CRUX OF ALL

EVALUATION OF PATIENT BEFORE ANY INTERVENTION

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INTERVENTIONAL RADIOLOGISTS
LILAVATI, HOLY FAMILY AND WOCKHARDT HOSPITALS
MUMBAI, INDIA

PEARLS OF WISDOM

"A successful and safe outcome often depends as much on pre-procedure and postprocedure care as it does on performance of the case itself."

Author of Overpriced IR Book

Responsibilities of the Interventional Radiologist

- Know your patient
- Communicate with referring physicians
- Decide on best treatment (consultant NOT technician)
- Develop a relationship with the patient (and family) → pre-procedure clinic visit
- Visit patient after procedure and document
- Arrange and ensure appropriate follow-up

Factors affecting patient satisfaction

- Physician availability
- Coordination of multidisciplinary team
- Competence
- Communication and relationships
- Ability to provide information
- Responsiveness to emotional needs
- Ability to support decision-making

Introduction

- Speak to the patient by name
- Acknowledge others in the room
- Sit down!!
- Introduce yourself and your position
- Tell the patient your experience/skills.
- Highlight the attending's experience/skills

Evaluation

- Obtain a fresh history
- Explain the procedure
- *Overestimate procedure time / hospital time*
- Be forthright about expected pain or inconvenience
- Provide a frank assessment of expected postprocedure course
- Answer all questions and offer any help as needed

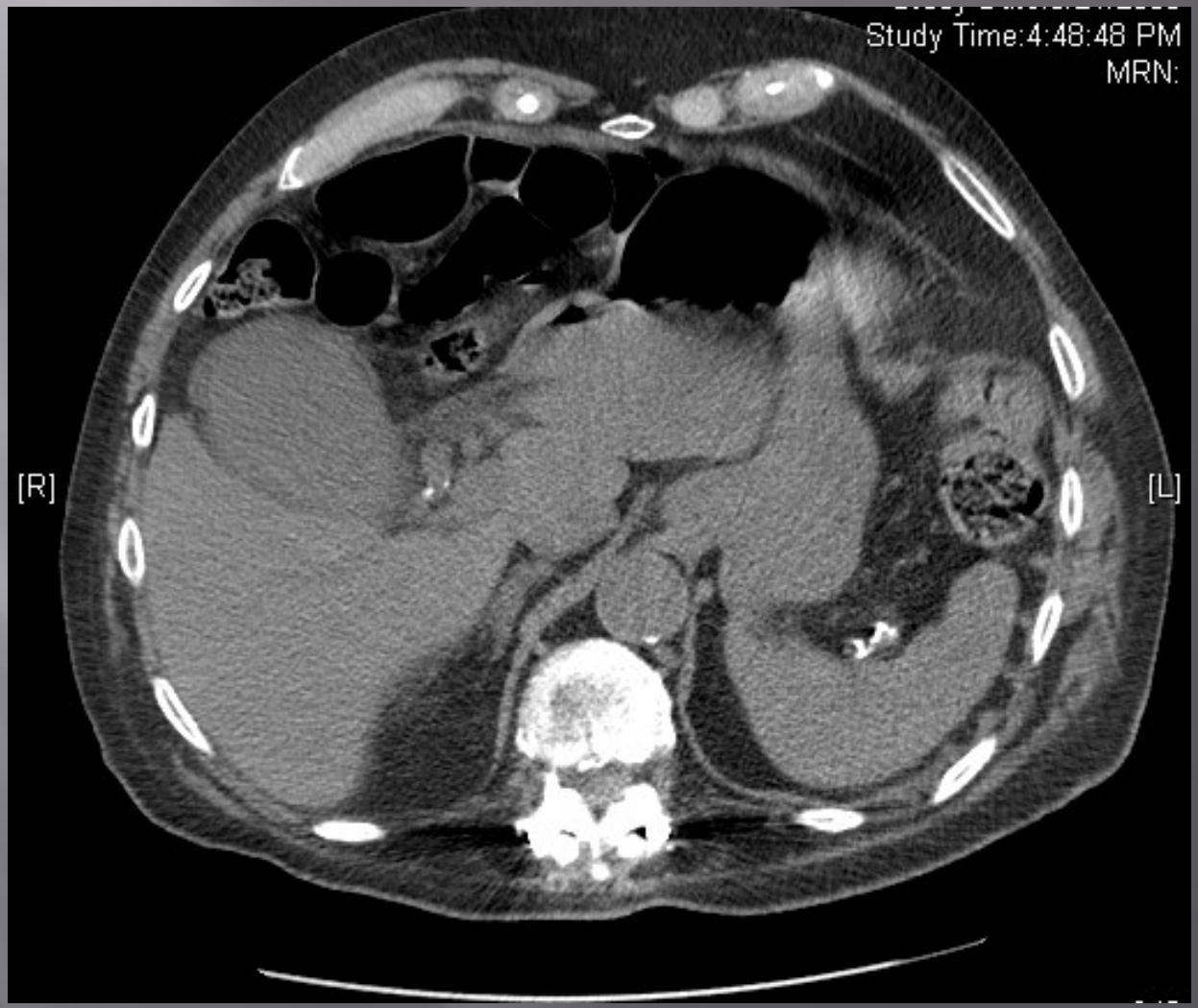
Initial Evaluation of the Patient

- History of current problem
- Pertinent medical and surgical history
- Review of major organ systems
- History of allergies
- Current medications
- Directed physical exam

