Circulation

AHA SCIENTIFIC STATEMENT

Evidence-Based Practices in the Cardiac Catheterization Laboratory

A Scientific Statement From the American Heart Association

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ABSTRACT: Cardiac catheterization procedures have rapidly evolved and expanded in scope and techniques over the past few decades. However, although some practices have emerged based on evidence, many traditions have persisted based on beliefs and theoretical concerns. The aim of this review is to highlight common preprocedure, intraprocedure, and postprocedure catheterization laboratory practices where evidence has accumulated over the past few decades to support or discount traditionally held practices.

Key Words: AHA Scientific Statements ■ cardiac catheterization ■ evidence based ■ percutaneous coronary intervention

More than 1 million cardiac catheterization procedures are performed every year in the United States, primarily to diagnose and treat patients with suspected or confirmed coronary heart disease and other related disorders.[1] Since the introduction of selective coronary angiography by Mason Sones in the 1950s, the catheterization procedure has rapidly evolved and expanded in scope and technique, and collectively now includes coronary, peripheral vascular, and structural heart procedures as well. During this evolution, many practices have emerged based on evidence, whereas many traditions have persisted based on beliefs and theoretical concerns. Some of these traditions are blindly followed and not based on sound contemporary evidence. The 2016 Society for Cardiovascular Angiography and Interventions expert consensus statement on best practices in the cardiac catheterization laboratory outlined the preprocedure, intraprocedure, and postprocedure practices,[2] focusing on the standard issues surrounding catheterization management. The aim of this present review is to highlight common preprocedure, intraprocedure, and postprocedure catheterization laboratory practices in which there is no universal agreement on the approach to care, but rather where evidence has accumulated over the past few decades to support or discount these practices.

PREPROCEDURE EVIDENCE–BASED PRACTICES

Optimal Duration of Nothing by Mouth Before the Procedure

Practice

It is a common practice to require patients to have "nothing by mouth past midnight" or "for several hours" before an invasive cardiac catheterization procedure.

Rationale

The rationale for this age-old practice is 2-fold. First, emesis was common when ionic, high-osmolar contrast agents were used and was also a risk during procedures using conscious sedation. In a state of decreased consciousness, airway protective reflexes could be attenuated. If emesis were to occur, there would be a risk of pulmonary aspiration. A second reason for maintaining

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nothing by mouth is avoidance of the risk of aspiration if complications during the procedure lead to the need for emergency induction of general anesthesia for intubation.

Evidence

The evidence to support extended (>12 hours) nothing-by-mouth practice is limited. The incidence of emesis in the modern era of practice with iso-osmolar or hypo-osmolar contrast agents is low. Moreover, the need for emergency surgery in patients undergoing percutaneous coronary intervention is also extremely rare (≤0.1%). In addition, there is no compelling evidence to suggest that prolonged nothing by mouth (or any nothing by mouth for that matter) will make procedures requiring conscious sedation any safer. Meta-analysis of randomized controlled trials (RCTs) comparing fasting times of 2 to 4 hours with >4 hours showed no difference in gastric volume and gastric pH with a shorter fasting time.[3,4] In fact, shorter fasting times were associated with less thirst and hunger (and therefore better patient satisfaction) and lower risk of aspiration.[3,4] Moreover, prolonged fasting can lead to adverse consequences, including dehydration; increased risk of acute kidney injury, especially in patients with diabetes and chronic kidney disease; hypoglycemia; and decreased patient satisfaction. In the recent single-center CHOW NOW trial (Can We Safely Have Our Patients Eat With Cardiac Catherization – Nix or Allow; The CHOW NOW Study),[5] patients were randomly assigned to standard fasting (nothing by mouth after midnight with clear liquids up to 2 hours before the procedure) versus nonfasting (no restriction on oral intake). The incidence of the primary composite outcome (composite of contrast-induced nephropathy, periprocedure hypotension, aspiration pneumonia, nausea/vomiting, hypoglycemia, and hyperglycemia) was evaluated in 599 patients undergoing cardiac catheterization. In this trial, the nonfasting group was noninferior (P=0.059) to the standard fasting group with respect to the primary outcome (11.3% versus 9.8%; P=0.65), with no differences in patient satisfaction and hospital length of stay.[5] In an RCT of 2091 participants referred for a nonemergency contrast-enhanced computed tomography scan, unrestricted consumption of liquids and solids up to the time of the scan was not associated with a greater risk of aspiration pneumonitis (primary outcome 0% versus 0%) or a clinically significant increase in rates of adverse gastrointestinal symptoms (vomiting: 2.6% versus 3.0% [P=0.58]) when compared with at least 4 hours of fasting.[5a]

Summary

The evidence to support extended fasting/nothing by mouth before procedures requiring conscious sedation is weak. The incidence of emesis or the need for emergency surgery in contemporary practice is low. In addition, prolonged fasting can lead to adverse consequences in susceptible individuals. The 2017 updated practice guideline from the American Society of Anesthesiologists recommends shorter fasting times than were traditionally put forth: clear liquids are permitted up to 2 hours before and a light meal up to 6 hours before the procedure.[3] Although recent clinical trials suggest that no fasting is noninferior to the standard current American Society of Anesthesiologists recommendations, further studies are required to evaluate whether "no nothing by mouth" provides a superior management strategy. Nothing by mouth should be at the discretion of the interventionalist and may not be necessary for patients who undergo procedures with only local anesthesia and no sedation, in which upper airway protective reflexes are not impaired and no risk factors for pulmonary aspiration are present.

