Mitigating Operator Risk in Complex Interventional Procedures

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Interventional

MEMBER SECTION

- Risk assessment
- Documentation
- Informed consent
- Public reporting
- Steps to reduce risk and improve patient outcomes

Who is at risk?

Risk to the patient

- Is the procedure indicated?
- Does it fit guidelines?
- AUC (NEW-ACS focus only)
- SCAI risk scoring

- ACEF (CABG pts)
- SYNTAX I and II (predicts outcomes of PCI vs CABG)
- Radiation and contrast use

Risk to you

- Reporting in Cath/PCI registry (NCDR)
- State reporting
- Risk Adjusted Mortality Rate (RAMR)
- Radiation safety

Institutional

- State reporting
- Payors

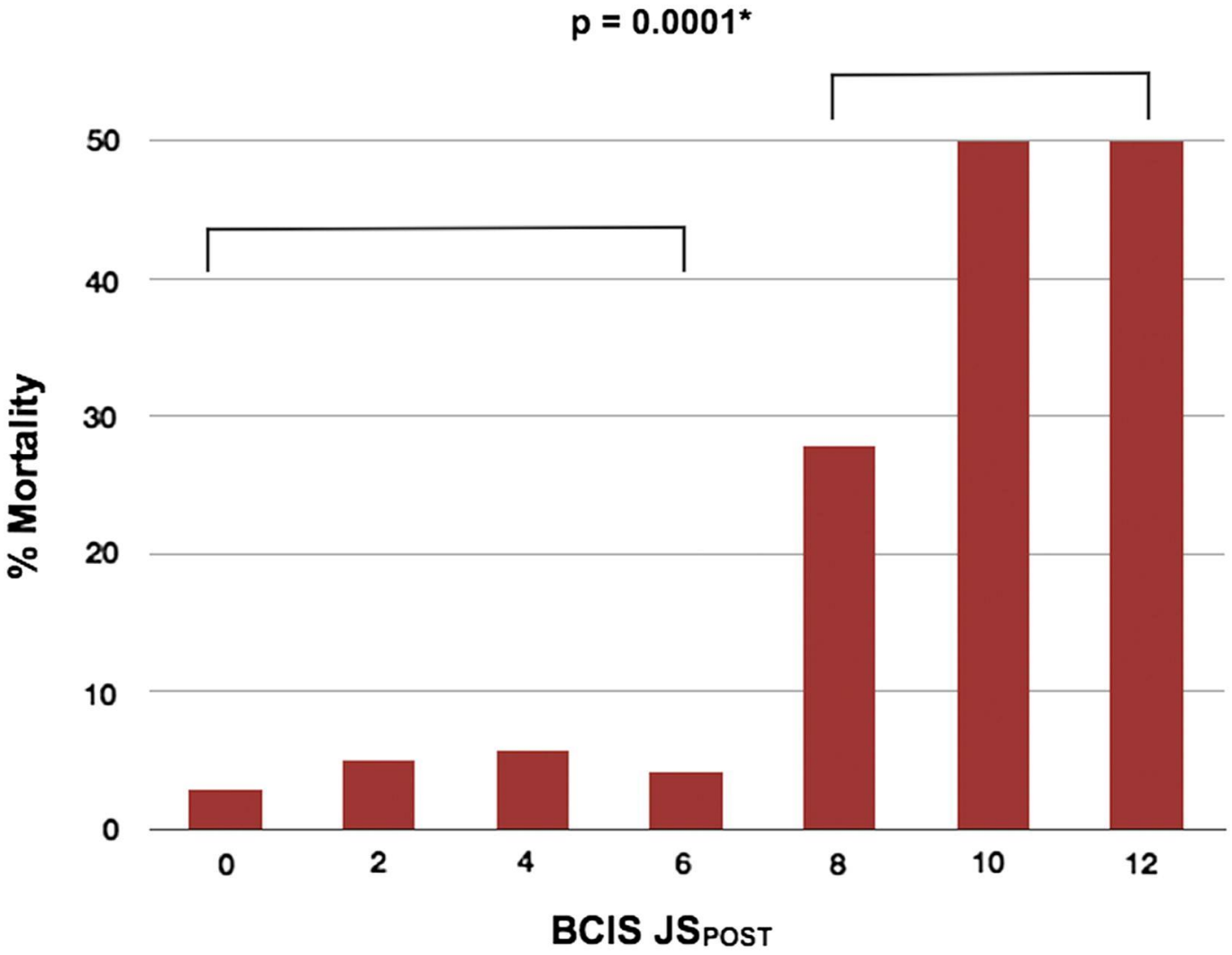
CRITERIA FOR HRPCI

1. Severe myocardial dysfunction
   (LVEF < 35 %)
2. Extensive zones of myocardial jeopardy during PCI

- ***Last patent vessel***
- ***Unprotected LM and distal LM bifurcation***
- ***Target vessel supplying collaterals to a vessel that supplies 40 % of the myocardium***
- ***3 VD with SYNTAX score > 33***

3. Surgically ineligible
4. Other high-risk scenarios (CTO, ?Atherectomy)

BCIS Myocardial Jeopardy Score for Classification of Coronary Disease Burden and Completeness of Revascularization



*BCIS JS_{POST} <6 vs. BCIS JS_{POST} > 6 by Fishers Exact Test

American Journal of Cardiology
Volume 111, Issue 2, Pages 172-177 (January 2013)

Pre procedure steps in non-emergent HRPCI that is referred to you from another MD or there is an ‘urgent’ transfer

- **Ideally review film online with referring MD prior to transfer**

(Often patients are referred with significant co morbidities and limited life expectancy)

- **Separate pre-PCI note in chart (either outpatient or inpatient)**

(This is important whether patient is seen in clinic or pre procedure. Document conversation, preferably witnessed and expectations)

- **Describe risk elements in cath report**

(As a minimum, mortality risk and risk of complications and documentation of discussion with patient. Heart Team or consultation with another MD, should be documented provided they give permission)