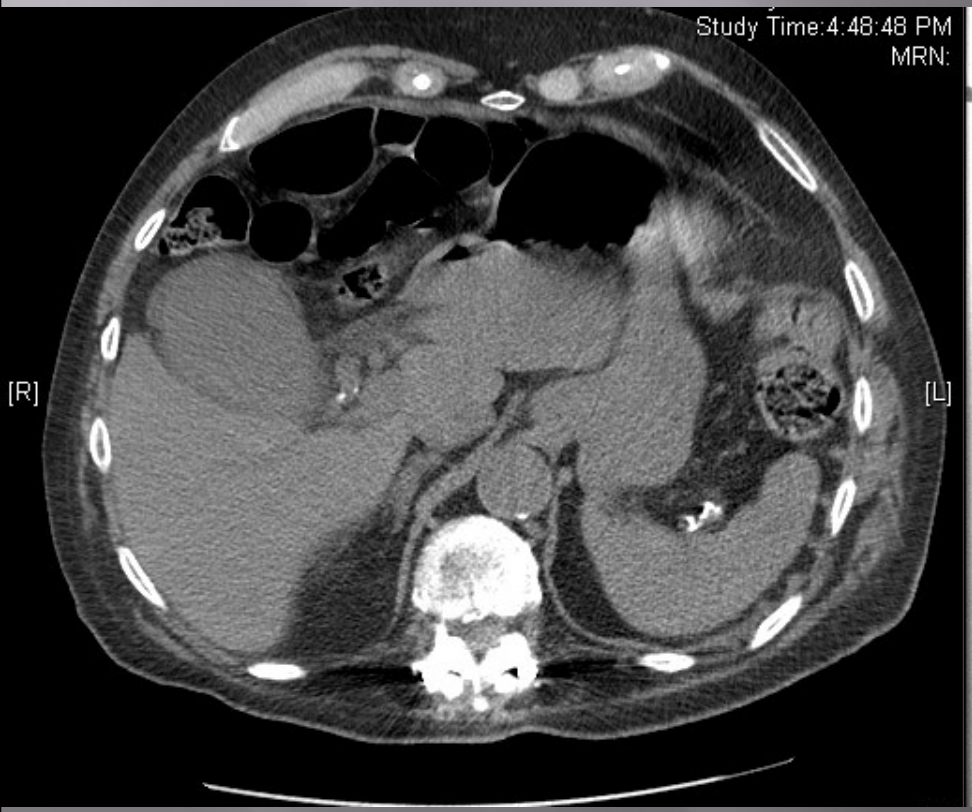
Examination Prior to Interventional Procedures

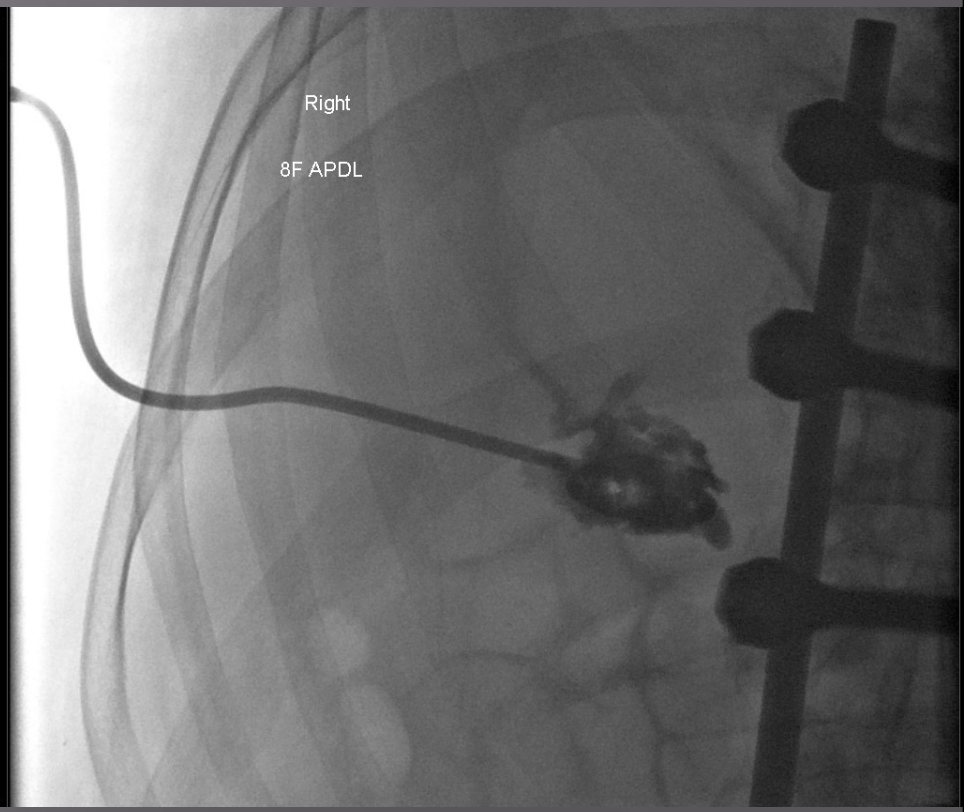
- Examine proposed puncture site (exclude CFA aneurysm, infection, overlying hernia, fresh incision or recent injury)
- Record extremity pulses (Doppler probe if necessary)
- Assess status of extremity