Medications

Practice

It is common practice to recommend holding medications such as metformin, glucose-lowering medications, renin-angiotensin-aldosterone blockers, and anticoagulants before the cardiac catheterization procedure. However, the evidence for these recommendations is not clear (Figure 1).

Metformin

Rationale

The general recommendation is to hold metformin on the day of the procedure and 48 hours after coronary angiography.[2] The rationale for this recommendation is that patients with diabetes have a high risk of contrast-associated acute kidney injury (CA-AKI) and that patients who develop AKI while on metformin have an increased risk of metformin-induced lactic acidosis, which is characterized by an elevated blood lactate concentration, decreased blood pH, increased anion gap, and higher mortality.

Evidence

The evidence to support this recommendation is weak. A randomized trial of metformin versus placebo initiated early after primary percutaneous coronary intervention (PCI) in patients with ST-segment–elevation myocardial infarction who do not have diabetes or renal dysfunction showed no increase in AKI with metformin.[6] Similarly, in a randomized trial of patients with diabetes with no or mild renal impairment, metformin continuation during angiography was not associated with higher CA-AKI or metformin-induced lactic acidosis compared with metformin discontinuation. In fact, in the group that continued metformin, the rate of reduction in estimated glomerular filtration rate (eGFR) after coronary angiography was significantly lower than in those who discontinued metformin, suggesting perhaps a beneficial effect of metformin on renal function.[7] Moreover, a Cochrane meta-analysis of 347 comparative trials and cohort studies, including 143 studies that allowed for the inclusion of patients with renal insufficiency, showed no cases of fatal or nonfatal lactic acidosis in 70 490 patient-years of metformin use or in 55 451 patient-years in the non-

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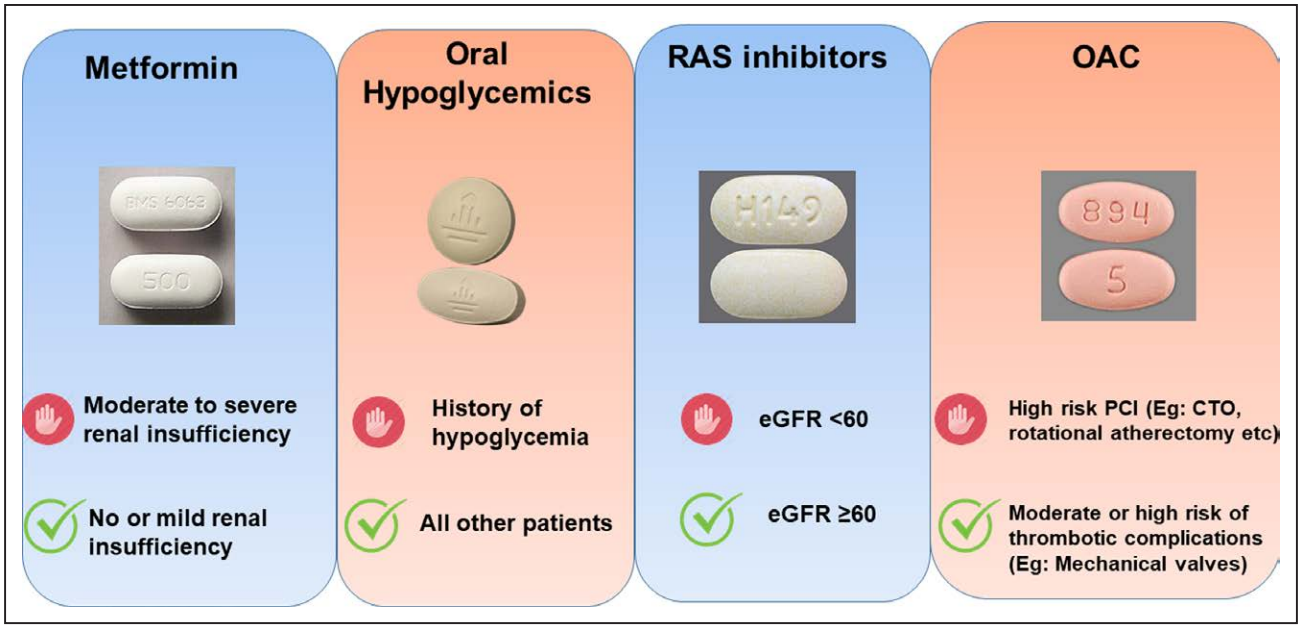

Figure 1. Holding medications before cardiac catheterization.
CTO indicates chronic total occlusion; eGFR, estimated glomerular filtration rate; OAC, oral anticoagulant therapy; PCI, percutaneous coronary intervention; and RAS, renin-angiotensin blockers.

metformin group, suggesting that metformin-associated lactic acidosis is rare.[8]

Summary

Available evidence does not support a deleterious effect of continuing metformin in patients with or without diabetes who have no or mild renal impairment.[9] The impact of metformin continuation during angiography in patients with moderate or severe renal impairment is unknown, because it is unlikely to be used in this patient population. Metformin is contraindicated in patients with eGFR <30 mL·min^{-1}·1.73 m^{-2} and recommended to be avoided in those with eGFR 30 to 45 mL·min^{-1}·1.73 m^{-2}, and it should be avoided altogether in these groups of patients.

