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Goals

1. Review Antibiotics Commonly Used in Prophylaxis

2. Review Wound Classification

3. Review Literature Regarding Antibiotic Prophylaxis in Clean Head and Neck Cancer Surgery

4. Review Literature Regarding Antibiotic Prophylaxis in Clean-Contaminated Head and Neck Cancer Surgery
Poll

When performing a submandibular gland excision in which you leave a closed-system drain, which prophylactic antibiotic regimen would you choose?

A. No antibiotics at all

B. One dose of IV antibiotics within 60 minutes of beginning the case

C. Perioperative IV antibiotics within 60 minutes of beginning the case and continued antibiotics for 24 hours after completion of the case

D. Perioperative antibiotics within 60 minutes of beginning the case and continued antibiotics until the drain is removed
Poll

When performing a laryngectomy in which you leave a closed-system drain, which prophylactic antibiotic regimen would you choose?

A. No antibiotics at all

B. One dose of IV antibiotics within 60 minutes of beginning the case

C. Perioperative IV antibiotics within 60 minutes of beginning the case and continued antibiotics for 24 hours after completion of the case

D. Perioperative antibiotics within 60 minutes of beginning the case and continued antibiotics until the drain is removed
Prophylactic Antibiotic Use

Infection vs Resistance, side effects
Favorable Qualities in a Prophylactic Antibiotic

Appropriate Coverage

Rapid Administration

Achieve Therapeutic Levels in Target Tissue

Favorable Side Effect Profile

Inexpensive
Commonly Used Prophylactic Antibiotics

Cefazolin:
- gram positives
- anaerobes

Clindamycin
- gram positives
- anaerobes

Flagyl
- anaerobes only

Zosyn
- gram positives
- gram negatives
- anaerobes

Ampicillin/Sulbactam
- gram positives
- anaerobes
- gram negatives
Wound Classification

Clean

Clean-Contaminated

Contaminated

Dirty
## Wound Classification

**National Academy of Sciences National Resource Council**

<table>
<thead>
<tr>
<th>Wound Class</th>
<th>Reported infection rate without abx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>&lt;1-5%</td>
</tr>
<tr>
<td>Clean-Contaminated</td>
<td>24-87%</td>
</tr>
<tr>
<td>Contaminated</td>
<td>-</td>
</tr>
<tr>
<td>Dirty</td>
<td>100%</td>
</tr>
</tbody>
</table>
Clean Wounds in Head and Neck Surgery
RISK OF INFECTION WITHOUT ANTIBIOTICS IS VERY LOW

1. Retrospective Review
   Johnson/Wagner ’87: n=356  \textbf{0.56\% SSI rate}

2. Compiled Review Articles
   Shapiro ‘91
   Weber/Callendar ‘92 -very low infection rate: <1-5\%
RISK OF INFECTION WITHOUT ANTIBIOTICS IS VERY LOW

3. Randomized-Controlled Prospective Study

Avenia 09- N=500- clean thyroidectomy surgery
-0.4% (without abx) vs 0.8% wound infection
-limitations: ***exclude high risk pts
Clean Wounds in Head and Neck Surgery

Conclusion: No good evidence to support routine use of perioperative antibiotics in clean head and neck surgery cases
Clean Wounds in Head and Neck Surgery

Neck Dissection: A Special Case?

Retrospective studies:

- Johnson/Wagner/Carrau '91
  - 10/99 (10%) vs 3/93 (3%)
  - **no statistically significant difference but higher rate

- Li Xing Man/Johnson et al 2011
  - SSI associated with Op time, flap, extent of surgery

Maybe
Clean Wounds in Head and Neck Surgery

Neck Dissection: A Special Case?

Retrospective Studies:

**YES**

- **Coskun 00**: 13% (N=54) of patients undergoing clean radical neck dissection despite use of abx compared to 1% for all other clean cases (N=207)
  - statistically significant

- **Seven et al 04**: non-randomized prospective study. (unasyn pre op and 4 doses post op)
  - 1/57 (1.2%) patients undergoing neck dissection had wound infections
  - 7/51 (13.2%) patients in control group (retrospective review of charts of patients previously undergoing neck dissection without antibiotics)
Clean Wounds in Head and Neck Surgery

Neck Dissection: A Special Case?

