

## EXCLUSION CRITERIA OUTPATIENT SURGERY CENTER REDWOOD CITY

### I. EXCLUSION CRITERIA

1. Overnight Stay Required for non-orthopedic reasons such as cardiac monitoring
2. Significant blood loss expected
3. Blood products needed \*\*\*\*
4. MI in last year
5. CVA or TIA in last nine months\*
6. AICD – With the exception of Pain and PM&R cases that are injections ONLY.
7. Wheelchair bound for non-orthopedic reasons. Unable to transfer, ambulate or do ADL's.
8. Requires Home O2
9. Pulmonary Hypertension:
  - a. PA mean  $\geq$  25mm Hg
  - b. RVSP  $\geq$  40mm Hg with S/S such as TR, RAE, RVE, RVH
10. Cardiac Stents (ONLY for patients temporarily discontinuing all anticoagulant medication\*\*\*)
11. Severe Aortic Stenosis with an aortic valve area (AVA)  $<1.0$  cm<sup>2</sup> and/or a mean transaortic pressure gradient (MPG)  $>40$  mm Hg and/or a peak aortic jet velocity ( $V_{max}$ )  $>4$  m/s
12. Severe mitral stenosis with valve area  $< 1$  cm<sup>2</sup> and/or a pressure gradient across the mitral valve of  $\geq 20$  mm Hg
13. CHF: LVEF  $< 40\%$
14. Post-op mechanical ventilatory support anticipated
15. BMI  $\geq 50$ ; weight  $< 80$  lbs/ 36.5kg
16. Patients must be at least 12 years old on the day of surgery and at least 80lbs.
17. Pregnancy
18. Epidermolysis Bullosa \*\*\*\*\*

### II. CASE BY CASE

- A. Any ASA 3,4
- B. Family or Personal HX MH
- C. Morbid Obesity with BMI 40 - 49
- D. Pacemaker
- E. Psychiatric issues requiring 1:1 nursing in PACU
- F. Anticoagulation
- G. CHF: NYHA functional class II, III, or IV, and objective class B, C, or D and LVEF  $\geq 40\%$  with cardiology clearance
- H. Pulmonary Embolus within last 6 months
- I. Moderate to Severe Sleep Apnea
- J. Suspected Difficult Airway (limited neck ROM, limited mouth opening, M4 airway, previous difficult airway)
  - A. Radiation to head, neck, or oropharynx
  - B. Hx Total neck dissection

- K. Cardiac Abnormalities: ex: New onset AFib/Aflutter, New LBBB
- L. Renal Insufficiency
- M. Hepatic Failure or Cirrhosis
- N. Severe asthma or COPD
- O. BP: systolic > 180mm Hg and/ or diastolic > 110mm Hg\*\*

### III. **EXCLUSION CRITERIA FOR KNEE/HIP ARTHROPLASTY & SPINE SURGERIES**

#### **A. Absolute Exclusion Criteria:**

1. Inability to participate in preop counselling
2. Lack of social support at home
3. ESRD on dialysis
4. Bleeding disorder likely to require perioperative blood products
5. Cirrhosis
6. Severe Aortic Stenosis with an aortic valve area (AVA) <1.0 cm<sup>2</sup> and/or a mean transaortic pressure gradient (MPG) >40 mm Hg and/or a peak aortic jet velocity (V<sub>max</sub>) >4 m/s
7. Severe mitral stenosis with valve area < 1 cm<sup>2</sup> and/or a pressure gradient across the mitral valve of ≥ 20 mm Hg
8. Severe pulmonary hypertension with a PA mean ≥ 25 or an RVSP ≥ 40 with RVE or RAE and symptoms
9. Cardiomyopathy with LVEF < 40%
10. NYHA class III or IV
11. BMI > 40
12. Significant urologic medical history, including hx of urinary retention (**this only applies to arthroplasty, not spines**)
- 13.. AICD present
14. Poorly controlled DM with an HgA1C ≥ 8.0

#### **B. Relative Exclusion Criteria:**

1. Age > 80 years old
2. BMI > 35
3. Severe cardiac disease NOS
4. Severe pulmonary disease
5. **Untreated** OSA
6. Severe mobility disorders and/or functional neurologic impairments
7. ASA > 2
8. Revision surgery (**this only applies to arthroplasty, not spines**)