Informed consent

1.Is it always possible?

Ad hoc in STEMI, Cardiac arrest and Cardiogenic Shock

2.Post procedure risk documentation

Is this right ?

No other choice but to document

Elements of Informed Consent:
Signature on a consent form is not enough

1. The interventionalist should obtain consent

2. Use standardized consent form specific for complex PCI (???)

Consent form or separate note should include:

- Estimated mortality and stroke risk
- Utilization of MCS and adjunctive tools e.g. RA
- Potential complications such as renal failure, bleeding, tamponade, vascular injury and complications from MCS devices
- The potential for post procedure dialysis, ICU care, ventilatory support and prolonged hospitalization

3. Emergent procedures may require 2 MD consent witnessed by a nurse in some states

4.Telephone consents from relatives should be witnessed by a nurse and another MD

Improving the process of informed consent for percutaneous coronary intervention: Patient Outcomes from the Patient Risk Information Services Manager (*e*PRISM) study (Spertus et al. AHJ 2015 (2) 234-241)

A personalized consent document improved the process of informed consent and shared decision-making with more frequent review (72% for *e*PRISM vs 45% for original consents) Marked heterogeneity across hospitals highlights that consent documents are but one aspect of engaging patients in understanding and participating in treatment.

Did not address HRPCI, but a step in the right direction

Online or IPAD based video descriptions of procedures, electronic and customized consent forms are in evolution

Table 4. NCDR CathPCI Registry Bedside Risk Scoring System

	Scoring Response Categories				
STEMI	No	Yes			
	0	6			
Age	<60	60–70	70–80	≥80	
	0	4	9	15	
BMI	<20	20–30	30–40	≥40	
	5	1	0	3	
CVD	No	Yes			
	0	2			
PAD	No	Yes			
	0	3			
Chronic lung disease	No	Yes			
	0	3			
Prior PCI	No	Yes			
	3	0			
Diabetes mellitus	No	Noninsulin	Insulin		
	0	2	3		
GFR	Renal failure	30–45	45–60	60–90	≥90
	16	11	7	3	0
EF	<30	30–40	40–50	≥50	
	9	4	2	0	

Mortality is "Risk-Adjusted"

