A Randomized, Double-Blinded Study for the Prevention of Exit Site Infections in Pediatric Peritoneal Dialysis Patients

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Background

- Infectious complications remain a major cause of morbidity in peritoneal dialysis (PD) patients
- Pediatric patients are particularly at risk
  - Higher utilization rate of PD compared to adults (60% vs. 8%)[2,3]
  - Higher incidence of infectious complications[1]
  - Overall, infections are the leading cause of hospitalizations[2], modality changes[3], and death[2] in pediatric PD patients.
- Therefore infection prevention is critical in pediatric PD patients

[1] USRDS 2000-2003, [2] USRDS 2006, [3] NAPRTCS 2006

Background

- Current recommendations for PD exit site care include the daily use of an antibiotic cream
- However evidence supporting a specific type of antibiotic is limited, especially in pediatric patients.
- Recently gentamicin cream was shown to be superior to mupirocin for the prevention of infections in adult PD patients (Bernardini et al., 2005).
  - Gentamicin cream resulted in a 57% reduction in exit site infections and a 35% reduction in peritonitis

Aim of the Study

- Compare the effectiveness of gentamicin to mupirocin for the prevention of exit site infections (ESI) in pediatric PD patients.

Methods

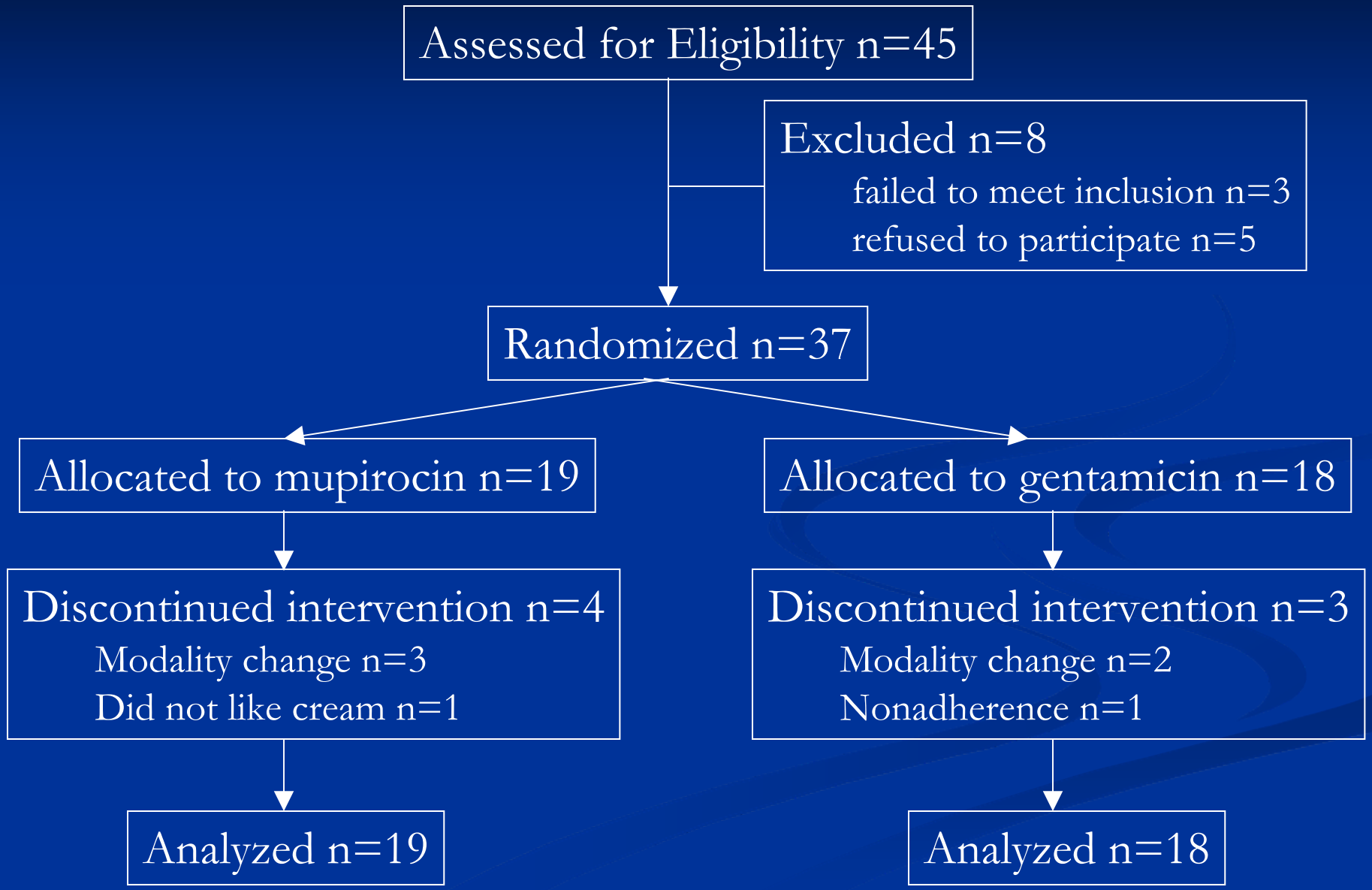
- Pediatric patients were enrolled in a prospective 9 month trial with the following inclusion criteria:
  - a minimum of 3 months on APD
  - treatment for S. aureus nasal carriage prior to randomization
  - no ESI or peritonitis in the past 30 days.
- Patients were randomized to receive mupirocin 2% or gentamicin sulfate 0.1% which was dispensed in identical containers.
- Patients, nurses and physicians were blinded to which cream had been prescribed.
- Daily exit site care protocol included the application of a small amount of cream (~1/4-inch dab) around the catheter exit site using a cotton swab.