Review of Prior Imaging Studies



Review of Prior Imaging Studies





Consequences of Ignoring Available Imaging Studies

- Aborting IJ vein placement of catheter due to SVC occlusion
- Attempting jugular access for transvenous liver Bx in OLT patient requiring femoral access in the past
- Inserting transplenic or transhepatic PCN
- Placing biliary drainage catheter through the colon
- Starting IVC filter placement in patient with existing filter
- Puncturing dialysis graft at site of prior angioplasty precluding direct treatment

Pre-Procedure Assessment of Sedation and Analgesia Requirements

ASA Physical Status Classifications

1 – Normal healthy patient

2 – Patient with mild systemic disease

3 – Patient with severe systemic disease (includes morbid obesity, significant airway issues)

4 - Patient with severe systemic disease that is a constant threat to life

5 – Moribund patient who is not expected to survive without procedure

Anesthesia Support for IR Procedures

- Young age
- Advanced age
- History of prior anesthesia requirement
- Potential airway compromise
- Chronic narcotic use or abuse
- Severe heart, lung, or kidney disease
- Increased risk of aspiration
- Very painful or prolonged procedure (TIPS, RFA, biliary)
- Morbidly obese patient
- Uncooperative/combative patient

Informed Consent

- Obligation of physician performing procedure to explain intervention
  - nature of procedure
  - alternatives
  - benefits
  - risks
  - long-term expectations

- Informed consent is both a medical and legal term
  - be aware of definitions in local jurisdiction
  - Maharashtra state: "reasonable patient standard"

- No consensus regarding extent of discussion re: risks (e.g., every procedure could end in death)

Informed Consent

- In the IR room
- With family member as interpreter
- Leaving task to referring team

Informed Consent

- As far in time and space from the procedure as possible
- Quiet, private place
- Sit down!
- Hospital interpreter if needed (and document)
- Included family members if possible
- Show images if possible

Informed Consent

- "Implied/presumed consent" is legal and ethical for **emergent** procedures on patients who cannot give consent AND surrogate not available
- If YOU OR REFERRING TEAM don't believe the patient's mental or physical condition allows him/her to give informed consent, approach legal surrogate
- Patient (or legal representative) MUST be able to understand you without intermediary bias (e.g., must use hospital interpreter for non-English speakers)
- Avoid "exceeding consent" – anticipate possible interventions
- Telephone consent requires a witness to your discussion with the patient
- DOCUMENT encounter in pre-procedure note, consent form, and dictated procedure note *(if you didn't write it down, it didn't happen)*

Outline of Informed Consent

1. Adverse events at access site (infection, bleeding, pseudoaneurysm, dissection, thrombosis)
2. Adverse events en-route (consider any structure on way to target that may be violated and consequences thereof)
3. Adverse events from medications moderate sedation

   contrast allergy or nephropathy anticoagulants
4. Radiation injury (if prolonged fluoroscopy anticipated)