Cardiogenic shock/PCI status	Sustained shock and salvage	Sustained shock alone or salvage alone	Transient shock but not salvage	Emergency PCI without shock/ salvage	Urgent PCI without shock/ salvage	Elective PCI without shock/ salvage
	54	43	37	22	11	0
NYHA class within 2 weeks	NYHA class IV	NYHA class <IV	No HF			
	7	3	0			
Cardiac arrest within 24 h	No	Yes				
	0	13				

Highest Risk

Brennan. JACC CVI 2013; 6: 790-9

NCDR

Complex CAD with co existent morbidities and concomitant terminal disease are not included in risk adjusted mortality

- ESRD or Liver failure
- End state lung disease
- Anemia or thrombocytopenia
- Terminal cancers
- Recent surgery
- Trauma
- Stroke
- Transplant
- Estimated survival and DAPT use
- Frailty

Procedural indication	Timing	AUC	Mortality risk	Heart team approach	Informed consent	Public reporting
Cardiac arrest	Emergent	A	> 50 %	Not possible	Generally none	Likely institutional
Cardiogenic shock	Emergent	A	30-50 %	Often not possible	Often not possible	Likely institutional
Ad hoc HRPCI	Emergent	M	5-15 %	Possible	On the table discussion with Patient and family Post hoc documentation	Yes
Left Main	Elective to urgent	A	0.6-2 %	Recommended	Yes	Yes
Multi-vessel HRPCI	Elective	M	5-15 %	Recommended	Yes	Yes
Surgical turn down and post graft failure HRPCI	Elective or emergent	A	5-15 %	Yes	Yes	Yes
CTO	Elective	TBD	1.1 %	Maybe	Yes	Yes

How do you reduce risk ?

In elective cases:

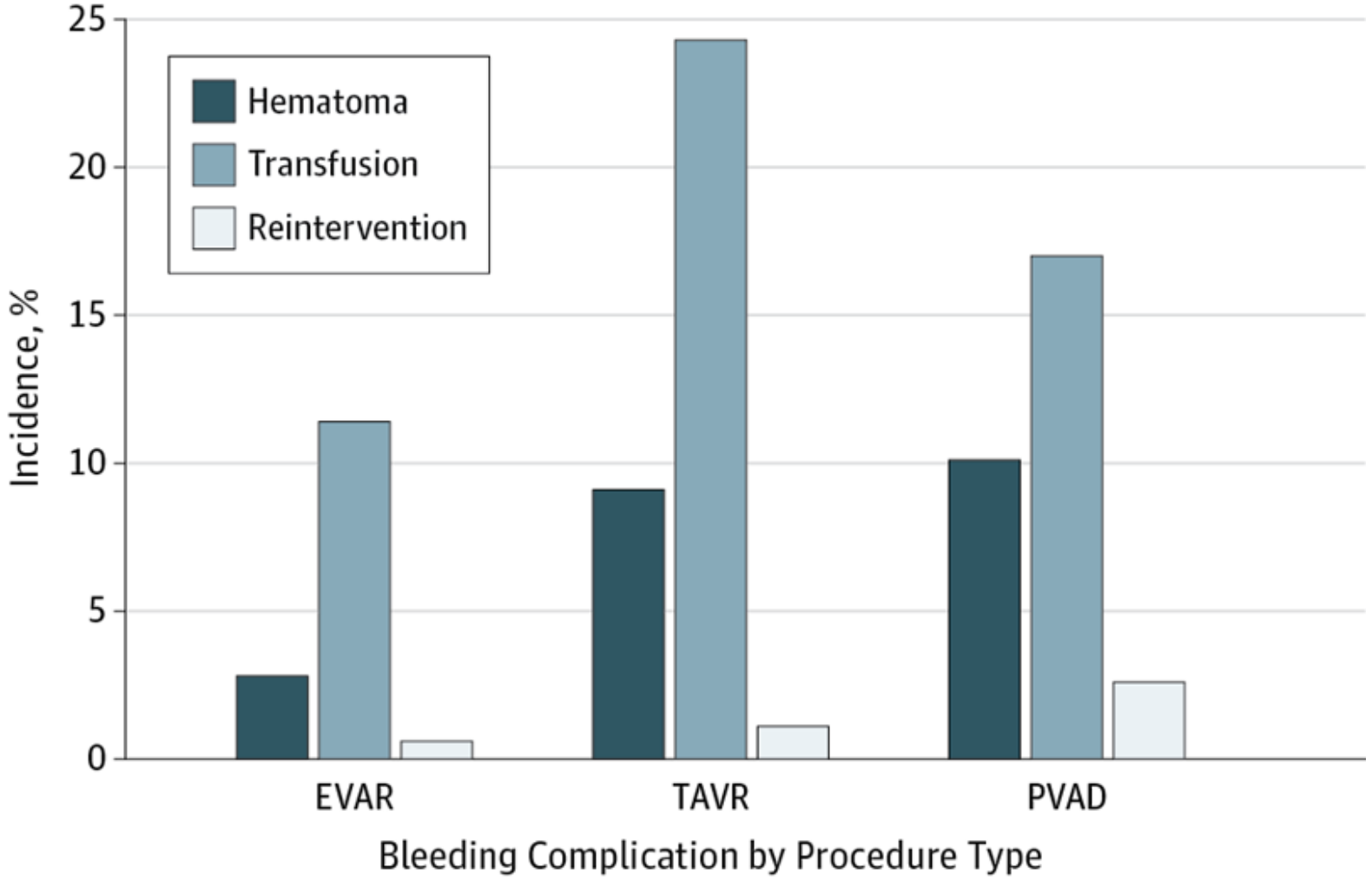
1. Proper case selection
2. Case discussion and angiographic evaluation (e.g. CTO's) Heart Team Approach
3. Informed consent and shared decision making with patients
4. Discussion of complications and outcomes with patient
5. Be facile with vascular access and large bore closure
6. Available tools at your disposal e.g RA
7. Decide early on MCS use

