

SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory: Update to the 2012 and 2016 Consensus Documents

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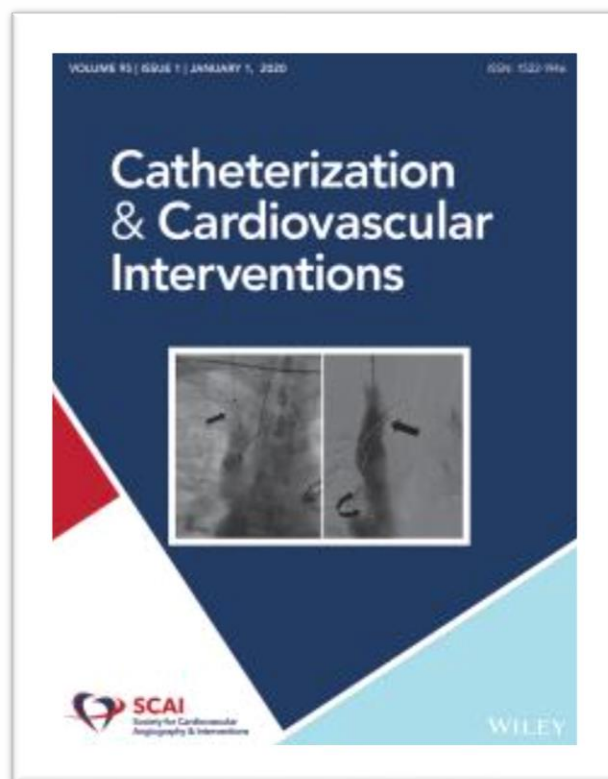
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CORE CURRICULUM

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SCAI expert consensus update on best practices in the cardiac catheterization laboratory

This statement was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) in April 2021

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Abstract

The current document commissioned by the Society for Cardiovascular Angiography and Interventions (SCAI) and endorsed by the American College of Cardiology, the American Heart Association, and Heart Rhythm Society represents a comprehensive update to the 2012 and 2016 consensus documents on patient-centered best practices in the cardiac catheterization laboratory. Comprising updates to staffing and credentialing, as well as evidence-based updates to the pre-, intra-, and post-procedural logistics, clinical standards and patient flow, the document also includes an expanded section on CCL governance, administration, and approach to quality

Multi-Disciplinary Representative Writing Group

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Multi-Society Collaboration & Endorsement

- American College of Cardiology (ACC)
- American Heart Association (AHA)
- Heart Rhythm Society (HRS)
- Society for Cardiovascular Angiography & Interventions (SCAI)



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Development Methodology

- SCAI Publications Committee oversight
- Diversity of perspectives and demographics, multi-stakeholder representation, and appropriate balance of RWI
- Literature searches performed section leads and initial drafts authored by the respective section teams
- Recommendations were discussed by the full writing group during a series of virtual meetings until all authors agreed on the text and qualifying remarks
- Draft manuscript was peer reviewed in December 2020
- Writing group unanimously approved the final version
- Endorsed as official society guidance in April 2021