Methods

- Exit sites were examined by a same physician and nurse at each monthly clinic visit.
  - ESI was defined by the presence of one or more of the following: erythema, edema, tenderness or drainage from the exit site*.
  - Peritonitis was defined as a cloudy effluent with >100/ul white cells with >50% PMNs*.
  - Treatment of infections was based on the ISPD consensus guidelines for pediatric patients.
- Intent to treat analysis was performed with a general estimating equation model used to compare ESI and peritonitis rates.

*ISPD 2000/2005 Guidelines

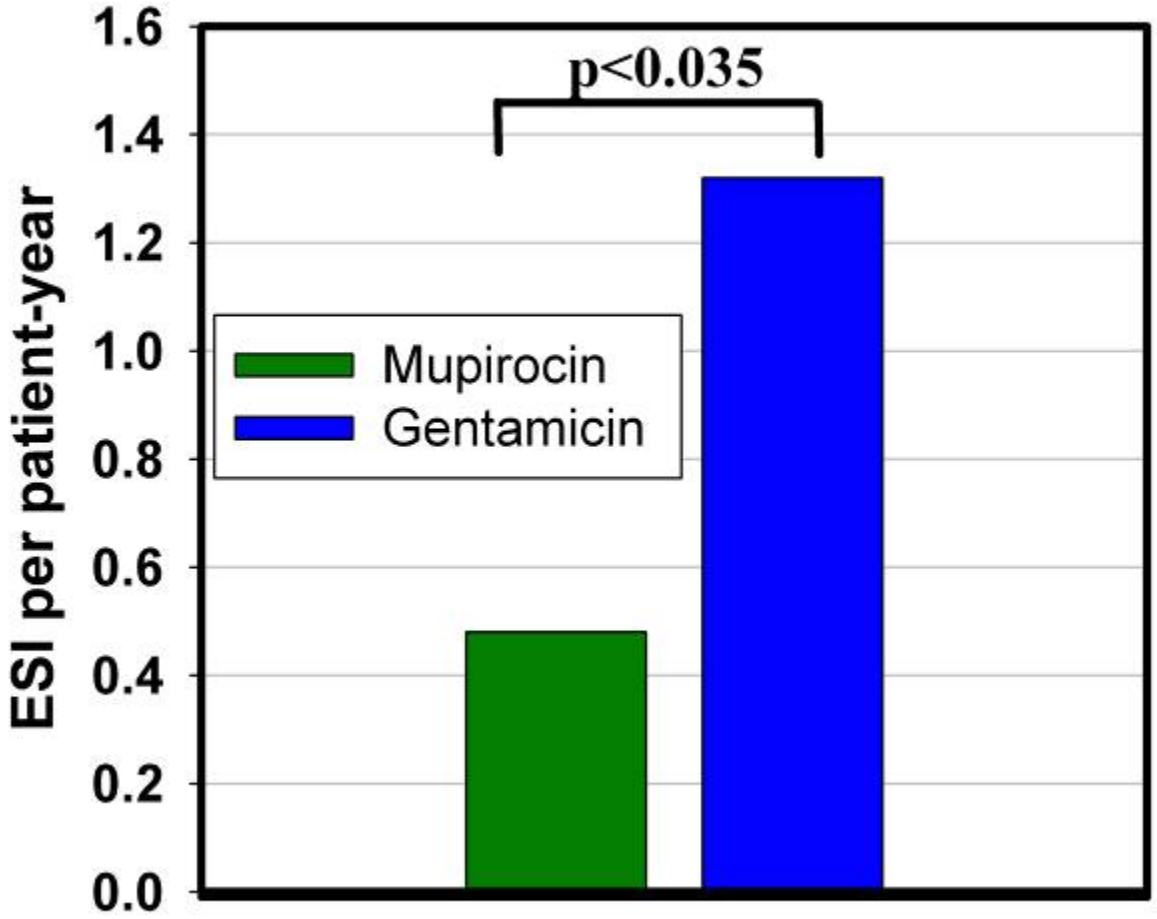
Allocation of Patients



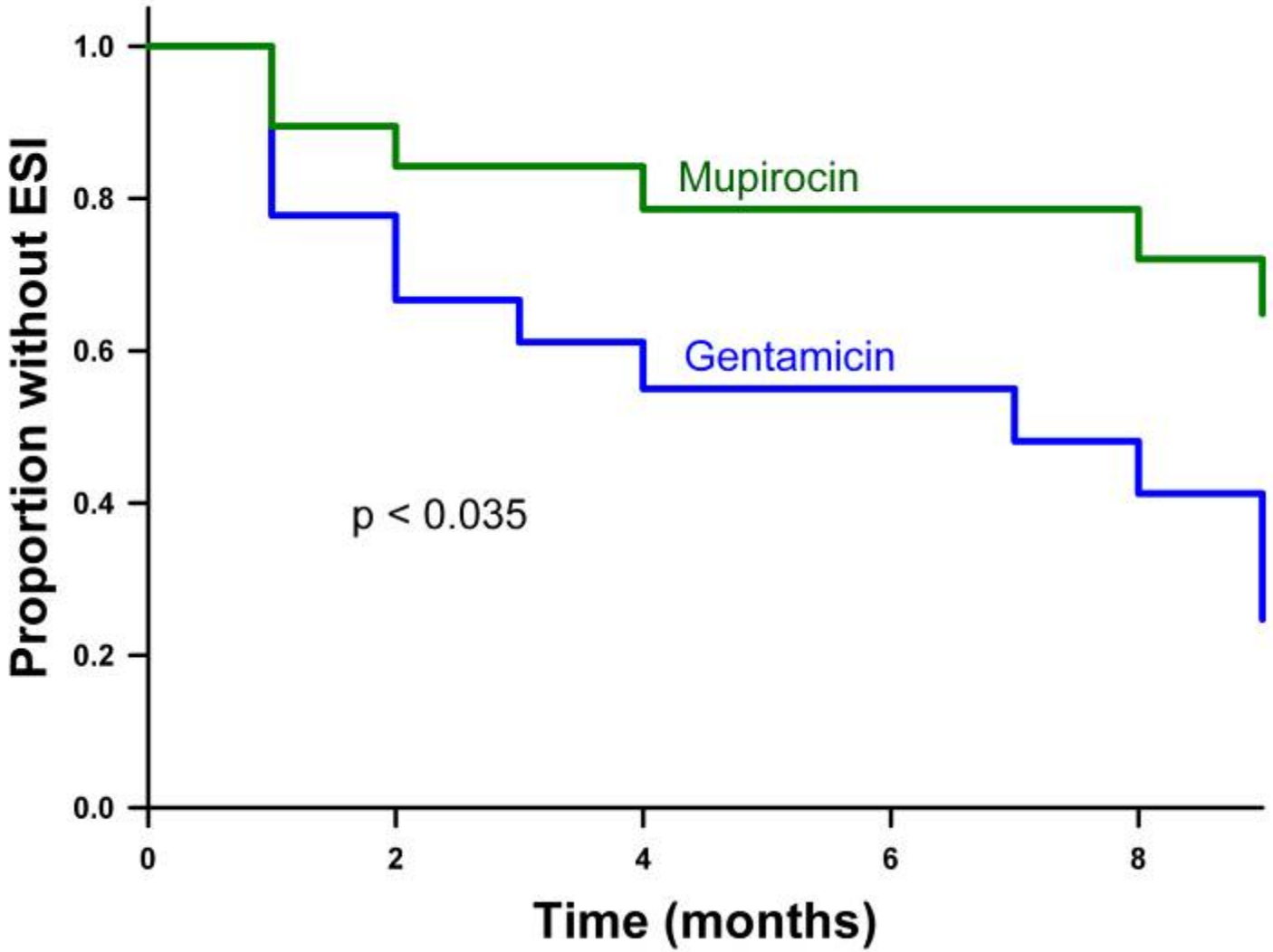
Patient Characteristics

	Mupirocin	Gentamicin	p
Patients (n)	19	18	NS
Age (yr)	14.5±5	13.7±6	NS
Male/Female (n)	12/7	11/7	NS
Time on dialysis (months)	13±4	12±4	NS
S. aureus Carrier (n)	0	1	NS
Study Time (patient-yrs)	12.4	12.1	NS