Bleeding and vascular complications are the largest outliers

- Understand large bore access
- Utilize micropuncture needle, fluoroscopic and US guidance
- Be facile with Pre close (e.g.utilizing 2 Percloses for large sheath access)
- If adequate hemostasis is not achieved with Perclose after the sheath is removed, be comfortable in leaving a smaller sized sheath and pulling it later
- Consider alternate access sites such as axillary or transcaval (if that expertise is available)
- Familiarity with crossover/endovascular rescue techniques

Bleeding Complications after Large-Bore Access

17,672 pts from NIS undergoing EVAR (12.6K), TAVR (3.2K), pVAD (1.8K)
Bleeding was associated with increased costs and mortality



Redfors et al, JAMA Cardiology 2017

Contemporary Outcomes in MCS/PLVAD devices

Trials	Indication	Number of patients	IABP	Devices	Survival	Complications
Kar et al	Severe CS	117	Refractory	Tandem Heart	60 % @ 30 days	Severe bleeding
Seyfarth et al	Severe CS	25	Refractory	Impella	54% @ 30 days	Hemolysis
USPella	Prophylactic HR-PCI		----------	Impella	88% @ 12 months	MACE: 8 %
PROTECT-2 (Redefined MACE (Q waves or CKMB 8 X ULN)	HR-PCI	452	226	226	MACCE: IMPELLA 22% IABP 31 %	
Ally et al	Prophylactic HR-PCI	54	----------	Tandem Heart	87 %	13% vascular complications
Nichol et al	Cardiogenic Shock or Cardiac arrest	84	----------	ECMO	50%	Vascular & Acute lung Injury
ECMO registry	Cardiac arrest	2,633		ECMO	27%	
Takyama et al	Cardiogenic Shock (CS)	143		ECMO	49 %	

Conclusions: Improved outcomes if these devices are placed prophylactically EARLY rather than LATE
Average 60 % survival with Impella, Tandem Heart and ECMO vs IABP

Radiation safety for the patient and operator

1.Minimize cine. Fluoro save has <10% radiation exposure of cine

2.Minimize steep angles of X-ray beam.

3.Minimize magnification modes. Utilize “Live Zoom” feature without significant degradation of the image. For example in lieu of magnification, in an 8 inch field of view with a zoom factor of 1.2 results in a 6.7 inch field of view, without added radiation.