Glucose-Lowering Medications

Rationale

It is common practice to recommend holding glucose-lowering medications (oral glycemic control therapies and insulin) or to continue a half-dose of insulin before cardiac catheterization procedures driven by concerns of hypoglycemia, given that patients may have nothing by mouth before the procedure.[10]

Evidence

In an RCT of patients with diabetes (172 patients) randomly assigned to continue versus hold glucose-lowering medications (including insulin) before coronary angiography, the continue group achieved better glycemic control at the time of the procedure than the hold group (117 [97–151] versus 134 [117–172] mg/dL, *P*=0.002), with no increase in adverse events, including the incidence of hypoglycemic events.[11] Two patients in the continue group developed hypoglycemic events (none in the hold group), and both of them were on long-acting insulin in addition to oral glycemic control agents. Moreover, in a subset of patients in the trial who underwent platelet activity measurements (n=75), the continue group had lower platelet activity than the hold group, suggesting a potential beneficial effect of continuing glucose-lowering medication.[11]

Summary

In the present era, for coronary angiography, where nothing-by-mouth times and procedure times are shorter, sedation is minimal, and patients are able to eat shortly after the procedure, continuing glucose-lowering medication (especially oral glycemic control agents) is reasonable, preserves optimal glycemic control, and avoids the potential deleterious effect of hyperglycemia including platelet activation. The common practice of reduced-dose insulin versus continuing full-dose insulin before the procedure has not been tested in clinical trials. Of note, there are no specific recommendations regarding newer agents (such as sodium-glucose cotransporter-2 inhibitors) that have a lower to no risk of hypoglycemia.

Renin-Angiotensin Blockers

Rationale

In patients at risk for CA-AKI, it is a common practice to advocate holding angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). The rationale for this practice stems from the notion that ACE inhibitors/ARBs decrease the glomerular filtration rate, resulting in an increase in serum creatinine and predisposition toward CA-AKI.

Evidence

Observational studies are conflicting, with some studies showing a reduction in CA-AKI,[12] whereas others have shown an increase in CA-AKI[13] in recipients of ACE inhibitors/ARBs compared with nonrecipients. Three randomized trials have tested holding versus continuing ACE inhibitors/ARBs before the procedure. In the trial by Wolak et al (94 patients),[14] there was overall no difference in the change in eGFR in the groups in which ACE inhibitors/ARBs were held versus controls in which the medication was continued. However, in the subgroup of patients with eGFR <60 mL/min at baseline, there was statistically a lower decline in eGFR in the held group. In the second trial by Rosenstock et al[15] (220 patients), in patients with eGFR <60 mL/min, there was a reduction in the incidence of CA-AKI when ACE inhibitor/ARB therapy was held compared with continued, but this did not reach statistical significance (3.7% [4/107] versus 6.2% [7/113]). Last, in the CAPTAIN trial (Angiotensin Converting Enzyme Inhibitors and Contrast Induced Nephropathy in Patients Receiving a Cardiac Catheterization; 208 patients), of the patients with moderate renal insufficiency,[16] holding ACE inhibitors/ARBs before coronary angiography lowered the incidence of CA-AKI (10.9% versus 18.4%; *P*=0.16) and resulted in a lower rise in mean serum creatinine (0.1±0.3 mg/dL versus 0.3±0.5 mg/dL, *P*=0.03).

Summary

In patients without renal dysfunction, ACE inhibitors/ARBs can be safely continued during coronary angiography. However, in patients with renal dysfunction (eGFR <60 mL/min), data from randomized trials suggest that holding ACE inhibitors/ARBs before the procedure may lead to potential benefit at reducing eGFR decline or reducing the risk of CA-AKI compared with continuing these medications before the procedure and resuming a few days after the procedure (when AKI has been ruled out or overcome). However, the strength of evidence is weak, and more studies are needed to test this conclusively.

Oral Anticoagulants

Rationale

In general, it is recommended to stop oral anticoagulant therapy (OAC; warfarin or direct OAC) before cardiac catheterization to minimize bleeding (both access and nonaccess sites) during and immediately after the procedure (Table 1). Moreover, in patients requiring PCI, continuation of OAC may pose issues regarding the choice of anticoagulant therapy at the time of PCI. However, the downside of holding OAC includes potential ischemic complications during the time the medication is held and prolonged time to return to a therapeutic international normalized ratio after restarting (with warfarin). As such, in patients at high risk of thrombotic complications (such as those with mechanical valves), bridging with low-molecular-weight heparin is often recommended.

Table 1. Timing of Holding Oral Anticoagulants Before Cardiac Catheterization Procedures

Oral anticoagulant	eGFR ≥80 mL· min^{-1}· 1.73 m^{-2}	eGFR 50–79 mL· min^{-1}· 1.73 m^{-2}	eGFR 30–49 mL· min^{-1}· 1.73 m^{-2}	eGFR 15–29 mL· min^{-1}· 1.73 m^{-2}
Warfarin	3 d before the procedure for a target international normalized ratio of <1.8 for transfemoral procedures and <2.2 for transradial procedures			
Dabigatran	≥24 h	≥36 h	≥48 h	Should not be used
Rivaroxaban	≥24 h	≥24 h	≥24 h	≥36 h
Apixaban	≥24 h	≥24 h	≥24 h	≥36 h
Edoxaban	≥24 h	≥24 h	≥24 h	≥36 h

Duration may differ based on access site (radial vs femoral) and the bleeding risk (diagnostic only vs percutaneous coronary intervention), and agent-specific Xa levels can be checked for guidance. eGFR indicates estimated glomerular filtration rate.