Administrative Aspects of the Cath Lab: Optimal Team, Heart Team, and Governance

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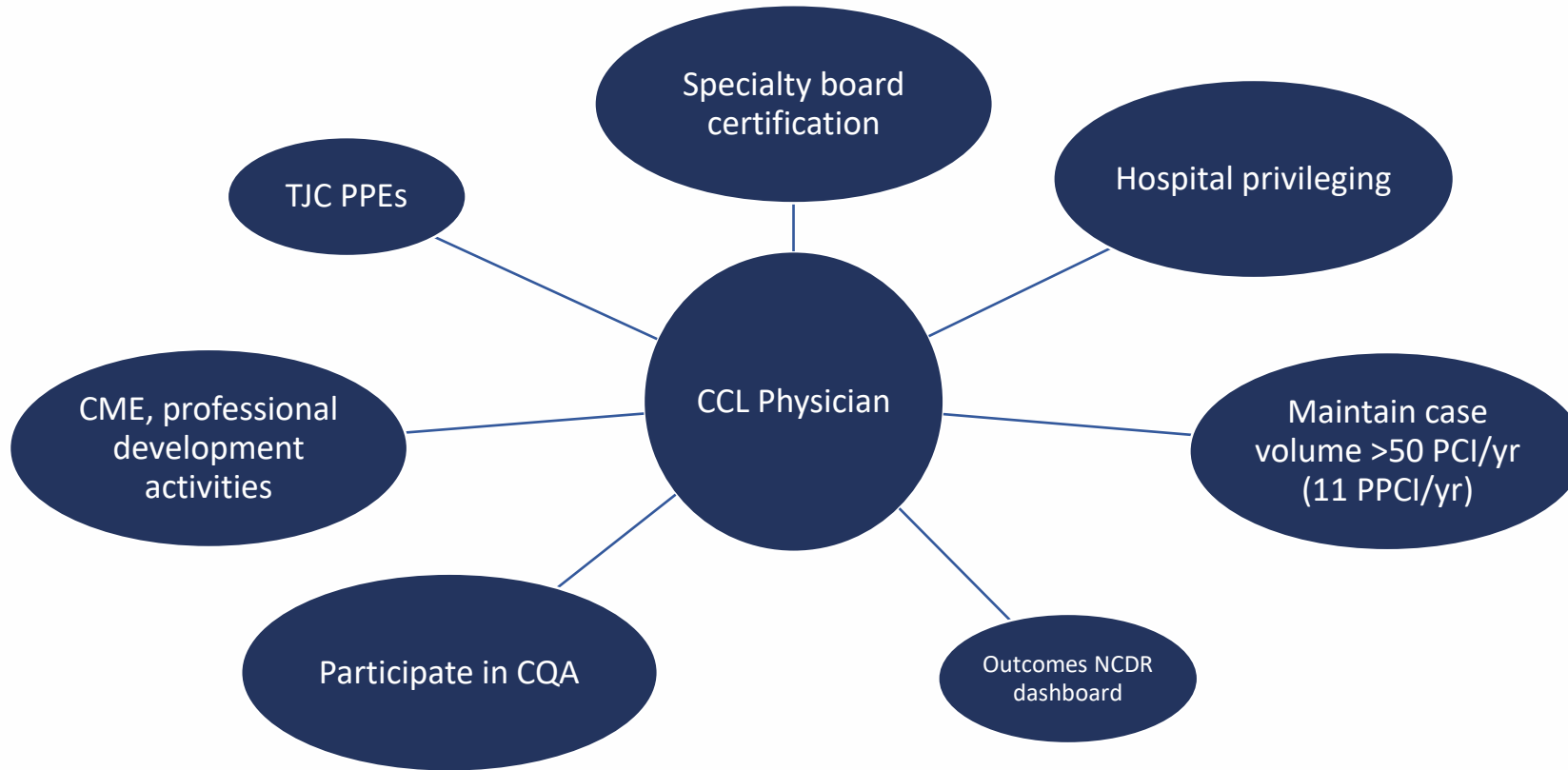
3 | INSTITUTIONAL AND OPERATOR QUALIFICATIONS AND COMPONENTS OF AN OPTIMAL CCL PROCEDURAL TEAM



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Operator competence



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CCL: provider competence and documentation

- The Joint Commission requirements include ongoing professional practice evaluations (OPPE) and focused professional practice evaluation (FPPE)
- Operator case volumes and outcomes should be documented
- Participation in quality registries (i.e NCDR) allows use of risk adjustment models and benchmarking which is optimal
- Tracking involvement in CQA (M&M)
- Non-physician staff including nurses and technologist need to meet experience, certification and continuing education requirements of their specialty
- Non-physician staffing of procedures in the cardiac catheterization laboratory may be flexible, as opposed to a static ratio, and should be based on the needs and risks of the procedure and potential for moderate or deeper levels of sedation.



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Institutional Requirements

- Minimum institutional volume of ≥ 200 PCIs/year (unchanged)
 - 36 PPCI/year, when possible
- Adequate staffing including physician extenders
- PCI centers without cardiac surgery on site should have experienced operators, consultative and transfer protocols in place (selected elective PCI cases and cardiac surgical services), report data to national registries
- PCI at freestanding ambulatory surgical centers, now reimbursed by the Centers for Medicare & Medicaid Services, must meet the same standards as acute care hospitals and have protocols in place for immediate consultation and transfer to tertiary care centers.



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7 | CATHETERIZATION LABORATORY GOVERNANCE