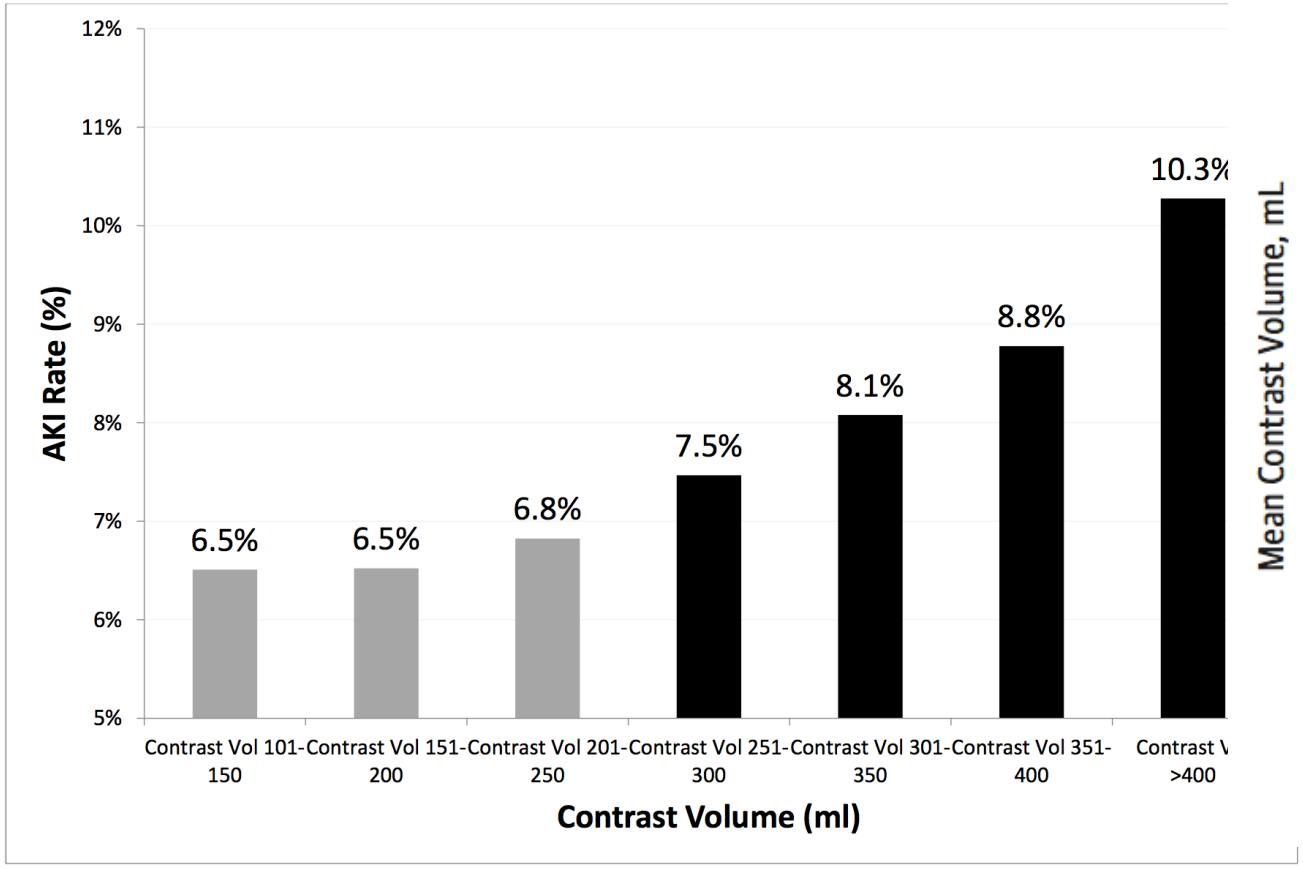
4.Minimize frame rate of fluoroscopy and cine. Long cases should be performed on 7.5 frames/sec fluoroscopy setting. Reduction of fluoroscopic pulse rate from 15 frames/sec to 7.5 frames/sec reduces radiation exposure by half