Retrospective Studies:

NO

-Slattery 95: 0% wound infection rate
Clean Wounds in Head and Neck Surgery

Conclusion

No evidence for routine use in clean cases

Neck dissections may represent a subset of clean cases that may benefit from perioperative antibiotics - more studies needed
Clean-Contaminated Wounds in Head and Neck Surgery
Clean-Contaminated Wounds in Head and Neck Surgery

Microbiology of Head and Neck Wound Infections

-Skin Flora: staph epidermidis, staph aureus
  -beta-hemolytic step
  -upper aerodigestive tract bacteria
Clean-Contaminated Wounds in Head and Neck Surgery

Saliva

High Bacterial Load

Polymicrobial
 - gm +
 - anaerobes
 - gm -?
  - not present in normal controls
  - more likely in h&n cancer

### Common Microbes Isolated from Head and Neck Wound Infections

<table>
<thead>
<tr>
<th>Gram Positive</th>
<th>Gram Negative</th>
<th>Anaerobic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staph aureus</td>
<td>Klebsiella pneumonia</td>
<td>Peptococcus</td>
</tr>
<tr>
<td>Staph epidermidis</td>
<td>E. Coli</td>
<td>Peptostreptococcus</td>
</tr>
<tr>
<td>Strep pneumonia</td>
<td>Enterobacter sp.</td>
<td>Fusobacterium</td>
</tr>
<tr>
<td>Strep faecalis</td>
<td>Pseudomonas</td>
<td>Bacteroides</td>
</tr>
<tr>
<td>-</td>
<td>Hemophilus sp.</td>
<td>Anaerobic strep</td>
</tr>
<tr>
<td>-</td>
<td>Proteus sp.</td>
<td>-</td>
</tr>
</tbody>
</table>
Clean-Contaminated Wounds in Head and Neck Surgery

Risk Factors for Post op Wound Infections

- Diabetes
- Advanced Stage of Disease/Extent of Surgery
- Presence of a Tracheostomy
- Flap Reconstruction (pedicle)
- Previous XRT
Clean-Contaminated Wounds in Head and Neck Surgery

Should prophylactic antibiotics be used routinely?

Which antibiotics should be used? (coverage)

How long should they be used?
Clean-Contaminated Wounds in Head and Neck Surgery

Should prophylactic antibiotics be used?
Clean-Contaminated Wounds in Head and Neck Surgery

### Prophylactic Antibiotics vs Placebo

<table>
<thead>
<tr>
<th>Author</th>
<th>study design</th>
<th>infection without abx (placebo)</th>
<th>Infection rate with abx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketcham ‘62</td>
<td>RCT** stopped early,</td>
<td>54.4% (n=11)</td>
<td>22.2% (n=9)</td>
</tr>
<tr>
<td>Dor et al ‘73</td>
<td>Double blind RCT</td>
<td>36% (n=50)</td>
<td>17.3% (n=52)</td>
</tr>
<tr>
<td>Becker ‘79</td>
<td>Double blind RCT</td>
<td>87% (n=23)</td>
<td>38% (n=32)</td>
</tr>
<tr>
<td>Saginur ‘87</td>
<td>Blinded RCT** stopped early</td>
<td>55% (n=9)</td>
<td>33% (n=11)</td>
</tr>
<tr>
<td>Sepehr ‘09</td>
<td>Retrospective review</td>
<td>7% (n=202) short 13% (n=205) long</td>
<td></td>
</tr>
</tbody>
</table>
Clean-Contaminated Wounds in Head and Neck Surgery

Conclusion: in clean-contaminated surgery peri-operative prophylactic antibiotics significantly decrease infection rate
Clean-Contaminated Wounds in Head and Neck Surgery

Which antibiotics should be used?
Clean-Contaminated Wounds in Head and Neck Surgery

Need Anaerobe Coverage?

