

# Utility of Procedural Checklists in SFA Interventions

The use of checklists can improve outcomes and ensure the safety and efficiency of endovascular SFA procedures.

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The use of checklists is a simple and cost-effective strategy to reduce errors. In medical practice, checklist use improves patient outcomes. Widespread use of the “Surgical Safety Checklist,” developed in 2008 by the World Health Organization as part of the “Safe Surgery Saves Lives” project, confirmed this.<sup>1</sup> Over a period of several years, multiple studies—including a large meta-analysis involving more than 37,000 patients—have demonstrated a reduction in major complications after implementation of surgical checklists.<sup>2-4</sup>

Another systematic review also found that health care team members’ perception of communication and teamwork in the operating room was improved when checklists were used (Figure 1). This is significant, as improving communication and teamwork has been identified as an important step in improving institutions’ “culture of safety.”<sup>5-7</sup> It may be easy to assume that everyone has the same understanding of what needs to be done, but the use of checklists confirms that everyone is on the same page. To quote the Russian proverb frequently cited by President Ronald Reagan, “Doveriyai no proveryai” (trust, but verify).

Although checklist use has been successfully implemented in the operating

room, relatively few studies have addressed the specific role and utility of checklist use in endovascular procedures. Fargen et al analyzed the effect of a checklist in the neurointerventional suite and found fewer adverse events and a perception of improved communication.<sup>8</sup> Despite the paucity of studies confirming the benefits of checklist use for endovascular procedures, it is recognized that many peripheral interventions involve



Figure 1. Checklists help ensure that critical steps are not missed in the setting of a busy endovascular suite.

## CHECKLISTS FOR THE SFA INTERVENTIONIST

### IMMEDIATE PREPROCEDURAL

- ☐ Presedation assessment completed
- ☐ The Joint Commission–mandated time-out, including patient identification, procedure verification, site marking
- ☐ Images from prior procedures or preprocedural studies available/displayed

#### Patient Factors

- ☐ Patient weight, creatinine
- ☐ Pregnancy status
- ☐ Ankle brachial indexes recorded
- ☐ Baseline pulse examination

#### Medications

- ☐ Allergies, including to contrast or heparin
- ☐ Sedation plan
- ☐ Prophylactic antibiotic prior to procedure (if indicated)
- ☐ Maximum contrast dose (5 mL X weight [kg]/serum creatinine)
- ☐ Adjunct renal protection: acetylcysteine or sodium bicarbonate, if needed
- ☐ Anticipated heparin dose (60 U/kg)

#### Procedural Items

- ☐ Proper patient positioning and exposure
- ☐ Ultrasound probe draped for access guidance
- ☐ Required equipment and supplies available

#### Patient-Specific Issues

- ☐ Anticipated procedural challenges discussed

### INTRAPROCEDURAL

#### Access Site Evaluation

- ☐ Correct location of access confirmed
- ☐ Determine presence or absence of contraindications to closure device use

#### Anticoagulation

- ☐ Heparin (or alternative) administered
- ☐ ACT check (repeat every 20–30 minutes)
- ☐ Additional anticoagulation if ACT is subtherapeutic (< 250 seconds)

#### Device Delivery

- ☐ Confirm sheath size/position is appropriate for devices to be used
- ☐ Confirm guidewire size is appropriate for devices to be used
- ☐ Place embolic protection device, if indicated

#### Interventional Device(s)

- ☐ Confirm appropriate device selected with read back and verbal confirmation
- ☐ Check that packaging is in good condition
- ☐ Check device/packaging expiration date
- ☐ Inspect on sterile field, confirm undamaged and correct item
- ☐ Prepare for use in accordance with the instructions for use (flush, etc.)