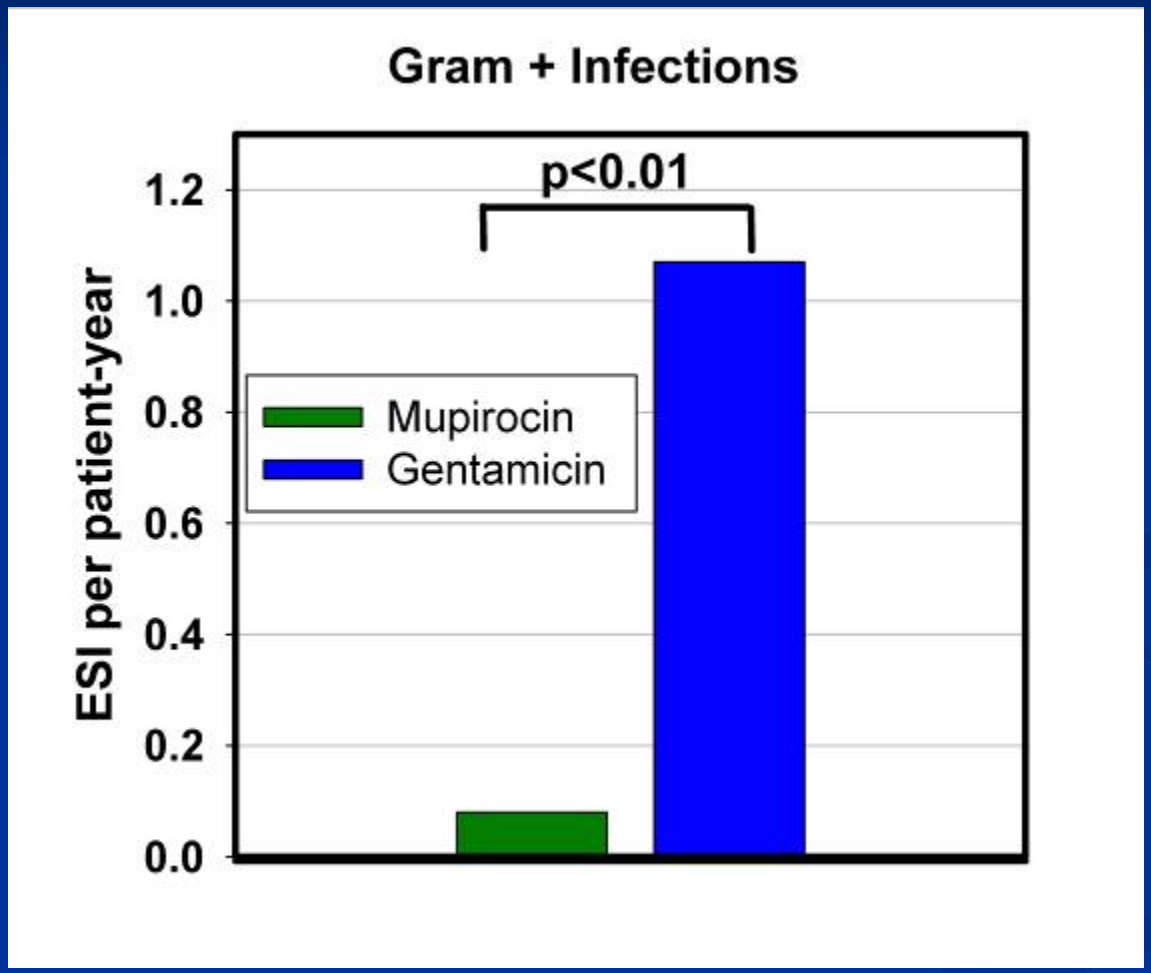
ESI Rates

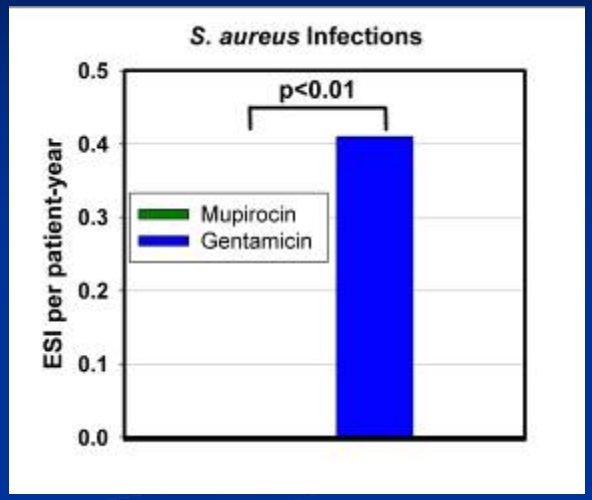

p<0.035
ESI per patient-year
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
Mupirocin
Gentamicin