**YES**

- Robbins ’90- randomized prospective study clean-contaminated procedures:
  - ancef vs ancef + metronidazole.
  - 23.9% infection with ancef only and
  - 11.9% with both

- Jonas Johnson ’87-randomized prospective trial ancef 1 day vs ancef 5 days vs clinda/gent: higher infection rate in ancef alone (25% vs 5.4%)

**NO**

- Rodrigo 97- double blind RCT comparing ancef, unasyn, and clinda + gent in H&N clean/contaminated surgery. (n=159)
  - overall infection rate 22%
  - no statistically significant difference in infection rates
Clean-Contaminated Wounds in Head and Neck Surgery

Need Anaerobe Coverage?

Yes- general consensus to coverage anaerobes with some conflicting studies
Clean-Contaminated Wounds in Head and Neck Surgery

Gram Negative Coverage?

Yes

- Weber/Frankenthaler 92- N=212. Prospective randomized blinded trial of unasyn vs clinda.
  - significantly fewer infections in unasyn group (13%) vs clinda (27%)
  - more gram negative organisms isolated from clinda group
  - overall infection rate for flap closure: 37%
Clean-Contaminated Wounds in Head and Neck Surgery

Gram negative Coverage?

No

- Johnson/Wagner 97: N=197- randomized to unasyn and clinda
  - no statistically significant difference
  - unasyn group (13% infection),
  - clinda group (12% infection) – higher rate of C. Diff (7 vs 1-)

- Skitaralec 07- randomized ancef vs amoxicillin/clavulanate: no statistically significant difference.
  - Ancef infection rate (24%)
  - amox/clav (21%).
Ampicillin/sulbactam
- still attractive option as perioperative antibiotic
- at least as effective as clindamycin
- favorable side effect profile
- favorable cost
Clean-Contaminated Wounds in Head and Neck Surgery

Gram Negative Coverage?

Conclusion - literature divided
Clean-Contaminated Wounds in Head and Neck Surgery

How Long Should antibiotics be given?
Clean-Contaminated Wounds in Head and Neck Surgery

Duration of prophylactic antibiotic use- 24 hours or less

-Johnson ’86: randomized 1 vs 5 days of cefoperazone in patients with flaps
  - no statistically significant difference in infection rate (18.9 vs 25%) (N=109)

-Righi 96: prospective randomized trial. N=162. Patients randomized to 1 vs 3 days of clindamycin
  -1 day: 2.5% infection rate
  -3 day: 3.7% infection rate
  -no statistical difference

-Carroll 03: randomized, blinded, prospective trial of clean-contaminated of head and neck patients undergoing hn tumor resection and free flap. Randomized into 1 vs 5 days of clindamycin -n=75
  -1 day: 11% infection rate
  -5 day: 10% infection rate
  -no statistical difference
Clean-Contaminated Wounds in Head and Neck Surgery

Duration of prophylactic antibiotic use - 24 hours or less

Conclusion: no good evidence to use prophylactic antibiotics beyond 24 hours
Clean-Contaminated Wounds in Head and Neck Surgery