#### Completion

- ☐ Retrieve embolic protection device, if used
- ☐ Completion angiography, including evaluation of runoff vessels for emboli
- ☐ Check ACT

### POSTPROCEDURAL

#### Patient Evaluation

- ☐ Evaluate access site
- ☐ Evaluate postsedation status/ Aldrete score
- ☐ Evaluate pulse examination distal to the access site
- ☐ Evaluate pulse examination distal to interventions
- ☐ Record total contrast volume administered and radiation dose

#### Management

- ☐ Confirm access site management plan
- ☐ Confirm anticoagulation plan, including consideration of reversal
- ☐ Confirm antiplatelet therapy
- ☐ Administer loading dose of antiplatelet drug, if indicated

#### Communication

- ☐ Keep accompanying family members informed of outcome and plans

## CHECKLISTS FOR THE SFA INTERVENTIONIST

### COMPLICATION MANAGEMENT: THROMBOSIS

#### Recognition

- ☐ Team member recognizing the angiographic finding, pulse deficit, or other evidence of thrombosis verbally states the problem

#### Consider Contributing Factors

- ☐ Evaluate hemodynamic status
- ☐ Evaluate arterial access, potentially obturating the sheath
- ☐ Angiography to confirm the cessation of bleeding

#### Treatment

##### *Medical*

- ☐ Bolus with heparin
- ☐ Check ACT, maintain therapeutic anticoagulation
- ☐ Consider vasodilator administration (intra-arterial nitroglycerine)

#### Treatment

##### *Interventional*

- ☐ Review options:
  - Treat inflow stenosis
  - Repeat angioplasty
  - Additional stent implantation
  - Aspiration thrombectomy
  - Catheter-directed thrombolysis
  - Mechanical or rheolytic thrombectomy
- ☐ Treat
- ☐ Repeat angiography to evaluate the result

### COMPLICATION MANAGEMENT: ARTERIAL HEMORRHAGE

#### Recognition

- ☐ Team member recognizing abnormal bleeding by hemodynamic instability verbally states the problem
- ☐ Call for help, if needed
- ☐ Ensure hemodynamic monitors are attached and functional
- ☐ Evaluate access site or site of suspected vascular injury, if accessible

#### Hemorrhage Control

- ☐ Apply manual direct pressure if bleeding is from an accessible, compressible site
- ☐ Maintain arterial access, but consider exchanging for a larger-diameter sheath, if needed
- ☐ Place an occlusion balloon
- ☐ Perform angiography to confirm cessation of bleeding

#### Resuscitation

- ☐ Large-bore intravenous line, consider more than one
- ☐ Bolus with crystalloid solution (saline or Plasmalyte)
- ☐ Notify blood bank, send blood specimen, and request for transfusion
- ☐ Consider reversal of anticoagulation (protamine 1 mg to reverse 100 units of heparin)
- ☐ Notify vascular surgeon if endovascular therapy is not practical or if the patient is unstable
- ☐ Notify the operating room staff

#### Treatment

- ☐ Covered stent

#### Communication

- ☐ Inform accompanying family members of situation and plans

multiple critical and sequential steps. Thus, these are situations for which checklists are ideally suited.

Considering necessary factors at key steps of a complex procedure, such as superficial femoral artery (SFA) intervention, can prevent wasteful maneuvers and thereby reduce procedural time, radiation exposure, and contrast use. Checklists may have particular value when not all members of the team have extensive procedural experience (Figure 2) or when procedures are performed in a different setting—a “standard” operating room as opposed to an interventional suite, for example. Endovascular procedures involve unique steps not routinely performed during open operations, making the use of checklists relevant to combined teams performing hybrid procedures. Hence, we have developed checklists that may facilitate delivering timely, efficient, and safe care during endovascular procedures for the treatment of SFA disease.

## PLANNING

Airplane pilots often quote the adage, “Plan the flight, then fly the plan.” Like careful aviators, careful surgeons and interventionists start each procedure with a plan. It is seldom a good idea to approach a potentially complex procedure with the attitude that, “We’ll see what we find and go from there.” As for all interventions, plans for SFA disease interventions should be developed in advance. Treatment plans must be based on the clinical circumstances and indications. Procedural planning should consider the findings from the patient’s history and physical examination, non-invasive studies in the vascular laboratory, and other preprocedural imaging (eg, CT angiography).