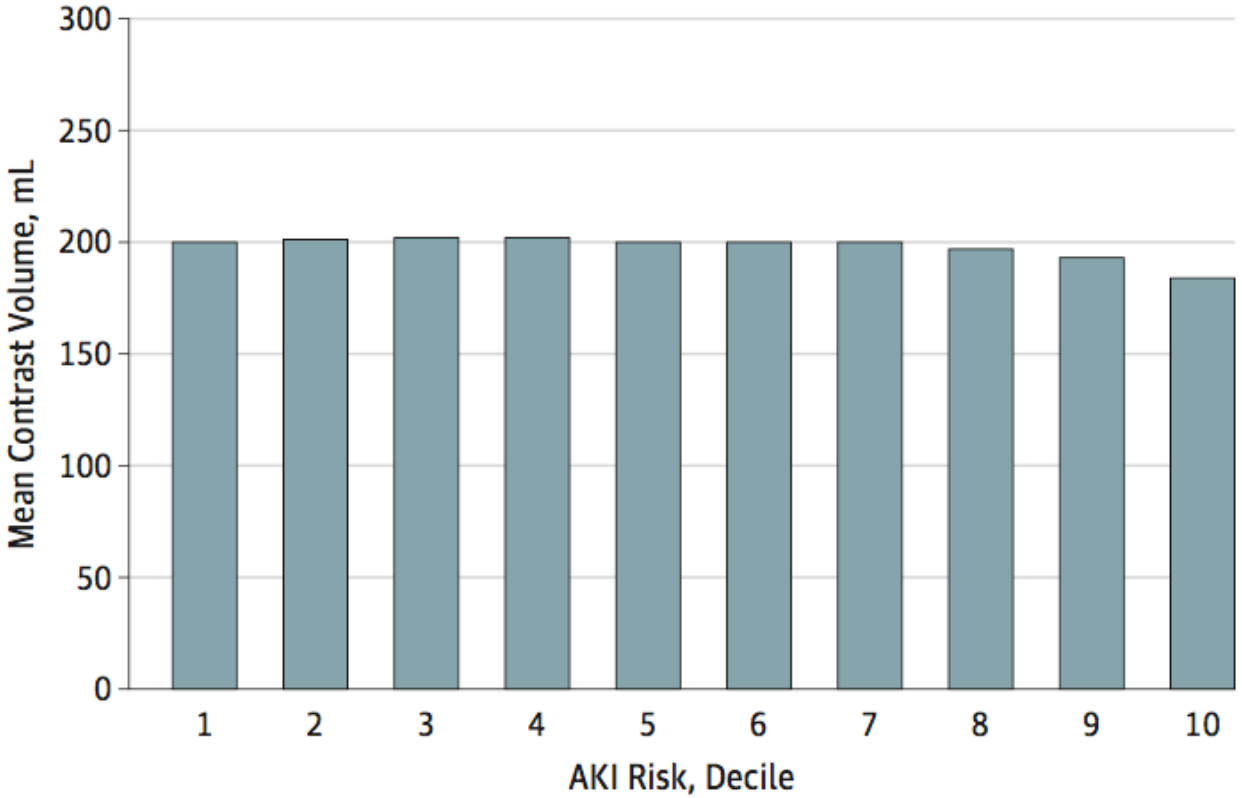
5.Keep the image detector close to the patient (low subject-image distance).Utilize collimation to the fullest extent possible

Maximum allowable: 5 Gy

Correlation of Contrast Volume with AKI

CathPCI study of 1.3 million PCIs





Amin et al JAMA Cardiology 2017

Contrast Preservation

- Estimation of maximal contrast volume to be used:

$$\frac{5ml \times body\ weight\ (in\ kg)}{Serum\ Creatinine\ (mg/dl)}$$

- Small manifold syringes (8 cc)
- Iso osmolar contrast
- 50:50 diluted contrast
- Biplane imaging
- Intravascular ultrasound (IVUS) in optimizing device placement and PCI outcomes
- Marker wires for lesion length and device position
- Mechanized contrast injectors delivering prefixed contrast amount
- Using contrast savers