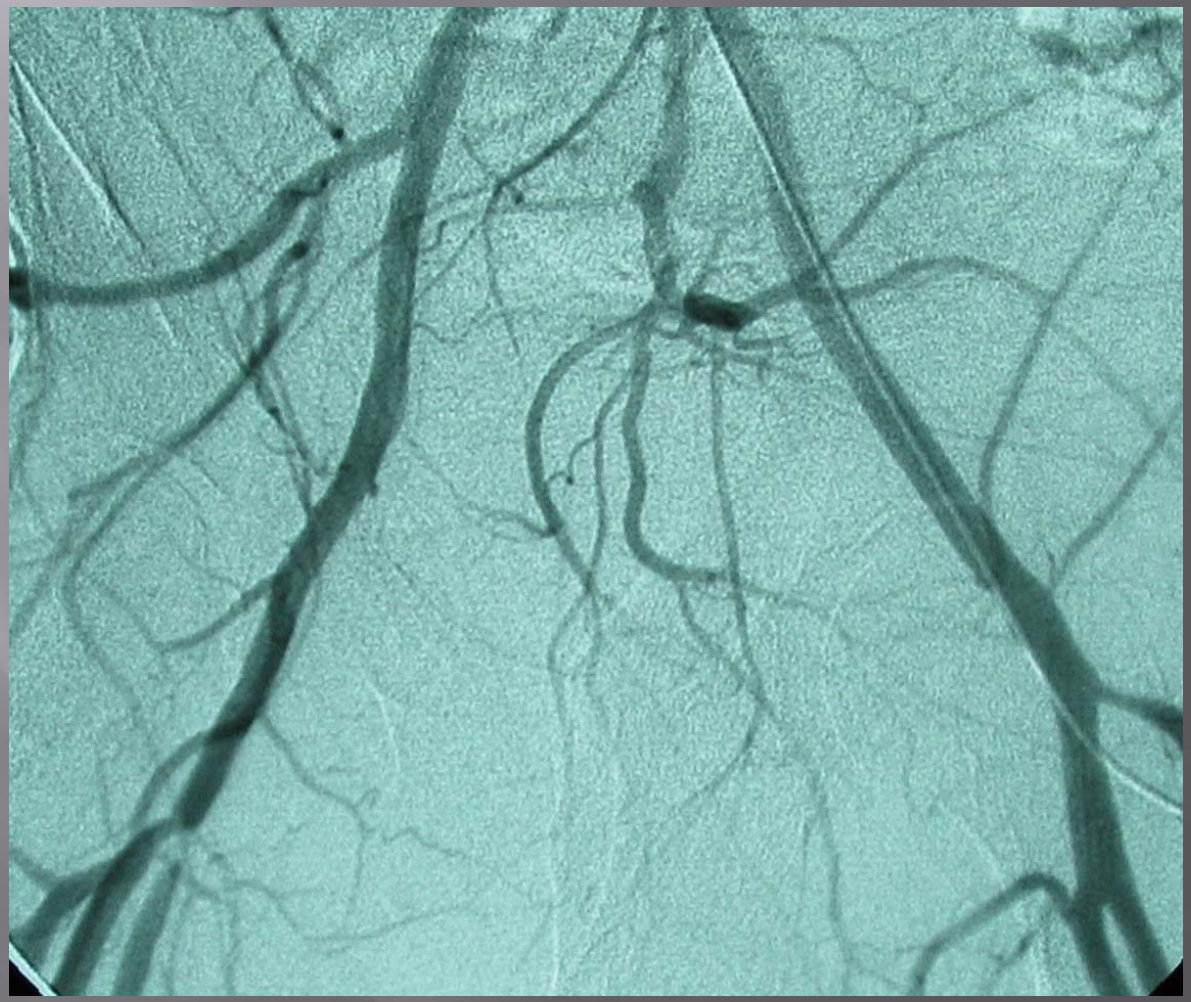
SIR Definitions of Adverse Events

- Minor
  - No therapy, no consequence
  - Nominal therapy, no consequence; overnight admission for observation only

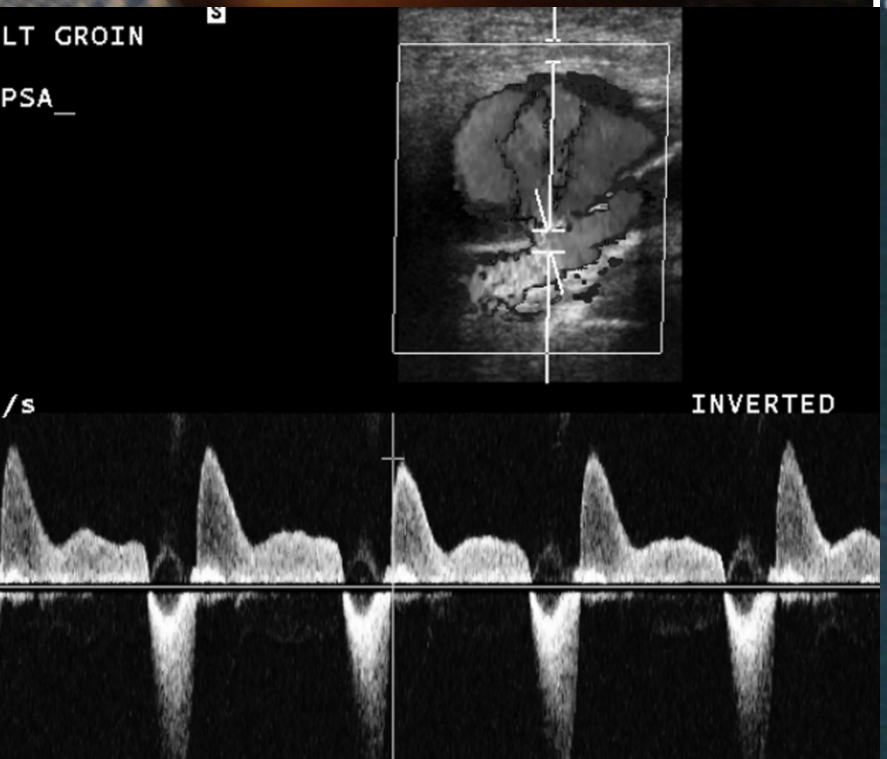
- Major
  - Requires therapy or hospitalization <48 hr
  - Requires major therapy, unplanned increase in level of care, hospitalization > 48 hrs
  - Permanent adverse sequelae
  - Death