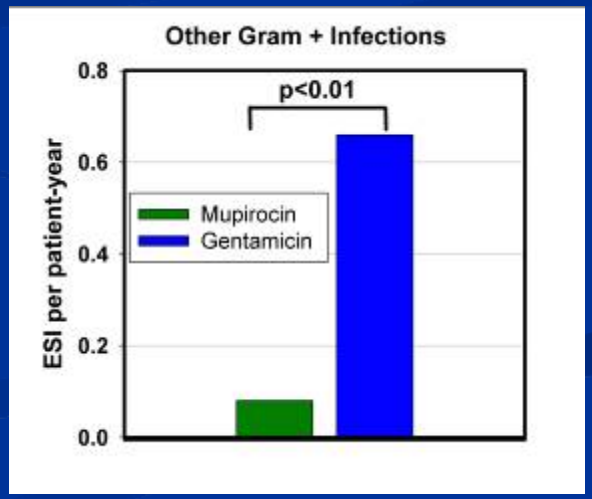
ESI Survival Analysis



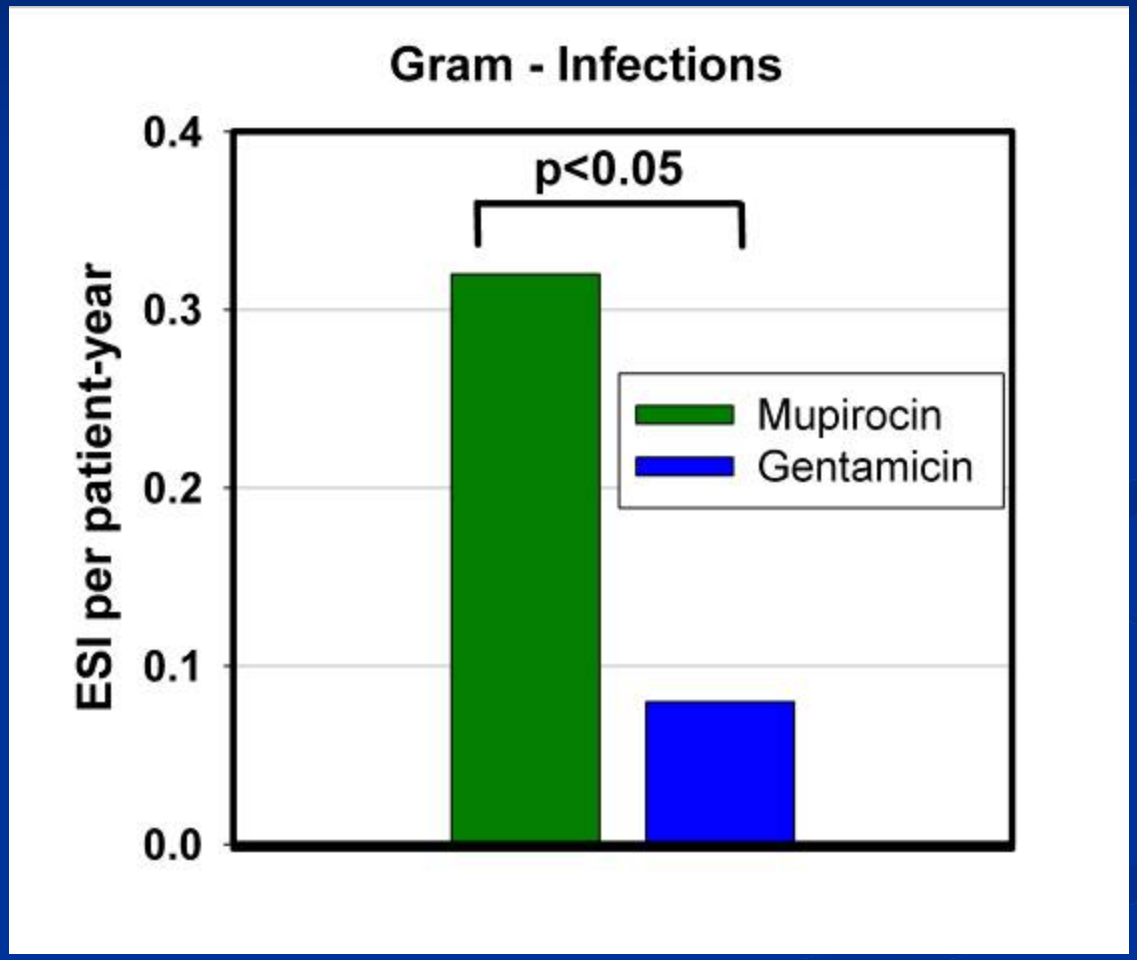
