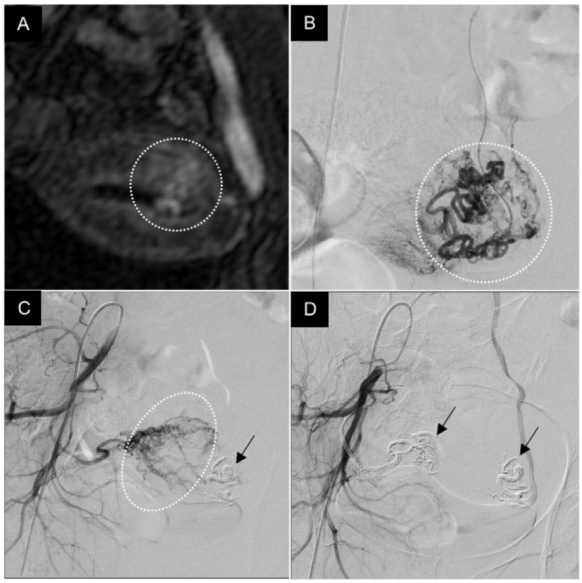

Figure 1 A 37-year-old lady with previous intracavitary maneuvers (1 myoma ablation and 2 curettages) causing uterine arteriovenous malformations (AVM). Contrast-enhanced magnetic resonance in coronal plane shows a focused irregular enhancement of the uterine wall, partially involving the uterine cavity, corresponding to an AVM (A, white dotted circle). Superselective digital subtraction angiography (DSA) of left uterine artery showing multiple tortuous and ectasic vessels with early venous wash-out (B, white dotted circle), angiographic finding of AVM. Superselective DSA of right uterine artery shows multiple tortuous and ectasic vessels with early venous wash-out (C, white dotted circle), corresponding to right refurnishment of the AVM; embolization cast of Onyx18 of the left side (C, black arrow). Right hypogastric DSA showing exclusion of the AVM from the blood flow after bilateral uterine artery embolization; the embolization casts are indicated by black arrows (D).

affected by gynecological malignancies, endovascular treatment of metrorrhagia could be a valid therapeutic alternative, especially in elderly patients with poor clinical conditions not suitable for surgery. A bilateral and superselective embolization using nonresorbable embolic agents should be performed, except for those cases in which there is infiltration of major vessels causing pseudoaneurysms or fistulas that require embolization.[19]

In the obstetric field, transarterial uterine arteries embolization is a recognized procedure for the management of postpartum hemorrhage that is a major cause of maternal morbidity and mortality; new endovascular techniques are proposed also as preventive strategies before partum in patients at high risk, especially those with abnormal invasive placenta.[11,20-22] Moreover, in case of ectopic/scar pregnancies, transarterial embolization combined or not with medical therapy has demonstrated to provide effective clinical results. Nonhemorrhagic emergencies in the antepartum and postpartum patient also include the diagnosis and treatment of deep vein thrombosis and pulmonary embolus, including inferior vena cava filter placement when appropriate.[14]

For each of the aforementioned conditions, it is mandatory to appropriately select the patients suitable for IR treatments on the basis of both clinical data and imaging findings, working in cooperation with gynecologists. In IR, as in all medical disciplines, the need for improvements in patient safety is progressively being recognized.[23-32] Patient safety is the absence of preventable harm to a patient during the process of healthcare and reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[24]

In IR, knowledge of periprocedural care is critical for building a successful patient-centered practice. Periprocedural care with respect to image-guided intervention refers to the spectrum of patient care and management before, during, and after a procedure.