Evidence

In a small randomized trial (n=61 patients) of holding warfarin ≥48 hours versus continuing warfarin (international normalized ratio, 2.0–3.0) in patients who underwent elective diagnostic transfemoral angiography followed by manual compression for hemostasis, there was no difference in hematoma, vascular complications, or duration of length of stay between the 2 groups.[17] In a meta-analysis of 8 angiography studies (7 observational and 1 RCT), in which 81% of patients had PCI and 35% had transradial access, uninterrupted OAC was associated with major adverse cardiac and cerebrovascular events and bleeding complications similar to interrupted OAC.[18] This meta-analysis included heterogeneous studies that included femoral and transradial access and bridging therapy. Uninterrupted OAC was also associated with lower bleeding compared with interrupted OAC with bridging.[18] In an observational study of patients who underwent coronary angiography or intervention on uninterrupted OAC with warfarin, radial access was associated with lower bleeding and vascular access complications compared with femoral access in the group that underwent PCI.[19]

Summary

In patients who are at moderate or high risk of thrombotic complications (such as those with mechanical valves or those with atrial fibrillation and a history of stroke), continuation of OAC is reasonable, especially when diagnostic coronary angiography or PCI can be performed via the transradial route.[20] The decision to continue OAC should be made based on the thrombotic risk of the indication for OAC, the bleeding risk associated with PCI (eg, chronic total occlusion, need for rotational atherectomy), urgency of the procedure, and radial expertise. In patients in whom OAC is continued and the access site needs to be switched, considerations should be given to contralateral transradial or the use of ulnar access before considering transfemoral access. For situations in which the bleeding risk is high and the ischemic risk of withholding OAC

is low, Table 1 depicts the optimal timing for withholding OAC.[21,22]

Allergies to Shellfish

Practice

Any type of allergy to medications, food, and even atopy should be clearly documented and the type of reaction noted when available. In addition, prior contrast exposure with an adverse reaction is taken as an early warning for a repeat episode. Even now, patients with shellfish allergy are considered at high risk of having an allergic reaction to iodinated contrast media and are often pretreated to prevent allergic reactions.[23]

Rationale

Studies in the 1970s showed a higher risk of reaction to radiocontrast agents in patients who had prior allergic reactions to shellfish or seafood. Because shellfish/seafood have a higher iodine content, this was propagated as iodine allergy.

Evidence

Iodine is present throughout the body (eg, thyroid hormones, amino acids) and therefore cannot be an allergen. The major allergen in shellfish is tropomyosin and not iodine.[24] Allergic reactions are mediated by IgE (immunoglobulin E) to tropomyosin, and, because of immune memory, each subsequent exposure can lead to a more severe anaphylactic reaction. The risk of reaction to reexposure for such an immune-mediated mechanism therefore approaches 100%. However, the reaction to radiocontrast agents is an anaphylactoid reaction and therefore not immune (IgE) mediated. The cause of the anaphylactoid reaction to radiocontrast agents is thought to be the hyperosmolarity of contrast compared with blood. If not an immune-mediated mechanism, the risk with reexposure is far less than 100% and is usually ≈7% with low-osmolar contrast media. In previous studies linking allergic reactions to shellfish with reactions to radiocontrast agents, a similar incidence of allergies to other substances such as milk was seen in patients who had a reaction to radiocontrast agents. Thus, general atopy (including asthma) is probably a risk factor for reaction to radiocontrast agents.

Summary

Patients with a history of shellfish allergy alone do not need premedication before undergoing cardiac catheterization. In patients with a previous moderate or severe acute reaction to contrast media, premedication prophylaxis for an allergic reaction is recommended.

Steroid Premedication: Oral Versus Intravenous

Practice

In patients with a prior reaction to contrast media, premedication prophylaxis with steroids (prednisone 50 mg orally 13 hours, 7 hours, and 1 hour before the procedure) and an antihistamine are commonly recommended. However, accelerated intravenous steroid regimens are used as an alternative when prolonged prophylaxis is impractical (eg, in patients who need urgent/emergency procedures).

Rationale

Accelerated intravenous steroid regimens can potentially reduce the indirect harms related to prolonged oral prophylaxis such as significantly longer hospital length of stay, a delay in diagnosis, significantly more hospital-acquired infections, and significantly greater health care–related costs.[25]

Evidence

In a trial of 6763 patients randomly assigned to a 2-dose corticosteroid regimen (32 mg methylprednisolone 12 hours and 2 hours before the procedure) versus a 1-dose corticosteroid regimen (32 mg methylprednisolone 2 hours before the procedure) versus matching placebo, the 2-dose but not the 1-dose regimen significantly reduced all types of reactions to ionic contrast media in average-risk patients.[26] However, high-osmolar ionic contrast medium was used in this trial, and the rates of reactions were comparable to the rates of patients who were not premedicated but received nonionic contrast media.[26] In a second randomized trial of patients receiving nonionic contrast media (N=1155), the 2-dose oral corticosteroid regimen was superior to placebo at reducing the overall reactions.[27] Patients with a history of severe reactions to contrast media were excluded from both trials. No randomized trial has compared oral steroid prophylaxis with accelerated intravenous prophylaxis. One observational study has shown noninferiority of a 5-hour intravenous regimen compared with the 13-hour oral pretreatment regimen in patients with a prior reaction to contrast media who underwent CT scan with low-osmolar contrast media.[28]