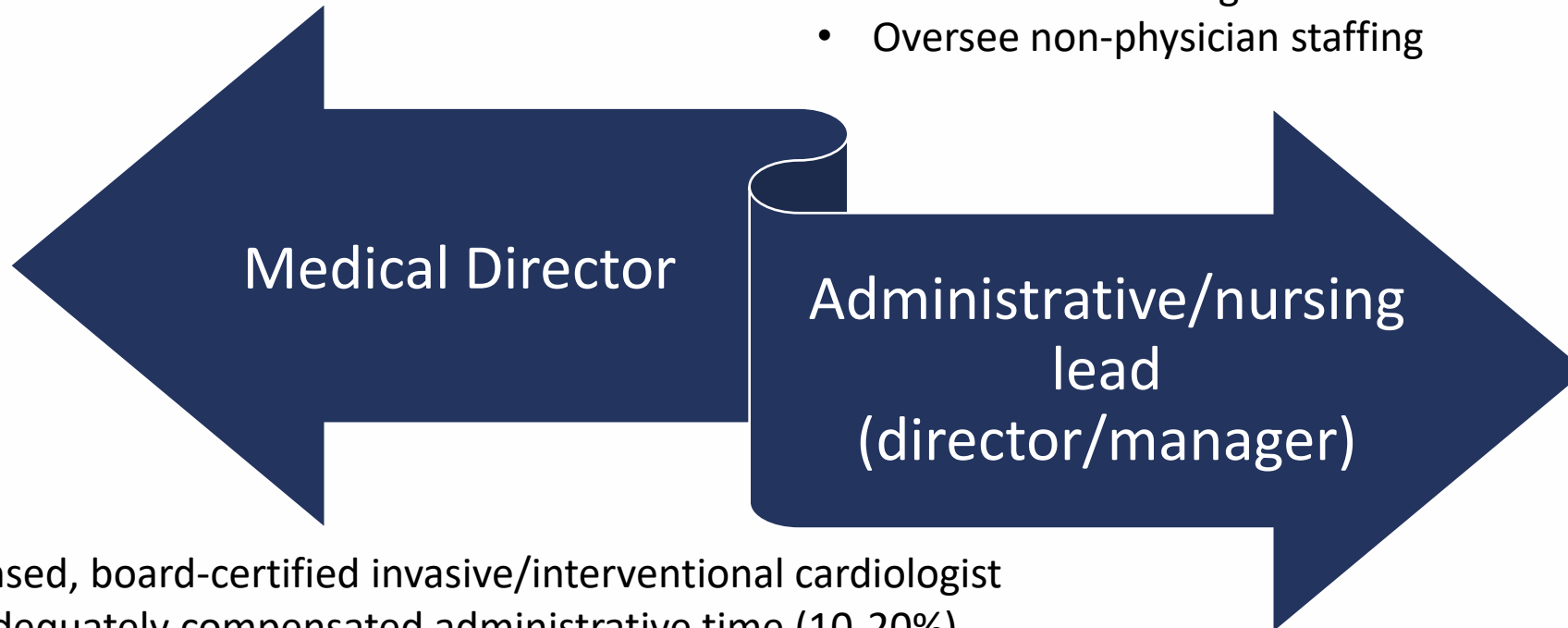


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Governance Dyad

- 5 years' CCL and/or critical care cardiology experience
- Administrative expertise to participate in institutional and CCL decision making
- Oversee non-physician staffing



- 5 years' Licensed, board-certified invasive/interventional cardiologist
- Dedicated, adequately compensated administrative time (10-20%)
- Appropriately resourced team



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Responsibilities of CCL medical director and the administrative/nursing director or manager

Administrative

- Co-lead CCL administrative meetings including representatives of pre- and post-procedure areas
- Resolve personnel problems in collaboration with CCL nurse manager
- Attend CCL staff meetings and serve as liaison between CCL personnel and physicians
- Lead administrative meetings of CCL physicians
- Resolve CCL issues among CCL physicians
- Coordinate CCL physician call schedule
- Co-lead (with CCL nurse manager) CCL Quality Committee meetings, including reporting data on NCDR outcomes, M&M conferences, adverse event reports, root cause analyses, Department of Health inspections and TJC or other accreditation body surveys
- Assist CCL nurse manager to prepare for Department of Health and TJC or other accreditation body surveys
- With CCL nurse manager and administration, assist in cost effectiveness and efficiency strategies

Quality improvement

- Oversee QI data collection and reporting processes for NCDR PCI Registry, review quarterly reports from NCDR and communicate with CCL physicians, perform annual review of individual physician data
- Quality review of non-registry procedures (e.g., atrial septal defect closures)
- Arrange for random case reviews and monitor results of reviews
- Ensure review of adverse events either by M&M conference or CCL Quality Committee
- Coordinate/oversee CCL M&M conference, report minutes to appropriate hospital committees
- Co-chair (with CCL manager) CCL Quality Committee responsible for all other aspects of CCL quality, including door to balloon initiatives
- Set criteria for privileging for CCL procedures
- Review physician performance as necessary for bi-annual re-credentialing for procedures



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Additional Sections CCL Governance

- Principles of management of industry relationships
 - Policies, oversight, purpose (clinical support)
- Incorporation of guidelines, new data, and new procedures
- Cost and Revenue (value)
 - Contracting, lab efficiency, capital expenses, assessing innovative technology
- Quality Assurance (QA) and performance improvement
 - Registry participation, M&M conference and public reporting
- Enhancing patient
 - Optimizing patient experience



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Preparedness for high risk, low frequency events: Protocols and simulation drills

- Examples of high-risk, low frequency complications for protocol implementation and simulation drills (Table 6)
- Following a complication debriefing should always occur, root-cause analysis may be appropriate
- Catheterization laboratories must have the capability to respond to emergent or unexpected circumstances that can affect the safety of laboratory personnel or patients or alter procedural volume, such as experienced with the coronavirus pandemic