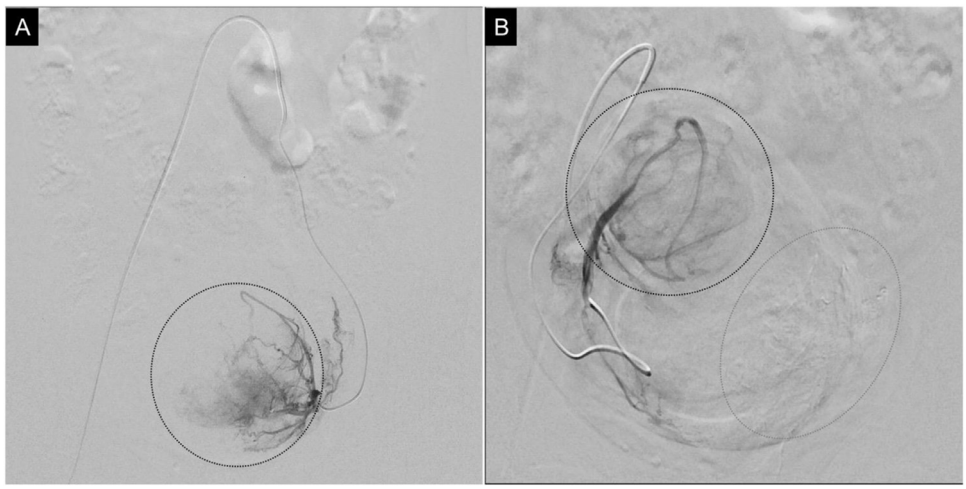

Figure 2 A 44-year-old lady with uterine myomas. Superselective digital subtraction angiography (DSA) of left uterine artery showing an irregular round-shaped vascularization (A, dotted black circle), corresponding to the dominant myoma of the left uterine portion. Superselective DSA of right uterine artery showing a similar irregular round-shaped vascularization (B, dotted black circle), corresponding to the dominant myoma of the right uterine portion; the cast of the left side embolization is also evident (B, dotted gray circle). Embolization was performed with 500-700 μm microparticles.

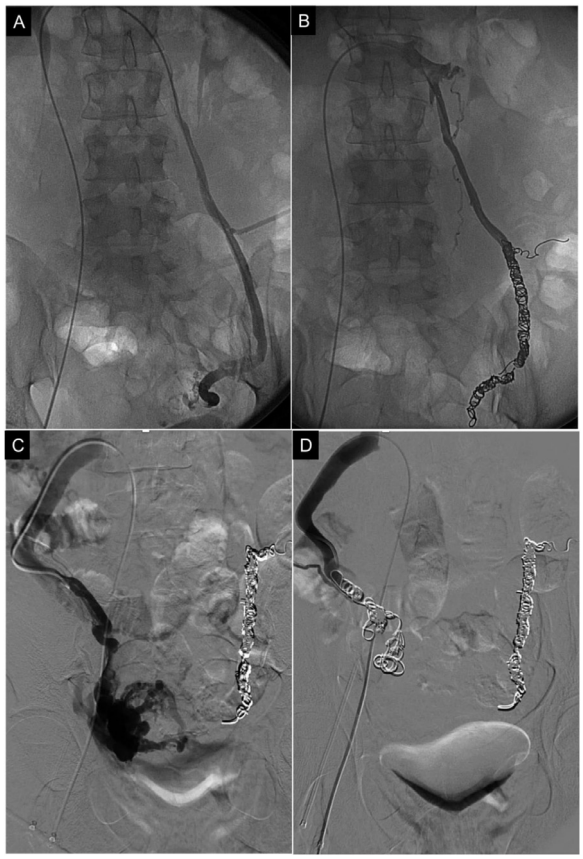

Figure 3 A 31-year-old lady with pelvic congestion syndrome causing pelvic pain for 1 year, treated by endovascular embolization. Fluoroscopy shows catheterism of an insufficient and ectasic left ovarian vein with parauterine reflux (A); sclerosant injection and coils embolization of the left ovarian vein (B). Controlateral digital subtraction angiography (DSA) demonstrating insufficiency and massive dilation of the right ovarian vein with marked parauterine reflux (C) that was similarly occluded with sclerosant coils (D).

In this article, we discuss the different components of IR periprocedural care in gynecology and obstetric practice with specific emphasis on patient safety.