Summary

Oral pretreatment regimen (prednisone 50 mg orally 13 hours, 7 hours, and 1 hour before the procedure or methylprednisolone 32 mg orally 12 hours and 2 hours before the procedure) are preferred to an accelerated intravenous regimen in patients with prior reaction to contrast media. Of note, the only 2 randomized trials excluded patients with prior severe reaction to contrast media. The protection against reaction even with extended oral corticosteroid is not ironclad, and breakthrough reactions occur at a rate of ≈2.1%.[29] The efficacy of accelerated intravenous prophylaxis has not been established in a randomized trial, but low-level evidence for noninferiority of a 5-hour intravenous regimen (intravenous methylprednisolone 40 mg or hydrocortisone 200 mg 5 hours and 1 hour before the procedure) to that of the 13-hour oral regimen was shown in an observational study. Many catheterization laboratories administer H1 (eg, Benadryl) or H2 (eg, famotidine) blockers along with steroids. However, there are minimal data to support or disprove this practice.

INTRAPROCEDURE EVIDENCE-BASED PRACTICES

Sedation, Anesthesia, and Analgesia Considerations

Practice

Most procedures performed in the cardiac catheterization laboratory are done using conscious sedation, with general anesthesia reserved only for the most complex and critically ill patients.[30] Best practice includes assessment and documentation of the suitability to receive moderate sedation (American Society of Anesthesiologists class and Mallampati scale). Evidence-based considerations are outlined below.

Combination of Benzodiazepine and Opioids

Rationale

Ideal sedation techniques provide an acceptable level of patient comfort and anxiolysis with minimal respiratory depression.[31] Midazolam is the most used short-acting benzodiazepine for sedation because it has a favorable pharmacokinetic profile with a half-life of ≈2 hours in nonelderly adults. A combination of short-acting benzodiazepine (such as midazolam) and opioids (such as fentanyl) is commonly used. The rationale is to use a combination of a sedative/anxiolytic with an analgesic. However, there is concern regarding the empiric use of opiates during medical procedures in light of potential opioid dependency and misuse. Considerable variability exists in clinical practice regarding sedation. In 1 survey, any sedation during cardiac catheterization was used by 92% of cardiologists in North America, but only by 38% in other countries.[32]

Evidence

The need for opiates for all procedures in the cardiac catheterization laboratory is unclear. In a randomized trial (n=90) of patients undergoing diagnostic coronary angiography, there was no difference in sedation scores, anxiolysis, and patient and cardiologist satisfaction between either midazolam+fentanyl versus midazolam alone.[33] Other trials have similarly shown no difference in pain score between a regimen with or without opiates.[34] In the PACIFY (Platelet Aggregation after Ticagrelor Inhibition and Fentanyl) randomized trial of patients undergoing coronary angiography with or without PCI,[35] mean self-reported maximal intraprocedure pain was 1.5 (on a 10-point numeric scale) with fentanyl versus 2.3 without fentanyl (P=0.14). However, the degree of platelet inhibition after a loading dose of ticagrelor, and ticagrelor concentrations, were lower in the fentanyl arm compared with the no-fentanyl arm because of slowed gastric emptying and impaired absorption of oral $P2Y_{12}$ platelet inhibitors.

Regarding anxiolytics, the half-life of typical sedatives is prolonged in elderly patients and the very young. The risk of respiratory compromise is more pronounced in elderly patients[36] who are also more susceptible to postprocedure delirium.[37–40] There are currently no high-level studies confirming that midazolam is associated with adverse events in elderly patients; however, consensus articles recommend that benzodiazepines should be minimized or eliminated in elderly patients.[41] A prospective randomized multicenter trial is currently underway to examine the impact of midazolam as a contributory factor in postprocedure delirium.[42]

Summary

In most patients, opiates may not be needed to achieve optimal sedation, and the risk of opioid dependency is a concern.[43] Further concern exists that absorption of orally administered agents given during the catheterization procedure could be reduced by opioids. For this reason, the use of opiates in nonelderly patients can be individualized based on the complexity of the procedure and the response to initial sedation with an anxiolytic agent alone. However, in elderly patients, benzodiazepines should be used with caution to avoid delirium, and thus consideration may be given to opioid-based regimens without a benzodiazepine.

Vascular Access

Since approximately 2006, the adoption of radial access for coronary angiography and PCI in the United States has steadily grown and, in many places, has become the default access method. RCTs and observational studies have shown that radial access reduces major bleeding and vascular complications, and in high-risk patients, like those with ST-segment–elevation myocardial infarction, may reduce mortality. Despite this body of data, the use of the radial approach lags behind in some subgroups. Some specific considerations are presented in the following sections.

Transradial Access in Patients With Prior Mastectomy

Practice. Transradial access is routinely avoided in patients with ipsilateral mastectomy.

Rationale. Patients who have undergone radical mastectomy are often advised to avoid any arterial or venous access, including phlebotomy, on the ipsilateral side because of the theoretical risk of infection and subsequent lymphedema.

Evidence. Yadav et al[44] retrospectively analyzed 129 patients with a history of breast cancer who underwent cardiac catheterization. Forty-two procedures were performed with radial artery access on the same side as the breast cancer, and 7 of these patients also underwent right-heart catheterization using ipsilateral forearm vein access. At 4 years of follow-up, there were no cases of postprocedure soft-tissue infection or lymphedema on the side of access.