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Summary

- Recognition of the complex nature of the CCL environment
- No major change to provider requirements
- Detailed responsibilities of CCL dyad to stakeholders (patients, physician and non-physician staff, administration, education)
- Additional sections on governance enhanced



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SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory

Pre-Procedure Best Practices

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North Shore Physician Group
Mass General Brigham Salem Hospital, Interventional Cardiology
Mass General Hospital, Clinical Affiliate



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Outline

- Pre-procedure H&P
- Pre-procedure risk assessment and decision making tools
- Informed consent process
- Sedation, anesthesia, & evaluation
- Patient preparation and pre-procedure checklist
- Considerations for vascular access



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H&P, Indications, AUC

- H&P documented w/in 30 days
- Review relevant studies
- Information to support possible PCI

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2016/2017 Appropriate Use Criteria
for Coronary Revascularization

Clinical Presentation:

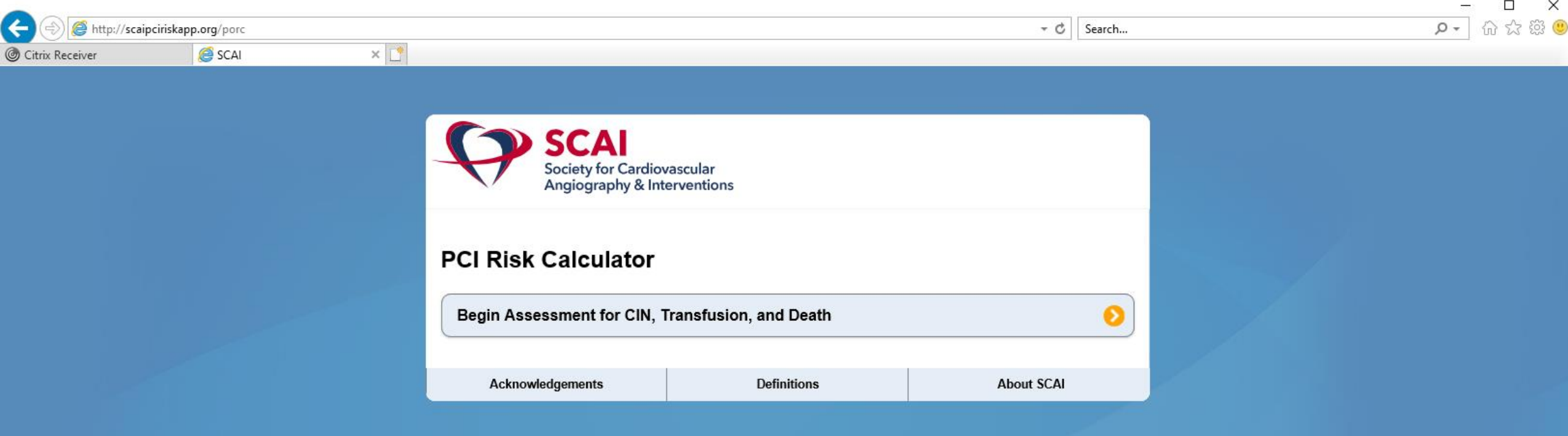
☒ ACS

☐ Stable Ischemic Heart
Disease (Non-ACS)

[Acknowledgements](#) [Definitions](#) [About SCAI](#)

Risk Tools

<http://SCAIPCIRiskApp.org/porc>



- Mehran's CIN Risk Assessment
- ACC CathPCI Bleeding Risk calculator

Informed Consent

Legal, *patient-oriented* process

- Competent, voluntary, prior to sedation

Barriers evaluated and addressed

- Language, health literacy, & cultural issues

Institutional written policy

- timing, surrogates, witnesses, & exceptions

Where, when, who?

- Where and when – neutral environment
- Who – APP or fellow but primary operator should review major concerns

Indication/benefits, alternatives, and risks

- alternatives include discussions re: ambulatory/hospital setting +/- surgical back up availability



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Sedation

- ASA classification
- Mallapati classification
- 2017 ASA guidelines for NPO
- CHOW NOW study ***