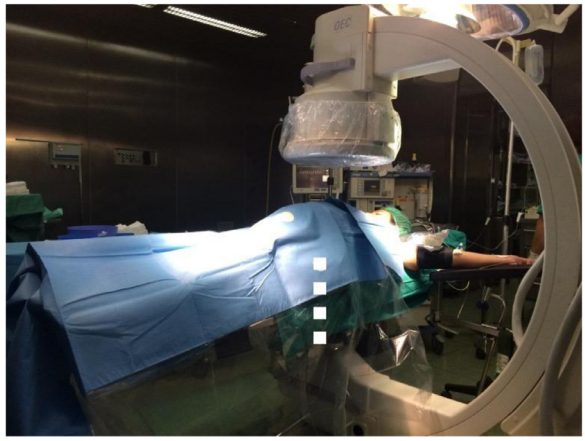

Figure 5 Operating theater with C-arm positioned for interventional procedures; the beam source is positioned below the patient and should be at maximum distance from the patient (white dotted arrow).

The IR suite

Perhaps one of the most critical, yet often overlooked, aspects of performing IR procedures is organization. A deficiency of correct planning and equipment unavailability have been shown to account for nearly one-third of errors in IR.[33,34] While each interventional radiologist will have his or her own preferred organization techniques, there are several important factors to consider when a specific strategy should be decided.

Figure 4 demonstrates the main components that make up an IR department.

Modern IR suites should have 1 or 2 rooms built to operating room standards which includes laminar air flow, mandatory air exchanges, a positive in-suite pressure with respect to the surrounding rooms and corridors and appropriate flooring. The IR table must accommodate versatile positioning, in particular, head down tilt for emergencies (Fig. 5).[35] Generally staffing of the IR suite itself requires one or more interventional radiologists, nurses, radiology technologists, and ancillary staff.

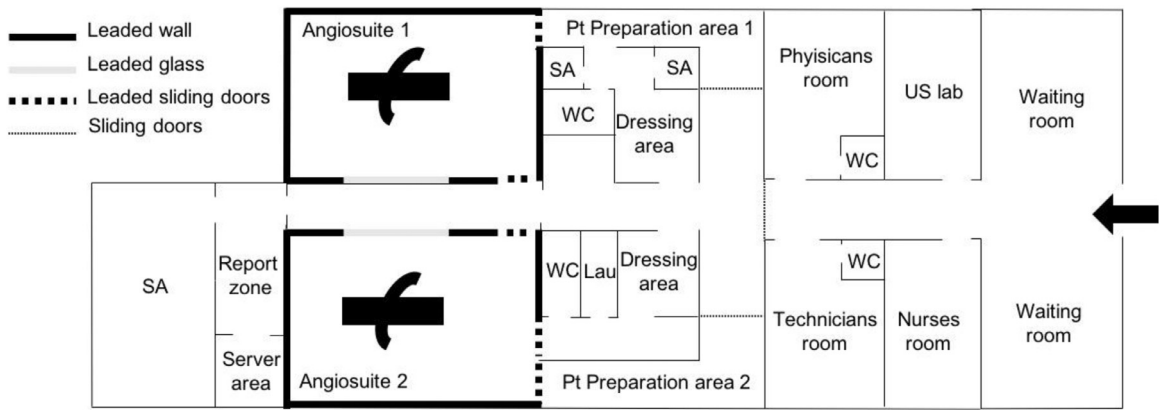

Figure 4 Example of planimetry related to an IR department. Not every room is represented in this schematic drawing, but it does show how some modalities and several suites can be planned close together, bringing benefits in patient care, efficient use of space by sharing some of the supporting rooms, good clinical communication and expertise sharing. Pt, patient; SA, storage area; Lau, laundry; US, ultrasound.