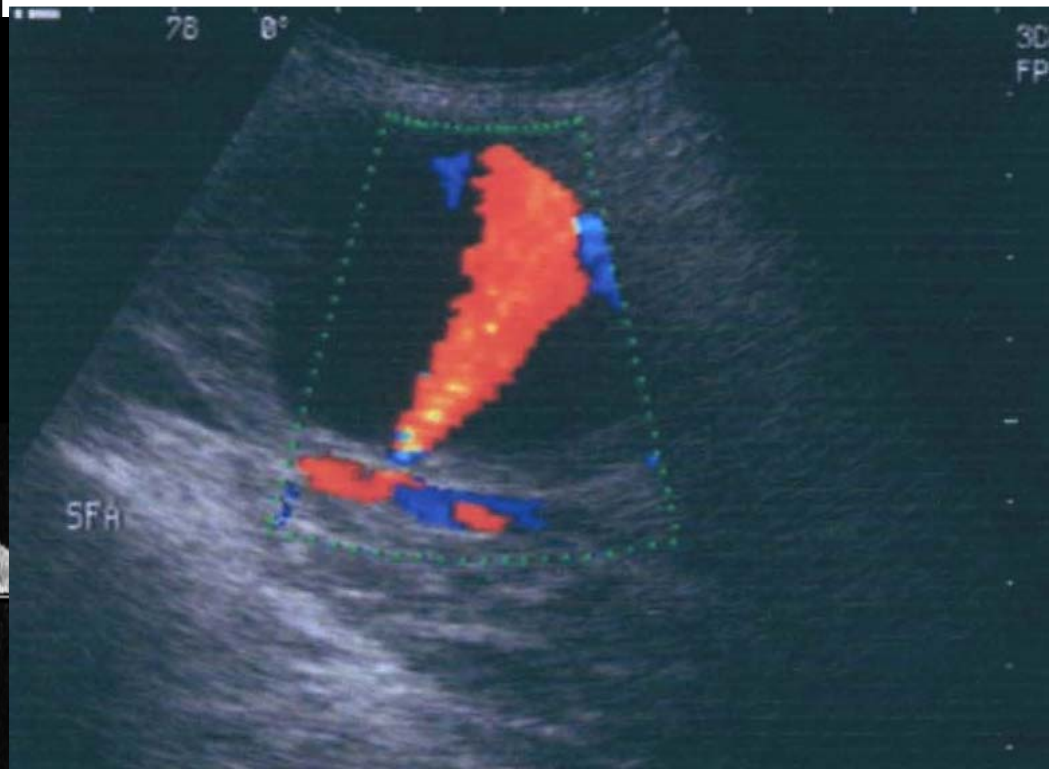
Complications after IR Procedures

• Angiography, minor	2-10%
• Angiography, major	1-2%
• Contrast-induced nephropathy	
– Transient	0.2-.14%
– Chronic dialysis	< 0.1%
• Contrast reaction	
– Moderate	0.2-0.4%
– Severe	0.04%
• Venous access placement	
– Local infection	1-7%
– Central venous thrombosis	1-4%
• Death	< 0.05%



FEMORAL PSEUDO-ANEURYSM





PSEUDO-ANEURYSM USG COMPRESSION

THROMBOSED PSEUDO-ANEURYSM POST COMPRESSION

Basic Steps in Pre-procedure Management

- Medication adjustment
- Risk for contrast allergy
- Laboratory screening
  - Contrast nephropathy (BUN, Creat, eGFR)
  - Coagulopathy (PT, PTT, INR, platelet ct)
- Prophylaxis
  - Contrast allergy
  - Renal protection
  - Normalize coagulation parameters
  - Antibiotics

Metformin

- Very small risk for severe lactic acidosis (from metformin accumulation) if contrast-induced renal failure occurs
- Virtually never seen in patients with baseline normal renal function
- With normal renal function and no relevant co-morbid conditions, hold metformin for 48 hours and restart without assessment of renal function
  - Hepatic dysfunction
  - Cardiac failure
  - Myocardial or peripheral limb ischemia
  - Sepsis

Metformin

- With normal renal function AND a co-morbid condition, hold metformin for 48 hours and restart after assessment (clinical or serum creatinine)

- With abnormal renal function (serum creatinine > 1.3 -1.5), hold metformin for 48 hours and ONLY restart after checking renal function

ACR Contrast Material Manual, 2008

LMW Heparins

- These agents will not significantly alter standard coagulation parameters.
- Studies in coronary interventions have failed to show a significant added risk when these agents are being administered.
- However, there is virtually no high level data on their effect during noncoronary interventions.
- Many practitioners will simply hold a dose before IR procedures.

Warfarin

- Stop 3-5 days before elective procedures
- Reverse or give FFP for urgent/emergent procedures
- Indications for anticoagulation "bridge" for warfarin discontinuation
  - Prosthetic heart valve (most cases)
  - VTE within 1 year
    - Severe thrombophilia
    - Active cancer
  - Atrial fibrillation with history of stroke/TIA and additional risk factor
  - Recurrent VTE

Thienopyridines – Clopidogrel [Plavix]

- Studies in coronary interventions have failed to show a significant added risk when these agents are being administered.
- No strong evidence regarding safety in the setting of IR procedures
  - Substanially increased incidence of "moderate or severe" bleeding in a review of 604 patients undergoing transbronchial lung biopsy (61% vs 3%, $p < .001$)
- Some practitioners favor discontinuation of the drugs about 5-10 days before elective, high-risk procedures (e.g., using deep-seated, large bore needles or catheters)
- DO NOT STOP PLAVIX WITHOUT CONSULTING PATIENT'S CARDIOLOGIST

Ernst A et al, Chest, 2006

Risk Factors for Contrast Material Reaction

- Previous allergic reaction to contrast agent
- Other drug allergy
- Asthma
- Reaction to skin allergens

Pre-treatment for Prevention of Contrast Material Reaction

- Medrol 32 mg OR prednisone 40 mg PO 12 hours, 7 hours (optional), and 2 hours before contrast is given
- Benadryl 25-50 mg PO 2 hours before contrast
- No evidence that PO or IV steroids are of any benefit given immediately beforehand

Thomsen, Acad Radiol, 2002
Wittbrodt, Ann Pharmacother, 1994
ACR 2008 Contrast Manual

Preprocedure Laboratory Testing

- Indiscriminate preprocedure testing of little value in EVERY large medical or surgical study reported
- Screening not warranted in otherwise healthy patients < 40 years old
- Testing advisable for elderly patients and those with established risk factors
- Tests performed within 1 month of procedure are valid if no change in clinical condition or new risk factors