Russel et. al 2012- Laryngoscope

<table>
<thead>
<tr>
<th>Study</th>
<th>Antibiotics</th>
<th>No.</th>
<th>Infections %</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson et al., 1984⁵</td>
<td>Cefazolin (500 mg IV q8h) vs. clindamycin (300 mg IV q8h) + gentamicin (1.7 mg/kg IV q8h) for 1 or 5 days</td>
<td>107</td>
<td>Cefazolin, 1 day: 33%; cefazolin, 5 days: 20%; clindamycin + gentamicin, 1 day: 7%; clindamycin + gentamicin, 5 days: 4%</td>
<td>&lt;.05 (for cefazolin vs. clindamycin + gentamicin); &gt;.05 (for 1 vs. 5 days)</td>
</tr>
<tr>
<td>Johnson et al., 1984⁶</td>
<td>Cefoperazone (2 g IV q8h) vs. cefotaxime (2 g IV q8h) for 1 day</td>
<td>87</td>
<td>Cefoperazone: 10%; cefotaxime: 9.4%</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Johnson et al., 1986⁷</td>
<td>Cefazolin (2 g IV q8h) vs. moxalactam (2 g IV q8h) × 4 doses</td>
<td>118</td>
<td>Cefazolin: 8.5%; moxalactam: 3.4%</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Johnson et al., 1987⁸</td>
<td>Clindamycin (600 mg IV q8h) vs. clindamycin (600 mg IV q8h) + gentamicin (1.7 mg/kg IV q8h) × 4 doses</td>
<td>104</td>
<td>Clindamycin: 3.4%; clindamycin + gentamicin: 3.4%</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Weber et al., 1992²</td>
<td>Clindamycin (500 mg IV q6h) vs. ampicillin-sulbactam (1.5 g IV q8h) × 8 doses</td>
<td>212</td>
<td>Clindamycin: 27.1%; ampicillin-sulbactam: 13.3%</td>
<td>.02</td>
</tr>
<tr>
<td>Johnson et al., 1986⁹</td>
<td>Cefoperazone (2 g IV q6h) for 1 or 5 days</td>
<td>109</td>
<td>Cefoperazone, 1 day: 18.9%; cefoperazone, 5 days: 25%</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Carroll et al., 2003³</td>
<td>Clindamycin (900 mg IV q6h) for 3 or 15 doses</td>
<td>74</td>
<td>Clindamycin, short course: 11%; clindamycin, long course: 10%</td>
<td>&gt;.05</td>
</tr>
</tbody>
</table>

IV = intravenous; q8h = every 8 hours; q6h = every 6 hours.
Clean-Contaminated Wounds in Head and Neck Surgery

Topical Antibiotic Prophylaxis

-Simmons et al 01:
-Prospective, randomized trial of clean contaminated head and neck surgery: IV zosyn perioperatively vs. IV zosyn with topical zosyn perioperatively and with zosyn added to the irrigation solution intraop
  -n=62  overall wound infection rate was 8.1%
  -6.4% of patients in IV abx alone had infections
  -9.7% of IV, topical, irrigation developed wound infections - not statistically significant

-Shuman 12: Prospective randomized trial - pts randomized to topical decolonization with mupriocin and topical chlorhexadine + abx vs abx alone
  -N=84-
  -topical + abx: 10% wound infection
  -abx alone: 24% wound infection
  -result - no statistical difference (but a trend)
Surgical Antibiotic Prophylaxis - Adult

**DISEASE SITE**
- Breast
- Melanoma
- Plastic Surgery
- Head and Neck
  - ENT - Clean Upper Gastrointestinal
- Head and Neck
  - ENT - Clean Contaminated
- Neurosurgery
  - Skull Base Only
  - Other than Skull Base
  - Orthopedics
- Lower Gastrointestinal
  - Colorectal, Pancreas, Liver
  - Rectal Only
- Gynecologic
- Thoracic
  - Pulmonary, Esophageal
- Genitourinary
- MRSA1
  - Any surgical patient with history of MRSA colonization or infection.

---

**24 Hours After Surgical Procedure**

- Less than 70 kg: Clindamycin 600 mg IV
- Greater than or equal to 70 kg: Clindamycin 900 mg IV
- And/or Gentamicin 1.5 mg/kg IV or Vancomycin 1 gram IV (for implanted prosthesis only)
- Ciprofloxacin 400 mg IV and Metronidazole 500 mg IV

---

**Does patient have penicillin drug allergy?**

- Yes
  - Head and Neck: ENT - Clean Contaminated
  - Thoracic: Pulmonary, Esophageal

- No
  - Gynecologic
  - Thoracic: Pulmonary, Esophageal
  - Neurosurgery: skull base ONLY
  - Head and Neck: ENT - Clean Contaminated

---

**Cefazolin 1 gram IV**

**Cefoxitin 2 grams IV or Ciprofloxacin 400 mg IV (endoscopy or procedures only)**

**Gentamicin 5 mg/kg IV (for implanted prosthesis only) or Cefazolin 1 gram IV or Ciprofloxacin 400 mg IV (for all other types)**

**Cefoxime 1.5 grams IV**

**Unasyn 3 grams IV**

---

MRSA1
- Any surgical patient with history of MRSA colonization or infection.