Staffing is guided by patient safety and resource efficiencies. The anesthesiologist is available for procedures requiring general anesthesia or moderate-deep sedation in selected cases (transjugular intrahepatic portosystemic shunt, intracranial vascular procedures, hemorrhagic urgencies, pediatric patients).[35,36]

Guidelines stated that each procedure required 3 personnel in addition to the physician: one to be scrubbed into the procedure along with the physician, one to circulate, and one to monitor the patient. In certain situations, 4 nonphysician healthcare practitioners may be needed per case.[30] IR physician and staff training and competency are an integral component of any successful IR program. Consistent, trained staff familiar with the standards of practice and particular care of patients undergoing a spectrum of IR procedures is crucial. IR staff members work as a team and are not interchangeable with nurses from other floors in the hospital or technologists from other areas in radiology.[30]

A wedge is needed for pregnant patients. In emergency situations, control of postpartum hemorrhage frequently involves transfer of the postnatal woman to the IR suite for the insertion of catheters. In the elective situation, the site of the caesarean section after the procedure remains a topic of debate. If catheters are placed in the obstetric theater, then an IR compatible table is necessary, but the radiological imaging quality through a C-arm is inferior. If catheters are placed electively in the radiology suite with subsequent transfer of the woman to obstetric theater for the caesarean section, then there is a risk of sheath and catheter displacement during transport.[35] In fact, good communication among a multidisciplinary team consisting of the interventional radiologist, obstetrician, anesthesiologist, nursing, and ancillary staff is essential for the safe and efficient management of these patients. Specific issues that should be discussed include fetal monitoring (equipment and nursing staff), recovery location (immediate postprocedure and intermediate-term and long-term recovery), and resource availability in the event of an emergency delivery.[35]

In case of pregnant patients, it is of paramount importance to strictly follow the SIR and CIRSE guidelines for the use of radiation during pregnancy.[37] Several measures should be applied to achieve an appropriate balance between image quality and radiation dose to the fetus. These measures include low-dose rate pulsed fluoroscopy with the lowest pulse rate allowed by the equipment, no angiography exposure, use of the "last image hold" to record the study and plan techniques, no enlargement of the field of view, use of a half-dose filter, posteroanterior beam projection, x-ray tube at maximal distance from the patient, and tube current as low as possible by keeping the tube potential as high as possible (Fig. 6). Finally, the fluoroscopy beam-on time is one of the primary factors that the interventional radiologists have been controlled in order to reduce both patient and staff doses.[38]

Another crucial topic-related patient safety is represented by hand hygiene and sterile technique.[39] The prominence of hand hygiene for reducing infection rates in healthcare environments was first described by Semmelweis and Holmes in the mid-19th century.[40] Since interventional radiologists perform so many procedures as part of daily practice, it is crucial to appreciate the current guidelines for both hand hygiene and sterile technique for procedures, especially central venous catheter placement. Hand hygiene, as defined by the 2002 Centers for Disease Control and Prevention Guideline for Hand Hygiene in Health-Care Settings,[41] requires decontamination of hands by using either an alcohol-based hand rub (recommended as a first-line method) or hand washing with antimicrobial soap (preferred) or plain soap (acceptable) and water. Good aseptic technique represents a serious step in reducing procedure-related infections. Skin sites can be disinfected by using 2% chlorhexidine-based agents (preferred), tincture of iodine, or 70% alcohol and should be allowed to dry completely before starting the procedure. For most procedures, it is also appropriate to use either clean or sterile gloves or a sterile drape. For the placement or guidewire exchange of central venous catheters, the Centers for Disease Control and Prevention guidelines require the use of maximal sterile barrier precautions, which mandate aseptic technique and the use of a cap, mask, sterile gown, sterile gloves, and sterile drape (Fig. 7).[42]

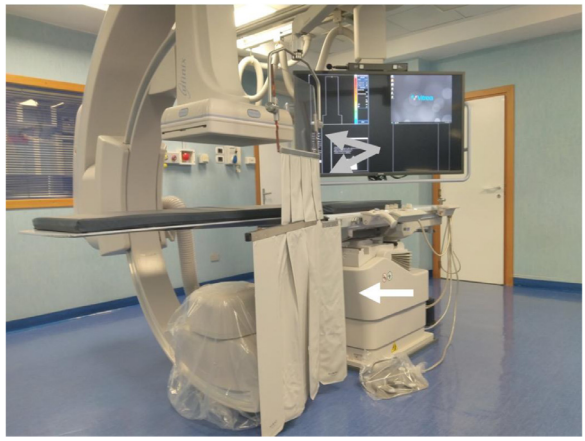

Figure 6 Angiosuite with leaded x-ray protections (white arrow: low protection with leaded curtain; gray arrows: high protection with leaded curtain and leaded glass).