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Pre-procedure Checklist

TABLE 1 Pre-procedure checklist for cardiac catheterization

Patient name: _____ MRN: _____
Procedure date: _____
<u>Planned procedure:</u>
Diagnostic cardiac catheterization
Diagnostic cardiac catheterization with possible PCI
Percutaneous coronary intervention
<u>History and physical examination:</u>
Elective outpatient procedures: H&P documented within 30 days? Yes No
Inpatient procedures: H&P documented within 24 h of admission? Yes No
History of prior PCI or CABG: Yes No
If yes, were reports obtained? Yes No
<u>Allergies:</u>
Contrast: Yes No
If yes, was the patient pre-treated? Yes No
Aspirin: Yes No
If yes, does the patient need desensitization? Yes No
Heparin (HIT) Yes No
If yes, consider alternative anti-thrombotic agents
Latex Yes No
If yes, remove all latex products from procedural use
<u>Medications:</u>
Is the patient taking aspirin chronically? Yes No
Is the patient taking clopidogrel or another P2Y12 inhibitor chronically? Yes No
Did patient take metformin within the past 24 h? Yes No
Did patient take sildenafil (or equivalent) within the past 24 h? Yes No
Did patient receive LMWH within the past 24 h? Yes No
If yes for LMWH, time and dose of last administration:
<u>Informed consent:</u>
Was informed consent obtained per institutional policy and updated on the day of procedure? Yes No
If the patient has DNR or DNI status, is it revoked for the procedure? Yes No
<u>Sedation, anesthesia and analgesia:</u>
Are ASA and Mallampati class documented? Yes No
Is there any contraindication to sedation present? Yes No
<u>Bleeding risk assessment:</u>
Is patient on chronic anticoagulation (e.g., warfarin, direct acting oral anticoagulants)? Yes No
<u>Laboratories and studies:</u>
CBC and basic electrolytes within 30 days (outpatient) or 24 h (inpatient)? Yes No
Was EKG performed within 24 h? Yes No
PT/INR performed within 24 h (for patients on warfarin or with liver disease)? Yes No
Does the patient require pre-procedure hydration? Yes No

Abbreviations: ASA, American Society of Anesthesiologists; CBC, complete blood count; HIT, heparin induced thrombocytopenia; LMWH, low molecular weight heparin.

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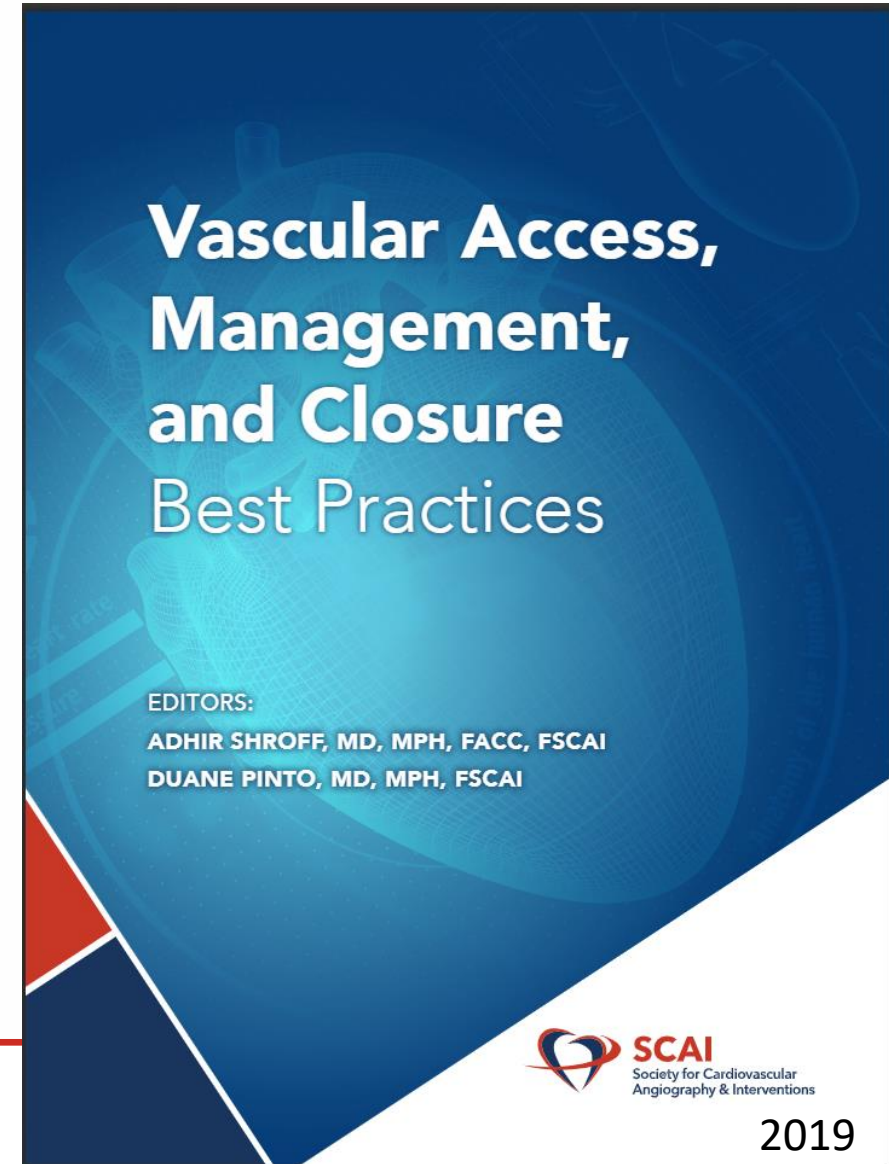
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Choice of Vascular Access

- Maintain competencies in both femoral and radial access
- Comfort with ultrasound guidance
- Radial vs femoral
- Large bore femoral
- Dual Access
 - CTO procedures
 - Access with MCS



Radial first considerations

Previous anatomy and procedural complexity

Arterial patency

Prior CABG

Guide catheter size

Hemodialysis fistulas (?)