---

*Vancomycin and Ciprofloxacin are to be initiated 60 to 120 minutes prior to incision and all other antibiotics are to be initiated within 60 minutes of incision.*

*1 Vancomycin screening, if results are positive give patient Vancomycin 1 gram at time positive results have been identified.*

*2 If patient has multiple known antibiotic drug allergies, administer antibiotics as clinically indicated.*

---

*Department of Clinical Effectiveness V4
Approved by The Executive Committee of the Medical Staff 02/28/2012*
### Table 2. (continued)

<table>
<thead>
<tr>
<th>Type of Procedure</th>
<th>Recommended Agents&lt;sup&gt;a,b&lt;/sup&gt;</th>
<th>Alternative Agents in Patients with β-Lactam Allergy</th>
<th>Strength of Evidence&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal&lt;sup&gt;+&lt;/sup&gt;</td>
<td>Cefazolin + metronidazole, cefoxitin, cefotetan, ampicillin-sulbactam,&lt;sup&gt;h&lt;/sup&gt; ceftriaxone + metronidazole,&lt;sup&gt;o&lt;/sup&gt; ertapenem</td>
<td>Clindamycin + aminoglycoside&lt;sup&gt;g&lt;/sup&gt; or aztreonam or fluoroquinolone&lt;sup&gt;h,i&lt;/sup&gt; metronidazole + aminoglycoside&lt;sup&gt;g&lt;/sup&gt; or fluoroquinolone&lt;sup&gt;h,i&lt;/sup&gt;</td>
<td>A</td>
</tr>
</tbody>
</table>

**Head and neck**

<table>
<thead>
<tr>
<th>Clean</th>
<th>None</th>
<th>None</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean with placement of prosthesis (excludes tympanostomy tubes)</td>
<td>Cefazolin, cefuroxime</td>
<td>Clindamycin&lt;sup&gt;d&lt;/sup&gt;</td>
<td>C</td>
</tr>
<tr>
<td>Clean-contaminated cancer surgery</td>
<td>Cefazolin + metronidazole, cefuroxime + metronidazole, ampicillin-sulbactam</td>
<td>Clindamycin&lt;sup&gt;d&lt;/sup&gt;</td>
<td>A</td>
</tr>
<tr>
<td>Other clean-contaminated procedures with the exception of tonsillectomy and functional endoscopic sinus procedures</td>
<td>Cefazolin + metronidazole, cefuroxime + metronidazole, ampicillin-sulbactam</td>
<td>Clindamycin&lt;sup&gt;d&lt;/sup&gt;</td>
<td>B</td>
</tr>
</tbody>
</table>
## ASHP Guidelines 2013