During the outbreak of the COVID-19 (coronavirus disease 2019), there is the need for a correct selection of IR procedures, and a well-organized preparation of staff and interventional suite before the arrival of patients; moreover, due to the high rate of aerosol transmitted infections and permanence on surfaces, segregation is one of the basic principles for prevention of new viral infections. Execution of IR procedures in situations with suspected airborne infections needs particular precautions to reduce the risk of transmission to the healthcare workers. As far as possible, procedures on patients with suspected or confirmed COVID-19 infection should be performed at a specially designed isolation facility.[43]

Adverse events and errors in IR

IR is a branch of radiology that performs a wide range of vascular and extravascular procedures, which share three common factors: a percutaneous approach, minimal or reduced

Figure 7 Wearable x-ray protections (white arrow: leaded gown; gray arrow: leaded collar; black arrow: leaded glasses; black dotted arrow: leaded cap).

invasiveness and imaging guidance (angiography, fluoroscopy, ultrasonography, computed tomography, magnetic resonance). An adverse event is one that results in unintended harm to the patient by an act of commission or omission, rather than by the underlying disease or condition of the patient. The term "adverse" does not imply whether the event may have been preventable (examples include a patient falling during transfer, contrast agent extravasation, a missed imaging finding, and a complication during an interventional procedure).[44] It has been estimated that 50% of all in-hospital adverse events are related to surgery and at least 50% of these could be avoided because they are caused by errors.[45] Error is defined as "the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (ie, error of planning)."[28]

Literature in IR indicates that the majority of errors in IR are preventable.[46] IR procedures place the team in circumstances comparable to those experienced in operating theaters (persistent stress, operator tiredness, team inexperience) that can lead to mistakes: this explains the need to enhance patient safety measures through larger standardization of procedures and enlarged quality of care in IR procedures. Moreover, in addition to the most commonly recognized errors in medicine, some errors are specific to IR and can potentially occur at any time during the patient's stay in the angiographic suite.[47] The American College of Radiology's Task Force on Patient Safety recommends a list of preventable patient errors.[48]

When considering the human contribution to adverse events, safety researchers further distinguish between 2 kinds of error: active errors (or failures), which are commonly associated with errors committed by frontline operators, and latent errors (or conditions), which reflect inherent faults in processes, equipment, or organization that later emerge to contribute to a failure.[44,47] Factors leading to error rarely occur in isolation and reflect a combination of events, including judgment errors, vigilance/memory failure, lack of technical competence, and communication breakdown.[49]

Apart from the surgical risk itself, also the patients' stay and transfer to and from the operating theater, the different health professionals involved in IR activity and the complexity of the procedures make the IR prone to error and therefore to adverse events.[50] In case of adverse event, it is necessary to perform a root cause analysis to estimate the causes and contributing factors. The analysis can reveal a deficiency of clarity regarding the organization and specific duties of the several healthcare professionals working in the radiology suite (definition of roles) and the procedure for side identification. A root cause analysis consists of three fundamental components: (1) identification of factors most directly associated with the adverse event; (2) analysis and prioritization of these factors to design the introduction of effective strategies to prevent them from recurring; (3) introduction, management, and, wherever possible, dissemination of effective countermeasures that are shown to have a beneficial effect.[44]

Safety checklist in IR

Checklists are an important tool for achieving standardization. Checklists safeguard consistency and team communication, thereby overcoming limitations in human memory and attention span. Checklists ensure that procedural steps are performed in the correct order and that the procedure is completed.[29]