### IV. **ACDF & Anterior Cervical Disc Arthroplasty specific criteria:**

#### **A. Patient Characteristics**

1. **Must be < 65 years old on the day of surgery**

2. ASA I or II
3. BMI  $\leq$  35
4. INR  $<$  or  $+$  1.2
5. No history or suspicion of difficult airway ( Neck circumference  $\geq$  45cm (20 inches), Mallampatti IV, micrognathia, etc)

#### B. Surgery Characteristics

- a. ACDF cases must *be first case of the day*
- b. No revision surgeries
- c. I- 2 levels only
- d. PACU stay will be minimum 4 hours and surgeon will remain on campus until the patient is discharged from PACU

#### V. Overnight Stay Criteria

1. Overnight stay at OSC is for the purpose of postoperative pain control only.
2. Patients may be excluded from eligibility for a 23-hour stay for the following reasons:
  - a. Criteria that make a patient more likely to have a difficult airway or be difficult to ventilate in a code situation
    1. BMI  $>$  40
    2. Abnormal airway anatomy
    3. Restricted neck range of motion
  2. Criteria that make a patient more likely to obstruct
    1. OSA without CPAP
  3. Criteria that make a patient more likely to have postop instability of any kind:
    1. ASA 3/4
    2. Prior MI or CVA
    3. History of hypercoagulability, DVT or PE

**VI. \*CVA:** A history of stroke was associated with increased risk of MACE and mortality in patients undergoing elective non-cardiac surgery, particularly if the time elapsed between stroke and surgery was  $<$  9 months. Low and intermediate risk surgeries seemed to pose at least the same relative risk of MACE in patients with recent stroke compared with high-risk surgery.  
<http://jama.jamanetwork.com/article.aspx?articleid=1887763>

**VII. \*\*BP** Ideally, all hypertensive patients should be treated before elective surgery. In practice, only patients with Stage 3 (systolic  $>$ 180mm Hg; diastolic  $>$  110mm Hg) are regarded as needing preoperative treatment, and therefore, deferral of case. If the patient shows signs or symptoms of end organ damage, the case must be CX and patient treated emergently. <https://academic.oup.com/bjaed/article/4/5/139/291003>  
See Appendix for managing BP in Pain/ PMR patients.

#### VIII. \*\*\*DES

Ideally, a patient with a DES on two drug anti-platelet therapy should remain on these drugs in the first 12 months after stent placement. There is a high incidence of major adverse cardiac events with pre-mature discontinuation of dual anti-platelet therapy in the first 12 months post-DES placement, and with discontinuation of single or dual anti-platelet therapy in the perioperative period after 12 months.

Perioperative thrombotic cardiac events related to DAPT discontinuation include myocardial infarction (MI), death, stent thrombosis, and the need for urgent repeat revascularization. Stent thrombosis is a proximate cause of death or MI.

The premature cessation of DAPT is the strongest predictor of stent thrombosis, especially discontinuation of both agents. Stent thrombosis can lead to high rates of MI (50 to 70 percent) and death (10 to 40 percent). The risk was related to the time from stent implantation to surgery, with a significantly elevated risk during the first year (adjusted odds ratio [AOR] 2.59, 95% CI 1.36-4.94). The risk was increased in patients with either DES or BMS.

All patients should be on life- time ASA. There is little evidence, with the exception of *cardiac, intracranial, posterior eye, and prostate surgery*, that there is a significant risk of hemorrhage. However, the risk of late stent thrombosis must be balanced against the risk of excess surgical bleeding.

For patients who have undergone previous stenting with either BMS or DES, and who will need cessation of one or both antiplatelet agents, we *defer planned non-emergent, non-cardiac surgery* until after the recommended duration of DAPT, which is 6 months for BMS and DES. The risks of non-cardiac surgery before 6 months are increased after both BMS and DES.

With the HOST-EXAM trial and other cardiac literature suggesting that clopidogrel (Plavix) may be superior to ASA for lifetime monotherapy, we expect to see more patients on clopidogrel monotherapy in our large population of patients with stents. Unfortunately, many of the procedures done at OSC, unlike ASA, require stopping clopidogrel 5-7 days in advance, leaving the patient at risk of stent thrombosis.