Specific elements of a treatment plan should include:

- Patient position and preparation
- Risk mitigation for patients with impaired renal function or history of contrast reaction
- Access site (brachial, contralateral femoral, antegrade [ipsilateral] femoral, or distal [tibiopedal])
- Lesion-crossing strategies (guidewire and support catheter, chronic total occlusion device, re-entry device)
- Potential use of adjunctive imaging (duplex ultrasound, intravascular ultrasound, optical coherency tomography, etc.)
- Potential need for distal embolic protection
- Primary treatment strategy (conventional balloon angioplasty, use of specialty balloons, atherectomy, stenting, etc.)
- Anticipated adjunctive or “bailout” treatment strategies



**Figure 2.** Checklists are useful for educating and training in interventional competencies. The use of simulation, as shown here, can employ checklists for introducing the order of key tasks or as a tool to help with evaluation of trainee performance.

Before scrubbing in for the procedure, the treating specialist should review the plan and the preprocedural imaging. Whenever possible, relevant images should be displayed in the procedure room. Consideration should be given to variations in anatomy, previous interventions, lesion location, and anatomic issues that may affect the access site choice.

## IMMEDIATE PREPROCEDURAL CHECKLIST

Before the start of the procedure, the patient’s weight, creatinine level, and estimated glomerular filtration rate should be recorded. This information may guide drug dosing, estimation of the anticipated heparin dose (60 U/kg is suggested),<sup>9</sup> maximum contrast dose (5 mL X weight in kilograms [maximum value of 300] divided by the serum creatinine),<sup>10</sup> and need for renal-protective adjuncts such as acetylcysteine or sodium bicarbonate.

The team should review the items on the *Immediate Preprocedural Checklist* and confirm that each critical item has been addressed. A standardized preprocedural checklist should contain all



of the requirements from the “Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.” In addition, it should address the specific technical requirements of endovascular procedures.<sup>11</sup>

A “time-out” should be performed with the immediate members of the team present and participating, including the surgeon/interventionist, anesthesiologist, nurse, technician, and any other members. The time-out should include positive identification of the patient and verification of the planned procedure and intended procedure (access and treatment) sites, ideally with the patient participating in the process. The procedure site marking should be confirmed. Prophylactic antibiotic administration (if indicated) should be confirmed. Completion and availability of required documentation should be verified, including the informed consent form. Uncommon but critical contraindications or precautions should be verified, such as contrast allergy, heparin allergy, or pregnancy.

Of particular importance for SFA procedures, the presence of required implants, devices, and special equipment must be verified in order to avoid unnecessary delays or additional procedures due to inadequate supply. On a fundamental level, the availability of required wires, catheters, sheaths, and other supplies should be verified. An appropriate range of balloon and stent sizes should be available. If use of laser or other atherectomy devices, intravascular ultrasound, or reentry catheters is possible, the availability of the specific system and disposables should be confirmed.

Finally, before access and the use of fluoroscopy, each team member in the room should be confirmed to be wearing the proper personal protective equipment, including lead garments and eye protection.

## INTRAPROCEDURAL CHECKLIST

The plan for postprocedural management of the access site must consider the location of entry into the artery, anatomic contraindications to closure devices use (eg, small vessel size, extensive scarring, etc.), or the presence of infection. Ultrasound-guided access is the standard of care for many endovascular specialists, but in addition to ultrasound imaging of the access site, the artery should be specifically evaluated as part of the arteriographic assessment.

Arteriography and other assessments confirm the appropriateness of the planned intervention (eg, intravascular ultrasound or translesional pressure gradients). Therapeutic anticoagulation is used for most SFA interventions, as this reduces the risk of pericatheter and perisheath thrombus formation, thrombosis of the

treatment site, or thrombosis of runoff vessels in the event of embolization. The *Intraprocedural Checklist* should be used to confirm that heparin (or another anticoagulant) has been administered and that an appropriate effect is confirmed by checking that the activated clotting time (ACT) is 250 seconds or greater. For lengthy procedures, the ACT should be checked every 20 to 30 minutes to guide anticoagulant dosing.