Starting from 2009, the World Health Organization developed its own Safety Surgical Checklist to standardize the surgical patient's pathway and enhance safety. This checklist led to a significant reduction in clinical adverse events and in morbidity and mortality caused by human error on patients during their stay in the operating room.[51] Subsequently, the Cardiovascular and Interventional Radiological Society of Europe published its own safety checklist recommending its use in IR suites.[50,52]

IR procedures have many aspects in common with surgery (complexity, fast patient turnover, urgency and emergency procedures, multilevel or diffuse diseases, teamwork) and consequently carry a risk for potential error. Therefore, implementing the use of safety checklists in the IR suite could have the same usefulness in increasing patient safety as surgical safety checklists.

Safety checklists provide a verification tool to support the interventional radiologists team, with the aim of facilitating adhesion to recommended patient safety standards and preventing avoidable adverse events.[52]

A safety checklist can be used in different healthcare environments because it includes the following 3 important safety goals: (1) improving accuracy in patient identification;

Table Patient Safety List in IR

Requisition form present
Correct patient identification
Correct procedure/examination/treatment
Correct side for procedure/treatment and labeling of laterality
Correct contrast agent/dose
Prior history known
Relevant imaging studies present
Contra-indications identified
Contrast allergy checked
Preparations for renal failure executed
Medication for procedure ordered/ in stock
Equipment present (stents/catheters/ etc.)
Informed consent present
Procedure explained to patient (parents)
Possible complications discussed with patient (parents)
Antibiotics administered
IV access present

(2) improving communication between healthcare coworkers; (3) eliminating all wrong-site, wrong-patient, and wrong-procedure interventions.[50] Table shows a spectrum of crucial points of a patient safety list in IR. The checklist is not proposed to replace current good practice or protocols already in place but is an additional safeguard. The checklist is designed to act as a "pause" to reflect before embarking on any procedure that requires the insertion of a needle into a patient for the purpose of biopsy or intervention.[53]

Morbi et al[25] identified ineffective procedure planning, communication error, and equipment difficulties as the main causes of preventable error in IR and planned their own version of a checklist, called "preprocedural team rehearsal," to target frequent preventable potential failures. Once implemented, they found preventable failures decreased from 54.6% to 27.3%.

Safety steps related to IR procedures

Before any procedural intervention, every patient must be evaluated. The clinical indication and need for the requested procedure must be determined and weighed against other potentially appropriate management options for each patient. With the increasing importance of clinical activity in daily IR practice, interventional radiologists play a key role not only in performing medically needed procedures, but also in helping referring teams determine when a given IR procedure may not be indicated or when risks outweigh benefits.[54]

After the patient's admission to the IR department, a radiologist usually checks the blood tests ordered for the requested procedure and verifies that the patient has received all information regarding the interventional procedure. Coagulation parameters and pharmacologic therapy should be clearly investigated before the procedure; the coagulation status of patients undergoing image-guided interventions should be assessed whenever the procedure involves direct entry into the arterial or venous system as an anticipated part of the procedure or whenever there is a possibility of inadvertent entry into the arterial or venous system with significant-sized interventional devices or tools.[55]

Before the patient enters the IR suite (preprocedural period), it is mandatory to check the following items:

- patient's name and surname correct identification;
- patient's knowledge of the type and side of the procedure, crosschecking with the information in the patient list and informed consent form;
- informed consent up to date and correctly filled;
- availability of a peripheral venous access;
- knowledge of risk of contrast-induced nephropathy and possible allergies;
- the patient has discontinued anticoagulant/antiplatelet therapy (when required).[50]

These are items that can be easily forgotten on a busy day in the interventional suite, but their omission could result in potentially dreadful complications for the patient.[56]