Patient preference



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Intra-Procedure Best Practices

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Patient Preparation in the Procedure Room

- Review of pre-procedure checklist or equivalent (NPO status, allergies, blood tests medications, advance directives)
- NCDR-related preprocedural information
- Non-invasive hemodynamic and oximetric monitoring to all patients
- Defibrillation pads on all STEMI patients and those at risk of cardiac arrest (ECMO placement, etc)
- Working IV prior to start of the procedure
- Plan for vascular access site



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Sedation, Anesthesia and Analgesia

- Document suitability to receive moderate sedations (5 ASA classes)
- Moderate sedation should be considered for all patients
- Consider O2 via nasal cannula if moderate sedation
- RN, or equivalent, should be continuously present to monitor for side effects, changes in respiration/O2, hemodynamic and electrical instability
- A combination of opioids (fentanyl 25-50 mcg) and benzodiazepines (midazolam 0.5-2 mg) is most frequently utilized
- Reversal agents (naloxone 0.4 mg and flumazenil 0.2 mg q minute to max 1 mg) should be readily available



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Infection Control in the CV Lab

- Infectious complications are rare but best practices for sterile technique are essential
- Prepare femoral access site with electric clippers
- Antimicrobial agents (chlorhexidine-based preparations)
- Sterile drapes
- Hand washing or FDA-approved surgical antiseptic solutions
- Hats, masks and gowns should be worn for invasive procedures
- Antibiotic prophylaxis not indicated for diagnostic procedures and prior to coronary stent placement, but are commonly used prior to structural heart procedures.



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Radiation Exposure and Occupational Hazards

- Keep radiation doses as low as reasonably achievable (ALARA)
 - Radiation protection: lead aprons, thyroid shields and leaded glasses
 - Table side radiation shields should be routinely employed
 - Total radiation doses should be recorded in Gray (Gy), inform the operator when safety thresholds are reached
 - All CCL must develop and conform to radiation safety policy
- Minimize risk of orthopedic injuries



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1. Select low dose settings on fluoroscope, such as lower dose per frame, lower frame rate (4–7.5 fps for fluoroscopy, 7.5–15 fps for cine)
2. Use “Fluoro Save” instead of cine when possible
3. Use collimation to lower radiation dose and scatter to patient and staff
4. Avoid working in steep angles and change working angles to “spread the dose”
5. Raise table height to decrease patient dose, and minimize distance between patient and detector to decrease patient dose and scatter to operator
6. Use lower magnification (example 22 cm FOV instead of 19 cm)
7. Keep patient's extremities out of the beam path and away from the x-ray tube
8. Maintain furthest possible distance from x-ray tube by using long tubing, especially for radial cases, and “taking a step back”. Ensure proper use of moveable lead shields and under-table drapes.
9. Consider moveable lead screens to protect CCL staff
10. Consider use of real-time radiation monitoring, radiation protection drapes and robotic PCI to lower operator radiation exposure
11. Regular assessment and upgrading of equipment (hardware and/or software) to minimize radiation dose

2 dedicated SCAI documents
published on radiation safety.
Ref 67 and 68



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Angiographic Contrast Administration

- Non-ionic, low-osmolar contrast (i.e., iohexol, iopamidol, ioversol) for most cases.
- Iso-osmolar contrast agents (iodixanol) may have no benefit in CKD
- Total contrast volume not to exceed $\text{eGFR} > 3.7$ to help limit AKI if possible
- Automated contrast injectors can be considered over manual devices.
Benefits include reduced contrast exposure, AKI, and radiation exposure



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Universal Protocol and “Time out” Procedure

- Goal: Team members should understand the intended procedure and sequence of that procedure.
- All members must be present
- Patient identification should be confirmed with unanimous agreement
- All solutions on the table must be labeled in real-time
- For SHD procedures, procedural-specific considerations (i.e. valve orientation) should be incorporated into the time out



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TABLE 3 The Joint Commission Standards for the pre-procedural checklist and “time-out”^a

Requirements for the pre-procedure “time-out”

1. The organization determines the exact items to be reviewed in the time-out
2. The time-out procedure is standardized.
3. The patient should be involved in the time-out when possible.
4. Performed immediately before starting the invasive procedure with all of the immediate members of the procedure team present
5. All relevant members of the procedure team actively communicate during the time-out.
6. Team members agree on correct patient identity, procedure to be done, and anticipated access site.
7. When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
8. Document the completion of the time-out. The organization determines the amount and type of additional documentation.
9. The procedure is not started until all questions or concerns are resolved.