Summary. Although it is generally recommended to avoid ipsilateral arterial or venous access because of

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concern for access site infection and subsequent lymphedema, the risk of infection with transradial access is exceedingly small, and observational studies suggest the safety of such an approach. However, it is important that the radial approach should be patient centered, and the decision to obtain ipsilateral radial access should be discussed with the patient.

Transradial Access in Patients With Abnormal Collateral Hand Circulation

Practice. Radial access is avoided in those with abnormal collateral circulation to the hand.

Rationale. The Allen or Barbeau tests were designed to assess the presence of an intact palmar arch connecting the radial artery with branches of the ulnar artery. The Barbeau test uses the pulse oximetric waveform pattern from the thumb after manual occlusion of the ipsilateral radial artery and categorizes the results into 1 of 4 categories: A, B, C, or D, with C and D categories suggesting the lack of an intact palmar arch. Radial artery access in patients with abnormal Allen or Barbeau test results is avoided because of the theoretical risk of hand ischemia if the radial artery occludes.

Evidence. Valgimigli et al[45] aimed to assess the risk of radial access in 203 patients with normal, intermediate, and abnormal Allen test results. At baseline, the Barbeau test results were consistent with the Allen test: patients with abnormal Allen test results more often had a type C or D Barbeau test. At 1 year of follow-up, 3 patients had persistent radial artery occlusion; there was no difference in the incidence of hand ischemia, handgrip strength, or discomfort across the 3 Allen test categories. In addition, the Barbeau test evolved such that a significant proportion of patients with baseline type C or D results developed type A or B results at 1 year.

Summary. Observational studies suggest that tests of collateral circulation are dynamic and do not predict hand ischemia. Thus, they are not useful for determining the safety of radial access.

Transradial Access in Patients Needing Coronary Artery Bypass Graft Surgery or Dialysis

Practice. Transradial access is increasingly used for coronary diagnostic and interventional procedures. However, there is concern that transradial access can compromise use of the radial artery for arteriovenous fistula or as a conduit for coronary artery bypass graft surgery in patients who need them.

Rationale. Transradial access can cause local puncture site injury and can potentially impact long-term graft patency or suitability for arteriovenous fistula.

Evidence. Acute radial artery injuries are common after transradial procedures. Intimal tears (67.1%) and medial dissections (35.6%) have been described in studies using optical coherence tomography.[46] These changes were more common in the distal segment than in the proximal segment and more common after repeat procedures.[46] Others have shown a significant increase in the radial artery intimal layer volume and a decrease in lumen volume 9 months after transradial PCI compared with baseline.[47] Heiss et al[48] showed that transradial catheterization not only leads to dysfunction of the radial artery (as measured by flow-mediated dilatation) but also the upstream brachial artery, which was more severe and sustained in smokers and with increasing numbers of catheters. In addition, 1 study showed reduced stenosis-free graft patency rates in patients who received radial artery graft with prior transradial access than without (77% versus 98%; P=0.017).

Summary. Evidence suggests high rates of acute and chronic changes in the radial artery after transradial access and reduced patency of the graft when used as a bypass conduit. Radial artery occlusion and injury rates can be minimized by following good transradial access techniques, including the use of smaller sheaths, hydrophilic sheaths, minimizing catheter exchanges, and using patent hemostasis techniques. It is preferable to avoid radial artery as a bypass conduit if it has been used previously for transradial access. In situations where conduit options are limited, it is preferable to avoid using the radial artery for at least 3 months after transradial access and to assess patency and flow characteristics with Doppler before use as a conduit. In patients for whom coronary artery bypass graft surgery is planned, alternative access (eg, dominant radial artery, distal radial artery, ulnar artery, or femoral artery) should be considered. Finally, in patients who need dialysis, alternative access (distal radial artery or femoral artery) should be considered.

Safe Femoral Access Technique

In comparison with transradial access, transfemoral access is associated with increased risk of bleeding and vascular complications. As such, a strategy of safe femoral access is advocated. This includes review of prior femoral angiograms when available to identify the optimal site for femoral puncture and the use of ultrasound guidance and micropuncture needle for access in addition to fluoroscopic landmarks.

Standard Access Versus Ultrasound-Guided Femoral Access

Practice. Standard transfemoral access includes the use of fluoroscopic landmarks for locating the head of the femur. However, ultrasound-guided access is recommended as part of the safe femoral access technique.

Rationale. Although fluoroscopic landmark is helpful to avoid a high femoral artery puncture, the variability in the relationship of the femoral bifurcation makes this an

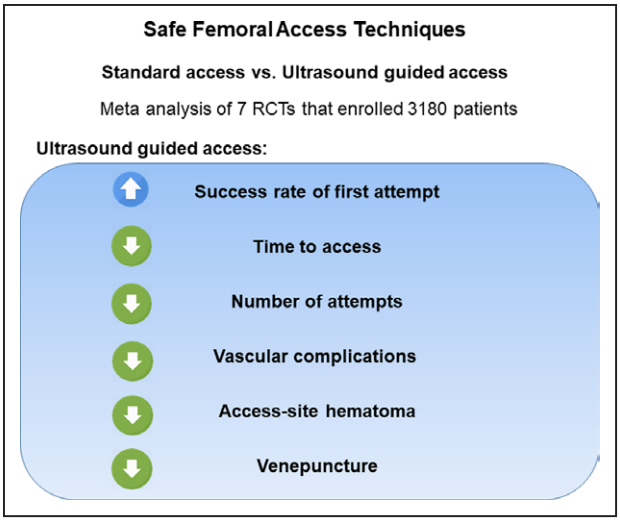

Figure 2. Safe femoral access technique.
Use of ultrasound guidance versus standard access technique. Data derived from Sorrentino et al.[49] RCTs indicates randomized controlled trials.

imprecise landmark. Ultrasound guidance permits visualization of femoral artery bifurcation and that of any overlying femoral vein and permits single wall puncture under direct visualization and, as such, has the potential to reduce the risk of vascular and bleeding complications.