For each type of intervention performed in the endovascular suite, it may be helpful to have a checklist to ensure that the necessary supplies are available and that equipment is set up correctly. Options for SFA intervention may include:

- Conventional balloon angioplasty (“plain old balloon angioplasty”)
- Angioplasty with a specialty balloon (cutting, scoring, embolic capture, drug coated, drug eluting, etc.)
- Atherectomy (orbital, rotational, directional, excimer laser ablation, etc.)
- Stent placement (including conventional nitinol, drug eluting, covered, woven nitinol [“biomimetic”), etc.)

Items on the *Intraprocedural Checklist* that are common to all types of SFA interventions include confirmation of the correct sheath size and guidewire size for the endovascular devices that are planned to be used. For every device or implant used, the packaging should be inspected before opening, the expiration date should be verified, and there should be positive confirmation that the size and specifications are correct (via verbal “read back”). This is a critical step, not only to ensure that the intended treatment is provided, but also to avoid waste from discarding items that are found to be other than what was intended. Devices and implants delivered to the sterile field need to be inspected prior to use to confirm that they are what were requested and that they are not damaged.

When the final intervention is performed and postprocedural diagnostic images are recorded, the ACT should be rechecked.

## POSTPROCEDURE

After the procedure is completed, the plan for postprocedure management of the access site, as well as plans for anticoagulation and antiplatelet therapy, should be confirmed on the *Postprocedural Checklist*. If loading doses of clopidogrel or other antiplatelet medications are elected, administration should be confirmed.

The access site and affected extremity should be checked prior to patient movement for hematoma, change in pulse exam, or neurologic symptoms.

## COMPLICATION MANAGEMENT

Major periprocedural complications are uncommon with SFA interventions, but they may manifest suddenly and can require swift and orderly response. Although the experience of the surgeon, nursing, and technical staff is important, the relative rarity of serious events makes the use of a checklist a valuable practice, helping to ensure orderly implementation of a preplanned response.

"Planning for failure" is a strategy used by good teams that perform procedures with significant risks. Patel et al reported improved endovascular outcomes with a preprocedural "mental rehearsal" in hybrid aortic cases.<sup>12</sup> In 2013, Chen developed a checklist for response to a cerebral artery aneurysm perforation and a separate checklist for thrombosis in neurosurgical interventions. The listed expected responses from the surgeon, anesthesiologist, nursing, and technologist staff, each with specific roles and responsibilities.<sup>13</sup> Therefore, we propose the *Arterial Hemorrhage Checklist* and *Thrombosis Checklist*.

For bleeding complications, the interventionist should clearly communicate to the staff about the complication and plans for correction. Serious bleeding from an SFA intervention is rare, but a high puncture or concomitant iliac artery intervention can lead to rapid blood loss into the pelvis. A retroperitoneal hemorrhage can quickly result in shock. Clearly and succinctly articulating the problem and the anticipated next steps is critical, and it is important to verbally confirm that team members have heard and understood what was said.

Arterial access should be maintained. Required equipment, such as a covered stent, tourniquet, or occlusion balloon, should be requested. The nurse should maintain fluids and blood products as necessary and request an anesthesiologist to assist if the patient is in extremis. The technologist should alert the operating room staff of the potential need for open conversion, and the operating room should be prepared if endovascular solutions are limited or if there is hemodynamic instability.

For thrombosis, the interventionist should record the ACT and request an empiric bolus of heparin based on the patient's weight and predetermined dose. If vasospasm is detected at the sheath, intra-arterial nitroglycerin should be given. The nursing staff should

administer fluids, and the technologist should prepare aspiration or thrombolysis devices.

## CONCLUSION

Surgical checklists have demonstrated safety and efficacy in the operative setting, and routine checklist use can be expected to improve the outcomes of SFA and other endovascular procedures as well. To be practical, checklists should be both simple and concise, without attempting to exhaustively address every detail or possibility. The proposed checklists for SFA interventions cover the key parts of the procedure to ensure efficiency and safety.

Building upon the basic endovascular checklist, customized and more complex checklists can be developed and implemented to suit the varying experience level of providers and specific procedures. ■

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