Johnson et al, Surgery, 1988

Kaplan et al, JAMA, 1985

Contrast Induced Nephropathy (CIN)

- Defined as rise in serum creatinine by 0.5 mg/dL or 25% of baseline within 24-72 hours of administration
- However, serum creatinine is poor indicator of actual renal function (GFR)
- Resolution typical at 7-10 days
- Risk
  - General population (GFR>60ml/min) 0.2-1.4%
  - Pre-existing mild dysfunction 5%
  - Severe renal dysfunction (GFR<30ml/min) 50%
    + diabetes

Risk Factors for Contrast-Induced Nephropathy

- Pre-existing renal dysfunction
  - Serum creatinine > 1.2-1.5 mg/dL
  - eGFR < 60 ml/min
- Diabetes
- Dehydration
- Hypotension
- Heart failure
- Large contrast dose
- Advanced age
- Anemia
- Concomitant nephrotoxic drugs

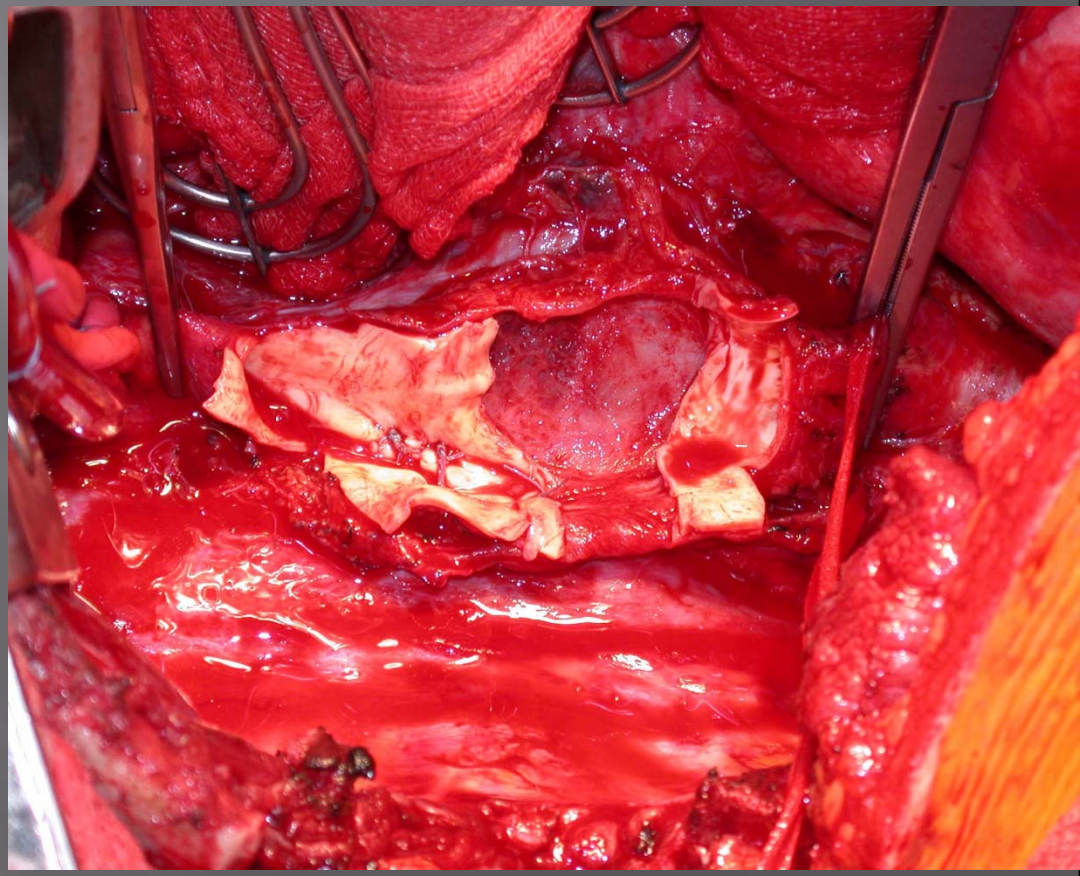
Prevention of Contrast Nephropathy

- IV saline hydration (1.0-1.5 ml/kg/hr)
  - 6-12 hours before and several hours after contrast is given
- N-acetylcysteine (NAC, Mucomyst)
  - Antioxidant that acts as scavenger of O2 free radicals toxic to renal medulla
  - 1200 mg PO BID day before, day of, and day after case
  - Results of RCT have been mixed, higher doses may be more effective
- Sodium bicarbonate IV infusion
  - Alkalinizes renal milieu, actual mechanism of action unknown
  - 154 mEg/L as 3 mL/kg/hr for one hr prior and 1 mL/kg/hr for 6 hr after
  - Results of RCT mixed but generally support this measure
- Minimize iodinated contrast dose or use carbon dioxide

Tepel et al, NEJM, 2000
Kay et al, JAMA, 2003
Jo S-H et al, Am Heart J, 2009
Merten et al, JAMA, 2004
Stenstrom DA, et al, JVIR, 2008

Risk Factors for Bleeding with IR Procedures

- Thrombocytopenia
- Anticoagulant medications
  - Antithrombin (heparin, bivalirudin, warfarin)
  - ??Antiplatelet (clopidogrel)
- Liver disease
- History of bleeding diathesis
- Malignant hypertension
- Malnutrition
- Hematologic malignancy
- Splenomegaly
- DIC
- Selected chemotherapeutic agents