OSC Policy:

- A. *There should be no elective surgery for any patient within 6 months of DES placement (or 6 weeks after BMS placement).*
- B. *Between 6 and 12 months after DES placement, elective surgery may occur when and if the Cardiologist decides it is safe to discontinue DAPT and will clear the patient. ASA must be continued without interruption.*
- C. *After 12 months, elective surgery may be scheduled if DAPT has been discontinued and the patient remains on ASA, or if DAPT can be discontinued with the cardiologist's permission. ASA must be continued without interruption.*

- D. Some cases, such as hand cases, can be done after 6 months with the patient continuing DAPT, but these *must have cardiac clearance*.
- E. Patients who must discontinue ALL (ASA and/or a thienopyridine) of their anti-platelet agents for a surgical procedure are inappropriate for OSC and must have surgery at ASC or MOR, where access to the Cardiac Cath lab is immediate.
- F. Patients who are on dual drug therapy and do not have increased risk factors for stent thrombosis can discontinue their thienopyridine therapy 5 days before surgery and remain on ASA ONLY with permission from their cardiologist.
- G. Patients who must discontinue clopidogrel monotherapy 7 days before a procedure should bridge with ASA. Seven days before surgery, when clopidogrel is stopped, a patient who weighs > 120 kg should take ASA 325 mg po, and then ASA 81 mg po for the next 6 days. For a patient < 120 kg, load with ASA 162 mg and then take ASA 81 mg po until the DOS. The patient's cardiologist must clear this, as well as decide if a loading dose of clopidogrel is necessary when it is resumed post-operatively.

## IX. Hemoglobin

*Any patient who needs or may need blood or blood products is inappropriate for the OSC because we have no access to a blood bank.* If a procedure has the potential for significant blood loss or enough blood loss to trigger the criteria below, that case is also inappropriate.

OSC uses guidelines rather than an absolute number, with consideration on a case by case basis. Relevant portions of the ASA practice guidelines:

- A. Transfusion is rarely indicated when the hemoglobin concentration is greater than 10 g/dL and is almost always indicated when it is less than 6 g/dL, especially when the anemia is acute.
- B. The determination of whether intermediate hemoglobin concentrations (6 to 10 g/dL) justify or require red blood cell (RBC) transfusion should be based on the patient's risk for complications of inadequate oxygenation.
- C. The use of a single hemoglobin "trigger" for all patients and other approaches that fail to consider all important physiologic and surgical factors affecting oxygenation are not recommended. Given the above, here are some numbers that are transfusion triggers and therefore inappropriate for OSC. Again, fixed numbers are not a good substitute for an assessment of risk for each patient:
  - 1. Blood loss >20 percent of blood volume when more than 100 mL
  - 2. Hemoglobin <8 g/dL
  - 3. Hemoglobin <10 g/dL with major disease (e.g., emphysema, ischemic heart disease)

## APPENDIX

## **PAIN/ PM&R OSC BLOOD PRESSURE (BP) PROTOCOL**

### **PRE-OP protocol:**

- Patients are advised to continue taking their regular BP medications, *at all times* prior to their scheduled intervention.
- Case will be cancelled for pre-op systolic BP above 180 or diastolic BP above 110.
- Patients with systolic BP above 150 or diastolic BP above 90 in Pre-op will have BP re-check at 5 and 10 minutes after the initial BP to better establish baseline range (a max of 30 mins will be allowed for the pt. to relax/ optimize their BP)

### **INTRA-OP protocol:**

- Patients receive routine BP monitoring during their time in the OR.
- If BP exceeds 180/110 while in the OR, the treating physician will assess for any adverse signs or symptoms (this may include irregular heart rate, dizziness, nausea, blurred vision, anginal pain, or shortness of breath) and terminate the case for presence of any adverse signs or symptoms. If none, the treating physician will determine whether to continue the case or terminate based on the clinical circumstances.

### **POST-OP protocol:**

For a patient whose BP exceeds the 180/110 threshold while in the OR:

- BP will be checked every 5 minutes in PACU
- The patient will not be discharged until BP lowers back to the pre-op baseline range.

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