Evidence. A meta-analysis of 7 RCTs that enrolled 3180 patients randomly assigned to standard access versus ultrasound-guided femoral access showed a higher success rate of first attempt (82.0% versus 58.7%; $P<0.0001$), reduced time to access, number of attempts, vascular complications (1.3% versus 3.0%; $P=0.02$), access-site hematoma (1.2% versus 3.3%; $P=0.01$), and venipuncture (3.6% versus 12.1%; $P<0.00001$), but there were nonsignificant differences in major bleeding (0.7% versus 1.4%; $P=0.19$) with ultrasound-guided femoral access compared with standard access (Figure 2).[49]

Summary. Cumulative evidence from randomized trials shows a significant reduction in vascular complications with ultrasound-guided femoral access compared with standard access. Ultrasound guidance is also useful to avoid areas where the common femoral artery is stenosed or has calcium in its anterior wall. Avoidance of a calcified segment facilitates closure with a vascular closure device. Ultrasound-guided femoral access should be used as part of safe femoral access technique to reduce the risk of complications.

Standard 18-Gauge Needle Versus Micropuncture Needle for Femoral Access

Practice. A standard 18-gauge needle is used for femoral access. However, a micropuncture needle is recommended as part of the safe femoral access technique.

Rationale. The micropuncture needle is a 21-gauge needle and the arteriotomy with the micropuncture needle is 56% smaller than that of an 18-gauge needle and, as such, can potentially reduce the risk of vascular and bleeding complications.

Evidence. Only 1 RCT, the FEMORIS trial (Femoral Micropuncture or Routine Introducer Study) has been completed thus far. This is a single-center trial that randomly assigned 402 patients (42% PCI) to an 18-gauge standard needle versus 21-gauge micropuncture needle.[50] The trial was stopped prematurely because of the withdrawal of funding from the sponsors. The primary end point of composite femoral access complications was lower with the micropuncture needle than with the standard needle (9.4% versus 15.5%; $P=0.10$) but did not reach statistical significance. In prespecified subgroups, such as those not undergoing PCI (3.3% versus 12.4%; $P=0.02$), women (5.8% versus 17.4%; $P=0.05$), elective nonacute coronary syndrome cases (8.6% versus 18.5%; $P=0.03$), and those with a final sheath size ≤6F catheter (6.4% versus 15.1%; $P=0.02$), the 21-gauge micropuncture needle was associated with lower rates of the primary end point.[50]

Summary. The evidence for the superiority of micropuncture access over standard 18-gauge access remains inconclusive because the only randomized trial conducted to date was prematurely terminated. Despite this, the micropuncture access technique offers theoretical advantages; the results from the randomized trial point to numerically lower femoral access complications and may be considered as part of the safe femoral access strategy.

Metal Allergies for Devices

Nickel allergy is a common cause of allergic contact dermatitis, often associated with earrings and other jewelry for body piercings.[51] US Food and Drug Administration–required package inserts for coronary stents specifically state that their use is contraindicated in patients who are allergic to any of the device's components, and specifically to nickel or surgical stainless steel 316.[52]

Practice. Stents and other nickel-containing devices should be used with caution in patients with a history of nickel allergy.

Evidence. Patients with nickel allergies developed increased intimal hyperplasia and restenosis with bare metal stents, but there were no reports of eosinophilic reactions.[53] However, other studies have not found a relationship between nickel allergy and restenosis, especially in the drug-eluting stent era.[54] Of note, all commercially available stents contain nickel, although the nickel content among different stents is variable.

Summary. The evidence to support nickel allergy and worse outcome with stents is weak. Testing for nickel

Table 2. Current Practices in the Catheterization Laboratory and New Best Practices