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Intraprocedural Anticoagulation Monitoring

- For patients who receive heparin, an activated clotting time (ACT) should be checked throughout the procedure to monitor adequate anticoagulation
- For PCI: Target ACT > 200 sec if IV antiplatelet agents used, > 250 sec if oral antiplatelets, and > 300 sec if no antiplatelet agents on board
- A single ACT measurement is acceptable for patients receiving bivalirudin



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Procedural Data Recording

- All elements of the procedure (vital signs, time and dosage of medications, ACT values, catheters used, target lesion, etc) should be entered into an electronic health record
- Records should be immediately available to the staff in the next level of care
- Physician responsible for ensuring accuracy and completeness



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Collaboration with EP

- Collaboration between EP and Interventional is common and should be encouraged given complimentary skillsets
- Examples include: diagnostic angiography during EP catheter ablation, emergent pericardiocentesis or hemodynamic support during VT ablation
- Issues to address *a priori* for a successful collaboration include appropriate consent and equipment



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SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory

Post-Procedure Best Practices

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Post-Procedure Best Practices

Direct Communication of Procedure Results

- Discussion with patient should be delayed until sedation resolved
- For outpatients, operator should discuss findings, interventions and management with patient/family directly
- When operator is not the managing physician, it is good practice to discuss findings and management with managing physician
- For inpatients, operator may discuss findings with patient/family or delegate discussion to the managing physician.
- Complications should be discussed directly with patient/family and opportunities for communication clearly defined.



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Post-Procedure Best Practices

Procedure Report

- Should be generated immediately post procedure
- If unable to be done, a brief progress note with sufficient information for post procedure care (indication, procedure, access site, EBL, plan etc)
- A formal report should be generate in 24 hours and include data to satisfy TJC requirements for operative procedures and AUC PCI criteria
- Structured reporting is the optimal form for procedure reports as outlined in the ACC/AHA/SCAI 2014 Health Policy Statement



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Post-Procedure Best Practices

Procedure Report

TABLE 4 Select elements of the procedure report

Element	Notes
Patient demographics	Age, gender, risk factors, medications
Primary operator and CCL team members	Primary and assisting physician, fellows, nurses, technologists, anesthesiologists
Procedures performed	Right/left heart catheterization, PCI, pressure wire, IVUS, OCT, peripheral angiography
Indications	Clinical presentation, symptoms, exam findings, prior studies
Access site	Specify vessel accessed and if ultrasound used, specify if access was obtained using direct visualization, description of vessel patency, image archiving
Equipment	Sheaths, catheters, balloons and other interventional equipment, wires
Drugs and doses	Cardiac medications, sedation and amount of fluid administered
Contrast data	Type and amount used
Radiation exposure	Dose
Complications	Clear description of complications, otherwise report "none"
Hemodynamics	Computer generated measurements must be verified by the operator. Reports may include initial and end aortic pressure, left ventricular systolic and end-diastolic pressure, valve gradients and areas, right sided chamber pressures, pulmonary artery pulsatility index, cardiac output, cardiac power output, mixed venous saturation, arterial oxygen saturation, shunt data
Left ventriculogram	Ejection fraction, wall motion abnormalities, valvular abnormalities
Coronary angiography	Detailed anatomy, lesions, variants, size of vessels, collaterals; include graphic if available
Interventional procedures	Procedure description including equipment, results and complications. TIMI flow pre- and post-PCI; include graphic if available
IVUS, OCT	Indication, artery segment evaluated, vessel diameter measurement and methodology used, plaque morphology, stent expansion, stent apposition, presence of dissection, changes in management
FFR, iFR, RFR	Indication, documentation of vasodilator used and route, location of lesion evaluated, results, pullback findings, assessment for drift, interpretation
Method of hemostasis	If VCD, comment on whether or not device successful. If hemostasis band used, comment on type of band and use of adjunctive therapy that is, hemostatic disc, gauze, and so forth
Summary of findings, diagnosis and follow up	Management plan, admission or observation status, follow up
Communication	Report that results and complications were discussed with the patient and/or family, receiving team, consultants and referring provider.

Abbreviations: FFR, fractional flow reserve; iFR, instantaneous wave-free ratio; IVUS, intravascular ultrasound; OCT, optical coherence tomography; RFR, resting full-cycle ratio; VCD, vascular closure device.