When the patient is prepared for the procedure in the IR suite (on the operating table, asleep, sedated or under locoregional anesthesia), with all of the team in the room, it is important to verify: (1) that all the team members are present and all the radiological images required for the procedure are ready (if necessary); (2) that the patient data displayed on the angiography system are correct and up to date and correspond to the patient submitted to the interventional procedure; (3) patient's identity, surgical site, type, and side (if required) of the procedure.[50]

At the end of the procedure and before the patient leaves the angiography suite, a team member in the recovery room verifies that:

- the nursing assessment and radiological report have been completed and attached to the patient's clinical record;
- the acquired images have been correctly uploaded and sent to the PACS;
- the biopsy or biological sample containers have been correctly labeled and the requests and forms for the pathology laboratory have been correctly completed.[50]

The informed consent

Given that patient-centered decision-making increasingly has been viewed as an eminent quality of care indicator, assessment of patients' desire for information about radiation exposure is imperative.[57-60]

Physicians have the responsibility to obtain informed consent from patients, and this involves the healthcare provider verbally explaining the risks and benefits of a procedure as well as alternative treatment options. Although the failure to do this properly is considered malpractice, and there is extensive difference on informed consent regulations internationally and among states, the practice of formalizing the informed consent process with a signed document has been worldwide embraced.[61,62]

Informed consent should be obtained for any procedure that exposes a patient to any substantial risk, including moderate sedation.

Topics to discuss during the informed consent process may include the purpose and nature of the procedure, the technique of performing the procedure, procedural risks and potential complications, the estimated benefits, the risks of not performing the procedure, reasonable alternatives and likely risks and benefits, and the right to refuse the procedure.[40,63,64]

Since the patient must be able to fully understand the consent process, the consent should be obtained before any sedation is administered. Finally, the necessary patient preparation for the treatment needs to be explained.[62]

Radiologists must discuss their own procedures with patients; informed consent for radiological procedures cannot be left to clinicians. The interventional radiologist who performs the procedure (or a suitable delegate) should obtain the patient's consent, preferably on the evening before the procedure, unless there are remarkable circumstances and the patient should be allowed sufficient time to decide on or even to refuse the proposed interventional procedure.

During the consent process, the patient and the patient's family should understand that the site of skin entry and the site of treatment may be different.[24]

Moreover, effective communication is fundamental to a successful woman-interventional radiologist relationship; shifting the communication model to be more patient centered has been shown to improve both quality of care and patient satisfaction.[17,65,66]

In emergency situations, the need for any immediate intervention must be documented in the patient's medical record, including situational details, the necessity for fast intervention, the magnitude of the situation, and the reason for not obtaining consent. If an intervention has a potential for higher levels of radiation, the risks of radiation-induced injuries should be included during the consent process: the medical record should note the estimated radiation dose received, and the patient should be advised of any potential radiation-related injuries with follow-up instructions.[57]

Conclusion

Today interventional radiology procedures are an excellent alternative to surgical interventions in the management of gynecological and obstetric diseases.

Interventional radiology is an invasive specialty with the potential for errors as with other invasive specialties.

Proper organization and training is essential to any procedural specialty. While many aspects of IR are similar to that of surgery, most often, interventional radiologists are themselves required to set up equipment and organize the procedural table.

The need for more standardization to improve patient safety and quality of care is increasingly being recognized in IR. Preprocedural planning and intraprocedural organization is important for time management, and more importantly, for patient safety. All interventional procedures require a time-out, which should observe the Joint Commission's universal protocol for preventing wrong site, wrong procedure, and wrong person surgery.

Of all the targeted and effective actions that can be undertaken to reduce adverse events, the use of safety checklists might have a prominent role. The advantage of a safety checklist for IR is that it ensures that human error in terms of forgetting key steps in patient preparation, intraprocedural care, and postoperative care are not forgotten. Nowadays, the integration of checklists in digital patient information systems helps to develop more checklists capable of offering information and links to other sources. The development of a safety culture will be the most important factor in determining the real success of safety checklists and their overall effects on patient safety. Developing a culture of safety can be a difficult process, but through safety education, dedicated teams, behavioral interventions, and executive support culture can begin to change.

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