Current practice	New considerations
Fasting after midnight before catheterization procedures	Fasting for 2 h for clear liquids and 6 h for solids (light meal) before catheterization procedures. No fasting has proven noninferior to fasting and should be explored further.
Hold metformin for 48 h after catheterization procedures	Continue treatment with metformin pre- and postprocedure in those without severe renal dysfunction.
Hold other glucose-lowering agents before catheterization procedures	Do not withhold glucose-lowering agents before catheterization procedures. Data on half-dose insulin regimens are insufficient.
Hold ACE or ARB inhibitors before catheterization procedures	Hold ACE or ARB inhibitors if eGFR rate <60 mL· min^{-1}·1.73 m^{-2} before catheterization procedures. Do not withhold ACE or ARB inhibitors if eGFR is normal before catheterization procedures.
Hold oral anticoagulants before catheterization procedures	Continue oral anticoagulants before diagnostic procedures in patients with high risk of thrombotic complications and when transradial access can be used.
Consider premedication to prevent an allergic reaction in patients with a history of an allergy to shellfish, but without a history of allergy to contrast agents	It is not necessary to use premedication to prevent an allergic reaction in patients with a history of an allergy to shellfish who do not have a history of an allergy to contrast agents. It is important to note that general atopy (including food) can increase the overall risk of other allergic reactions, including that to radio contrast agents.
Accelerated intravenous corticosteroids are effective alternatives to extended oral corticosteroid prophylaxis in patients with contrast allergy	Efficacy of accelerated intravenous corticosteroids remains to be proven.
Procedure sedation can be given with a cocktail of a benzodiazepine and opioid agent to achieve the best sedation	Procedural sedation should be individualized based on the patient's age, underlying cognition, and risk of opioid addiction.
Ipsilateral transradial access in patients with prior mastectomy should be avoided	Ipsilateral transradial access in patients with prior mastectomy can be performed with a low risk of infection or other related complications and should be individualized based on a thorough discussion with the patient.
Routine assessment of radial and ulnar patency should be performed using the Allen or Barbeau test	Routine assessment of radial and ulnar patency using the Allen or Barbeau test is not necessary.
Transradial access can be considered for patients on dialysis or in those who require coronary artery bypass graft surgery	Alternative access should be considered for such patients (eg, access using the dominant radial artery, distal radial artery, ulnar artery, or femoral artery).
Standard access (without ultrasound) is used for femoral arterial cannulation	Ultrasound-guided access should be considered as part of a safe femoral access technique.
Stents should be used with caution in patients with an allergy to nickel	Consider use of a drug-eluting stent with a durable polymer in patients with a nickel allergy.
Avoid the use of nonemergency magnetic resonance imaging examination in the 4 to 6 wk after stent implantation	Recent coronary stent implantation is not a contraindication to magnetic resonance imaging.

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; and eGFR, estimated glomerular filtration rate.

allergy is not recommended. In addition, all commercially available stents contain nickel, although in small quantities. It may be prudent to consider implantation of a durable polymer drug-eluting stent in such patients because the polymer will isolate the metal surface from being in contact with the tissue.

POSTPROCEDURE EVIDENCE-BASED PRACTICE

Magnetic Resonance Imaging in Patients With a Newly Implanted Coronary Stent

Practice

Avoid the use of nonemergency magnetic resonance imaging (MRI) examination in the 4 to 6 weeks after stent implantation.

Rationale

Medical implants with ferromagnetic properties, including early coronary stents, pose a potential hazard within the active magnetic field during diagnostic MRI. These proposed hazards include device migration if exposed to a magnetic field before stent reendothelialization and heating and tissue damage within the strong magnetic field required for imaging.[55] Such concerns have resulted in some institutions and practices instituting a prohibition of MRI within 2 to 6 weeks of coronary stent implantation and requirements for MRI device compatibility assessment in patients with stents before the performance of MRI, resulting in potential significant delays in diagnostic testing.[55–58]

Evidence

MRI affects ferromagnetic materials via attraction, creating potential for a projectile effect or the po-

tential to move in space. In addition, ferromagnetic materials may act as antennae for the pulsed radiofrequency energy used during MRI and heat, creating the potential for local thermal damage and vascular injury or disruption of the stent coatings (polymeric coatings or drug components of drug-eluting stents).[55–57] Most currently used cardiac devices, including all commercially available coronary stents, exhibit minimal or absent ferromagnetic properties.[55] In vivo and ex vivo testing have demonstrated early and intermediate-term safety regarding the lack of heating or migration with contemporary stent designs and materials, including in the early postimplant period.[55,56,58–60] MRI labeling information is available for all contemporary commercially available coronary stents in "Instructions for Use"[52] and other packaging and patient materials, and the updated database for MRI safety,[61] although mandatory review of these materials is unnecessary before the performance of MRI. Safety data are most robust for modern stent designs subjected to magnetic fields of ≤3 Tesla, with whole body averaged specific absorption rate of 2 W/kg and a suggested limit of 15 min/pulse sequence for MRI of patients with coronary stents or prosthetic heart valves. Local artifact may occur in the presence of metallic coronary artery stents, potentially limiting coronary patency assessment by cardiac magnetic resonance techniques and should be a consideration in the selection of diagnostic testing.

Summary

Current consensus maintains that recent coronary stent implantation is not a contraindication to MRI. There are no published reports of adverse events associated with performing MRI in a patient following commercially available coronary stent implantation.

CONCLUSIONS

Cardiac catheterization procedures have evolved over the past decades. Evidence has accumulated over commonly held practices to either support or discount these practices (Table 2). For details of other procedure considerations (such as other aspects of access considerations, closure devices, and choice of stents), readers are referred to the relevant guidelines.[2,62,63] Important considerations include a shorter nothing-by-mouth time before the procedure, continuation of medications (except for perhaps ACE inhibitors/ARBs in those with eGFR <60 mL/min) previously recommended to hold before the procedure, avoidance of the use of opiates as part of the sedation cocktail, not requiring allergy prophylaxis in those with shellfish allergy, safety of radial access in those with prior mastectomy or in those with abnormal Allen or Barbeau test, safety of drug-eluting stents in those with nickel allergy, and safety of MRI in those needing MRI soon after stenting. The institution of these practices can potentially improve patient experience and safety, avoid complications, and reduce cost.

ARTICLE INFORMATION

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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*Modest.

†Significant.

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