The Safety of Topical Vancomycin for Neurosurgical Wound Prophylaxis in a Multicenter, Randomized Controlled Trial

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Introduction

There is a need for additional prophylaxis for Surgical Site Infections (SSIs) to improve quality of care in neurosurgery, because SSIs:

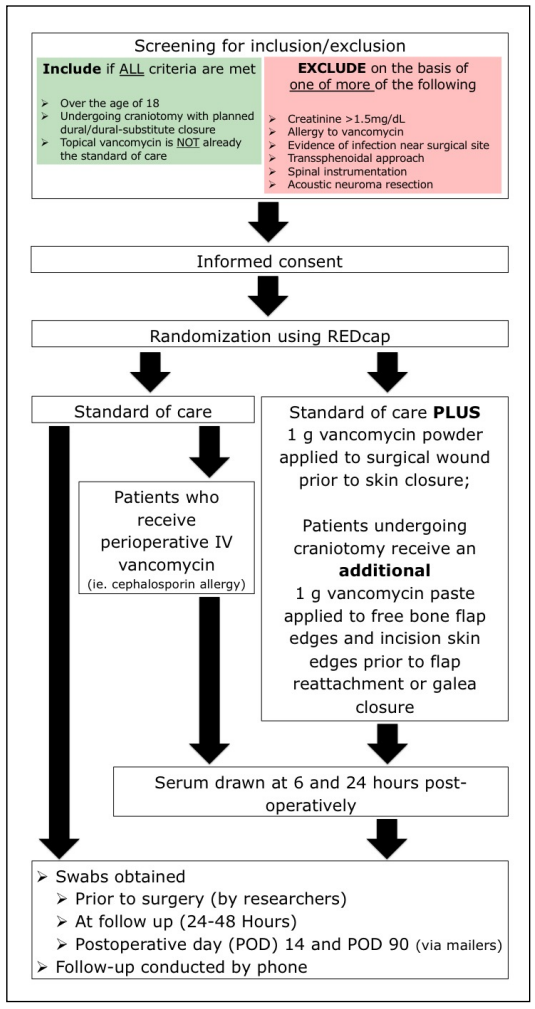
- Comprise approximately **20% of nosocomial infections.**
- Cost approximately **$1.6 billion USD annually.**
- Are a major cause of **30-day readmission.**
- Complicate **2-5% of craniotomies.**
- Result in **significantly higher morbidity and mortality** in neurosurgical patients than in most other specialties.

Topical vancomycin applied at wound closure has been shown to **decrease the rate of SSIs** after cardiothoracic and instrumented spine procedures, with minimal systemic exposure.

Our ongoing, multicenter randomized controlled trial at New York-Presbyterian Hospital-Columbia and Cornell, **"Topical Vancomycin for Neurosurgery Wound Prophylaxis"** (NCT02284126; enrollment began in Oct 2014) will determine whether topical vancomycin reduces the incidence of SSIs at postoperative day 30 in patients undergoing craniotomies.

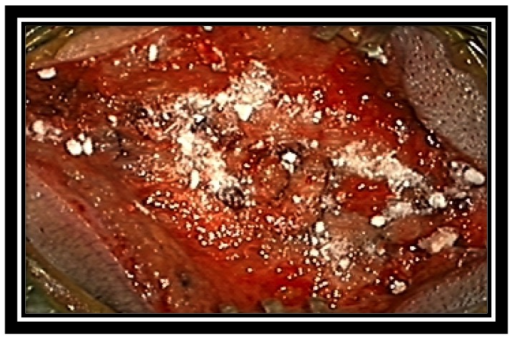
Here we report the level of systemic absorption and incidence of adverse effects of **topical vancomycin applied to the wound and bone flap** at closure after craniotomies.

Methods

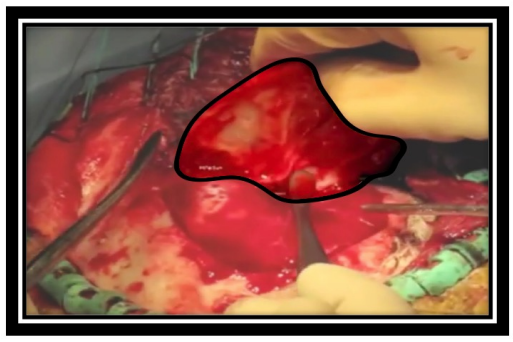


Treatment Group: 2g of vancomycin

- Paste is applied to bone flap margins (1g vancomycin / 1cc 0.9% NaCl)
- 1g vancomycin powder applied to incisional skin edges prior to closure of galea



Vancomycin powder applied at incisional site



Boneflap retracted from the cranium. Outline indicates margins where vancomycin paste is applied.

Assesment of Systemic Exposure

- Serum vancomycin levels measured postoperatively at 6 and 24 hours in treatment group
- Positive control: Patients receving intravenous (IV) vancomycin as standard perioperative antimicrobial prophylaxis

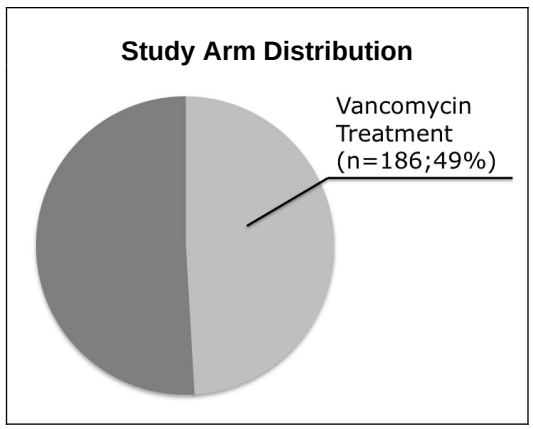
Outcome Measurement

- Follow-up telephone interviews between postoperative days 14-30
- Screen for adverse effects of vancomycin including allergy, vertigo, sensorineural hearing loss.

Results

Third Quarter Enrollment: 379 Patients (Fourth Quarter Ongoing)

- Among patients who received topical vancomycin only serum levels were weakly positive (>3.0 mg/dL at Columbia & >3.5 mg/dL at Weill Cornell) in 2 of 64 cases (3.1% of cases). Levels for the two positive patients were 3.0 mg/dL and 7.6 mg/dL.
- The average serum level was 10.8±6.24 mg/dL among patients who received IV vancomycin.
- **At follow-up:** No statistically significant difference in hearing loss, vertigo, or allergic reactions between the treatment and control groups.



Conclusion

Our preliminary data suggest that **topically-applied vancomycin is safe** in neurosurgery, having minimal systemic absorption and no detectable adverse effects. In addition to the primary endpoint of the rate of SSIs at 30 days, this phase III trial will continue to evaluate the safety of topical vancomycin over the next 4 years.