Screening for Bleeding Risk

- Diagnostic and most therapeutic vascular procedures
  - Routine screening unnecessary, screen if risk factors present
- Thrombolytic procedures
  - CBC, coags, fibrinogen, T&C
- Non-vascular IR procedures
  - Associated with occult bleeding at inaccessible sites
  - Routine screening recommended for most cases

Safety Thresholds for Coagulation Parameters

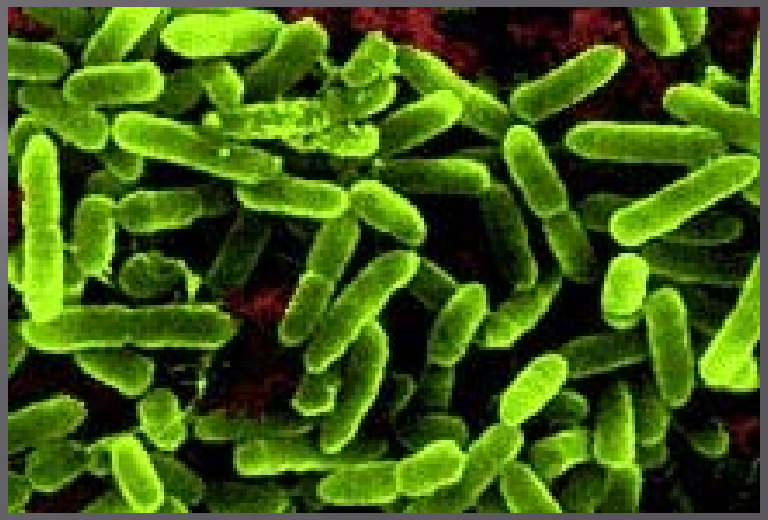
• PT	<3 sec control
• PTT	<50 seconds
• INR	<1.6 - 1.8
• INR (venous, no tunnel)	<3.0
• Platelet ct (nl INR)	>50,000/mm3
• Platelet ct (abnl INR)	50-100K/mm3
• Bleeding time	<8 minutes

Correction of Coagulation Abnormalities

INR	Withhold warfarin, bridge with heparin or LMWH
	FFP 2 – 4 Units
	Vitamin K 1-3 mg IV
PTT	Withhold heparin 2-4 hr before case FFP 2-4 bags
Platelets	Transfusion (10U to increase 50-100K)
BT	Cryoprecipitate 0.2 bag/kg
	DDAVP 0.4 mcg/kg over 30 minutes
	Platelet transfusion

Prophylactic Antibiotics in Interventional Radiology

- Used when infected tissues or colonized mucosal surface may be breached
- Used before ablation
- Indications for use are very controversial
- Surgical practice dictates administration 20 minutes before procedure
- In some cases, antibiotics should be continued after the procedure



Use of Antibiotic Prophylaxis in IR Procedures

- Anecdotal evidence in some situations (e.g., biliary drainage, PCN with stone disease) strongly supports use
- No high level scientific evidence for or against use in any IR procedure
- Several possibly relevant studies exist

Prophylactic Antibiotics for Tunneled Central Venous Catheters Placed by Surgeons or IRs

- Meta-analysis of 4 randomized controlled trials with 588 patients from 1966-2006
- Prophylactic vancomycin/teicoplanin vs. placebo prior to catheter insertion
- Effect of giving antibiotic in gram positive catheter infections OR=0.42 [0.13-1.31] – NOT SIGNIFICANT

Van de Wetering et al, Cochrane Database Syst Rev, 2007

Recommendations for Prophylactic Antibiotics

Yes

Virgin biliary procedures (and Tx cholangiograms)
Most GU procedures
Drainage of suspected abscesses
Embolization for target ischemia/infarction (TACE, UAE) TIPS
Endograft placement
Hx of MRSA
Prolonged case or breach of sterility

Recommendations for Prophylactic Antibiotics

Maybe

Gastrostomy
Ports
Tunneled venous catheters
Dialysis graft interventions
RF ablation of solid tumors
Vascular stent placement
Thrombolysis