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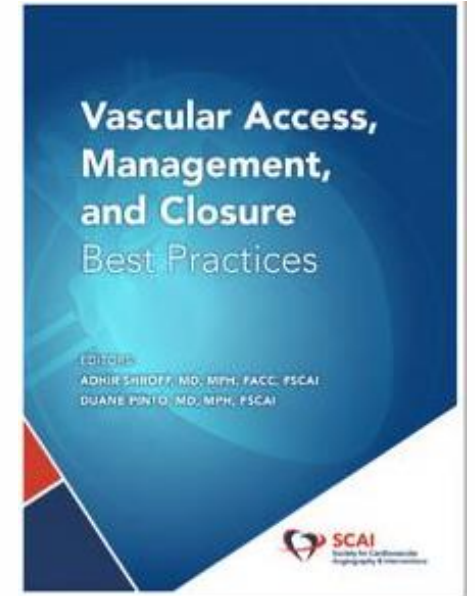
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Post-Procedure Best Practices

Access Site Management and Closure Devices

Radial Access

- Hemostasis usually obtained with wristband compression
- Patent hemostasis technique
- Sheaths removed immediately post procedure
- After recovering from sedation, ambulation not restricted but lifting/activity restricted 2-4 hours after
- Employing evidence based techniques and establishing standardized hemostasis protocols improves efficiency and patient safety



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Post-Procedure Best Practices

Access Site Management and Closure Devices

Femoral Access

- Manual compression and VCD's may be used and should be guided by clinical characteristics and femoral angiography (mandatory for VCD)
- Shorter time to hemostasis, early ambulation and reduction of resources among potential VCD benefits
- VCD's are noninferior to manual compression but may have higher infection rates



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Post-Procedure Best Practices

Access Site Management and Closure Devices

Large Bore Access or Mechanical Circulatory Support (MCS)

- Require special post procedure consideration
- When MCS left in place, assessment should include distal limb perfusion and use of limb perfusion techniques when needed
- Proper MCS positioning should be confirmed and device secured
- Post procedure care should be protocolized and include instructions on limb immobilization and patient activity
- Large bore vascular access closure can include assisted manual compression, suture based/large bore closure device and proximal balloon occlusion



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Post-Procedure Best Practices

Appropriate monitoring and length of stay

- Post procedure telemetry monitoring in unit specializing in post cardiac procedure care
- Personnel should be trained in access site management and recovery from sedation
- Vital signs monitored every 15 min for first 2 hours
- Electrocardiogram immediately post procedure
- Length of stay post cardiac catheterization 2-6 hours (vascular access and nursing assessment)



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Post-Procedure Best Practices

Appropriate monitoring and length of stay (cont)

- Length of stay post PCI dependent on access site complications, comorbidities, need for further procedures, absence of ischemic symptoms/findings
- Selected patients after elective PCI should be considered for same day discharge (SDD) after appropriate monitoring (4-6 hours)
- Select EP procedures may also be considered for SDD



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Post-Procedure Best Practices

Appropriate monitoring and length of stay (cont)

Assessment of discharge readiness should follow framework outlined in SCAI and ACC consensus documents on length of stay and SDD after PCI

CLINICAL DECISION MAKING WILEY

**Length of stay following percutaneous coronary intervention:
An expert consensus document update from the society for
cardiovascular angiography and interventions**

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EXPERT CONSENSUS DECISION PATHWAY

**2021 ACC Expert Consensus Decision
Pathway on Same-Day Discharge After
Percutaneous Coronary Intervention**

A Report of the American College of Cardiology Solution Set Oversight Committee

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Post-Procedure Best Practices

Discharge instructions and patient information

- Summary of procedure should be provided to patient/caregiver
- Card with device information should be provided if stent received
- Routine instructions regarding secondary prevention
- Limitations on physical activity and driving and follow up
- If at risk for CIN, serum creatinine should be checked 3-5 days
- All patients (especially SDD) should have a contact number for questions/complications and contacted by a CCL member within 24-72 hours



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Post-Procedure Best Practices

Discharge instructions and patient information (cont)

Radiation exposure

- > 5 Gy – patients should be educated re potential skin changes and follow up scheduled to detect late radiation damage
- > 10 Gy – a qualified medical physicist should calculate peak skin dose and skin examined at 2-4 weeks
- > 15 Gy – considered a sentinel event by TJC and hospital risk management and regulatory agencies contacted within 24 h
- Suspected tissue injury should be referred to a specialist/biopsy



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Post-Procedure Best Practices

Medication reconciliation

- Medication reconciliation and review of GDMT should be performed, clearly documented and reviewed
- Expected duration of DAPT should be based on guidelines and documented; importance of adherence stressed
- For patients requiring “triple therapy”, duration should be the least amount of time possible; duration of each medication explicitly stated
- Use of single platelet therapy with oral anticoagulation should be considered instead



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Post-Procedure Best Practices

Appropriate follow up evaluation

- Follow up visit with physician/ACP in 2-4 weeks or earlier with testing for patients with baseline CKD, anemia or complications
- Access site should be assessed symptoms/complications
- Medical therapy should be assessed for effectiveness, side effects, compliance and conformity with guidelines
- Should address lifestyle modification, smoking cessation and plan for long term follow up
- All patients after PCI should be referred to cardiac rehabilitation



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