<table>
<thead>
<tr>
<th>Antimicrobial</th>
<th>Recommended Dose</th>
<th>Half-life in Adults With Normal Renal Function, hr</th>
<th>Recommended Redosing Interval (From Initiation of Preoperative Dose), hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicillin-sulbactam</td>
<td>3 g (ampicillin 2 g/sulbactam 1 g)</td>
<td>0.8–1.3</td>
<td>2</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>2 g</td>
<td>1.1–1.9</td>
<td>2</td>
</tr>
<tr>
<td>Aztreonam</td>
<td>2 g</td>
<td>1.3–2.4</td>
<td>4</td>
</tr>
<tr>
<td>Cefazolin</td>
<td>2 g, 3 g for pts weighing ≥120 kg</td>
<td>1.2–2.2</td>
<td>4</td>
</tr>
<tr>
<td>Cefuroxime</td>
<td>1.5 g</td>
<td>1–2</td>
<td>4</td>
</tr>
<tr>
<td>Cefotaxime</td>
<td>1 g&lt;sup&gt;d&lt;/sup&gt;</td>
<td>0.9–1.7</td>
<td>3</td>
</tr>
<tr>
<td>Cefoxitin</td>
<td>2 g</td>
<td>0.7–1.1</td>
<td>2</td>
</tr>
<tr>
<td>Cefotetan</td>
<td>2 g</td>
<td>2.0–4.6</td>
<td>6</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>2 g&lt;sup&gt;c&lt;/sup&gt;</td>
<td>5.4–10.9</td>
<td>NA</td>
</tr>
<tr>
<td>Ciprofloxacin&lt;sup&gt;f&lt;/sup&gt;</td>
<td>400 mg</td>
<td>3–7</td>
<td>NA</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>900 mg</td>
<td>2–4</td>
<td>6</td>
</tr>
<tr>
<td>Ertapenem</td>
<td>1 g</td>
<td>3–5</td>
<td>NA</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>400 mg</td>
<td>6 mg/kg</td>
<td>NA</td>
</tr>
<tr>
<td>Gentamicin&lt;sup&gt;p&lt;/sup&gt;</td>
<td>5 mg/kg based on dosing weight (single dose)</td>
<td>2.5 mg/kg based on dosing weight</td>
<td>NA</td>
</tr>
<tr>
<td>Levofloxacin&lt;sup&gt;f&lt;/sup&gt;</td>
<td>500 mg</td>
<td>6–8</td>
<td>NA</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>500 mg</td>
<td>6–8</td>
<td>NA</td>
</tr>
</tbody>
</table>
Summary

1. No good evidence in literature to support routine use of prophylactic antibiotics in clean head and neck surgery

2. There is strong evidence to support use of prophylactic antibiotics in clean-contaminated head and neck surgery
   a. Gram positive and anaerobes should be covered - coverage of gram negatives is controversial
   b. Literature supports limiting duration of antibiotics to 24 hours after surgery

3. Topical antibiotics for head and neck surgery are controversial - more studies needed

4. ASHP Guidelines recommend administration of prophylactic antibiotics within 60 minutes of start of procedure and re-dosing after 2 half-lives of the drug
Dr. Patton, that’s a very nice review of the literature that’s out there. It’s certainly an important topic as we progress in medicine. with our decreased spectrum of choice of antibiotics for surgical infections. There are some really critical risk factors that we have come to understand as we come late to his topic. I didn’t catch a whole lot of discussion in these papers about them. For example, we know diabetes is an issue as well as radiotherapy and importantly chemoradiotherapy. These are significant issues in the head and neck. From personal experience, even in cases where you do clean neck dissections status post chemoradiotherapy, you get the sense that things perhaps are different there.

The first question for you is how many of these papers really broke down their cohorts in such ways as to early dichotomize any kind of treatment recommendation? Has there been anybody putting forth a recommendation regarding prophylaxis with this level of categorization?
The level of intervention and the cost of failure are important drivers in decision making. You look at large composite resections with reconstructions in patients that need to move forward to adjuvant therapy in a timely fashion for what we understand will be better outcomes. Your cost of failure defined as postoperative infection with either failure the cost of that is you come up with a second solution or simply a delay to the completion of the treatment package which can be rather high.

We can have academic discussions about this issue but up until there is a definitive study with good methodology that really assesses some of these important risk factors that I believe most people agree likely play some role. I think that most of us who treat these patients are simply going to be more aggressive with antibiotic coverage. My suspicion is that that has been and remains the case across the country. I hope that in the future there is such an initiative. It would be complicated and the numbers would have to be quite high. We are entering the era of databases and patient information categorization and the like so it could be that we are moving forward to a time where these questions can be asked appropriately. I don’t believe that they have been thus far, not in a way that will change most people’s practice.
References Consulted


Russel MD, Goldberg AN. What is the evidence for use of antibiotic prophylaxis in clean-contaminated head and neck surgery? Laryngoscope 2012. 122:944-946


Questions/Comments