Recommendations for Prophylactic Antibiotics

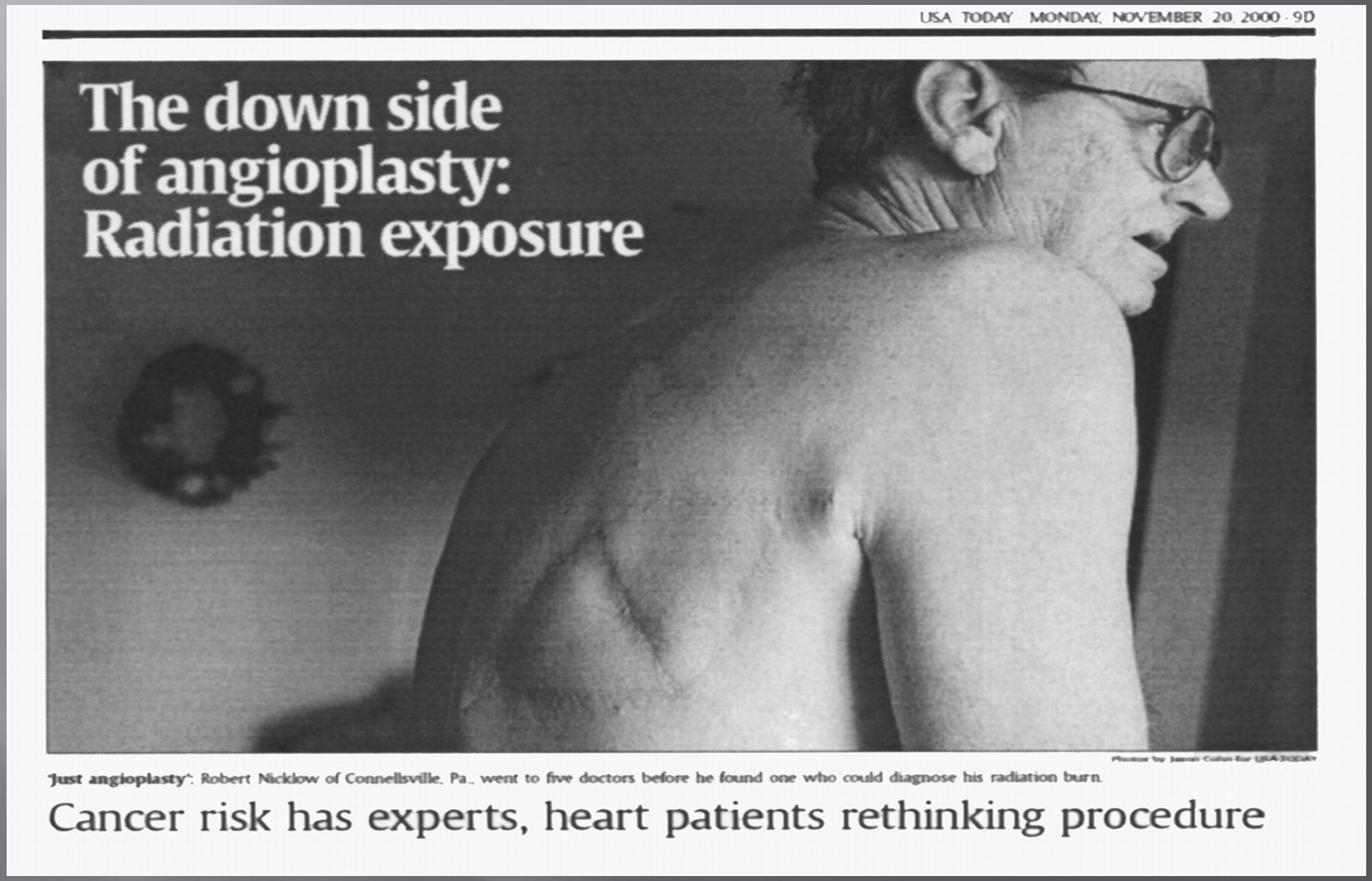
No

Routine angiographic procedures
GU tube changes and checks without infection
Clear fluid aspirations
IVC filters
Endovenous laser ablation
Biopsy (unless transrectal route)

Recommendations

- Biliary interventions
  - Ceftriaxone one gram IV [community]
  - Zosyn (piperalcillin/tazobactam) 3.375 g IV [SNF/hospital]
  - Levaquin (levofloxacin) 750 mg IV [PCN allergy]
- GU interventions
  - Levaquin 750 mg IV
  - Ciprofloxacin 400 mg IV
- Percutaneous gastrostomy
  - Cephazolin one gram IV
- TACE
  - Cephalzolin two grams IV
  - Metronidazole 500 mg IV
  - Levaquin 750 mg IV [PCN/cephalosporin allergy]
- Ports
  - Cephazolin one gram IV
  - Vancomycin one gram IV + Cephazolin one gram IV [MRSA]
  - Clindamycin 600 mg IV [PCN allergy]

Headline and photograph accompanying article published in USA Today [2] reporting juryaward of $1 million to 57-year-old man who sustained serious skin injury after two coronaryartery angioplasties that occurred 5 months apart



USA TODAY · MONDAY, NOVEMBER 20, 2000 · 9D

The down side of angioplasty: Radiation exposure

'Just angioplasty': Robert Nicklow of Connellsville, Pa., went to five doctors before he found one who could diagnose his radiation burn.

Cancer risk has experts, heart patients rethinking procedure

Berlin, L. Am. J. Roentgenol. 2001;177:21-25

Patient Follow-up

- Follow-up is your responsibility – *residents, PAs, nurses, and referring MDs are only around to help*
- Guidelines found in VIR handbook
- When adverse events occur, frequent documented follow-up and communication with patient and family is critical

Effect of patient satisfaction

- Effect of improved patient satisfaction
- Compliance with treatment
- Symptom resolutions
- Functional outcome
- Pain control
- Emotional status
- Measurable outcomes (such as HbA1c levels)

Ochsner Journal 2010;10:38-43
Diabetes med 2003; 20:486-90
Mayo Clinic Proc 2003;78:211-214

Effect of unhappy patients

- For every patient that complains 20 dissatisfied patients do not
- Of those dissatisfied patients who do not complain, 90% do not return
- It is 10X more expensive to recruit new patients than to keep established ones
- The average wronged patient will tell 25 others

Gentle words of wisdom…

Your Consultation is the patient's first impression of your program, so…

- Be accurate
- Answer the question that's asked
- Be terse/tight
- Have documentation to back up your answers
- Start early – it takes months to write a good PIF
- This is not something your mother, spouse, best friend, or admin asst. can do for you!

THANK YOU