Etiology of ESI

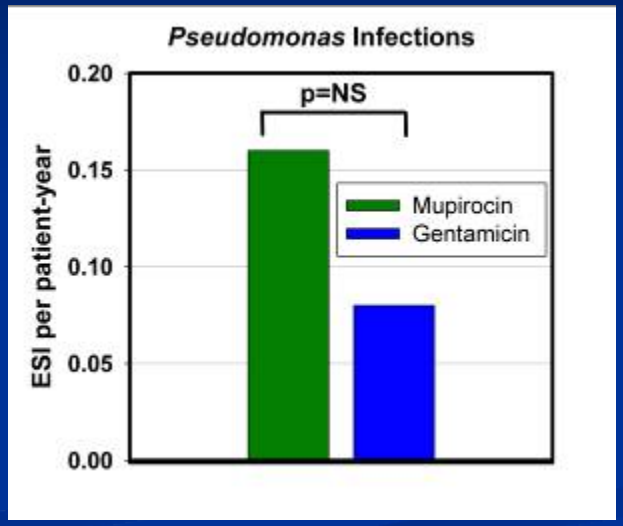


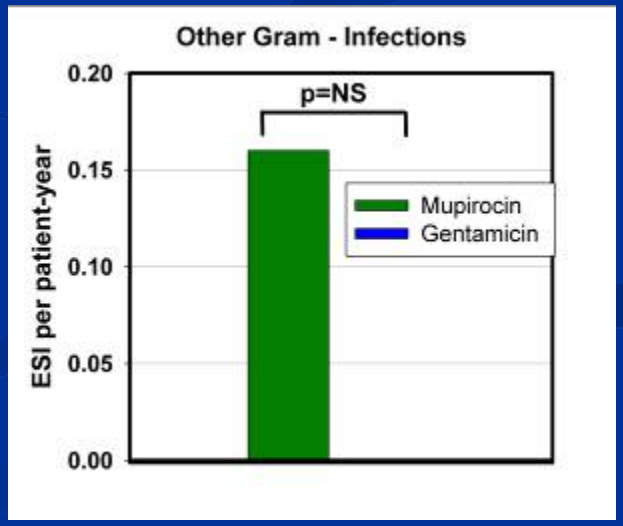




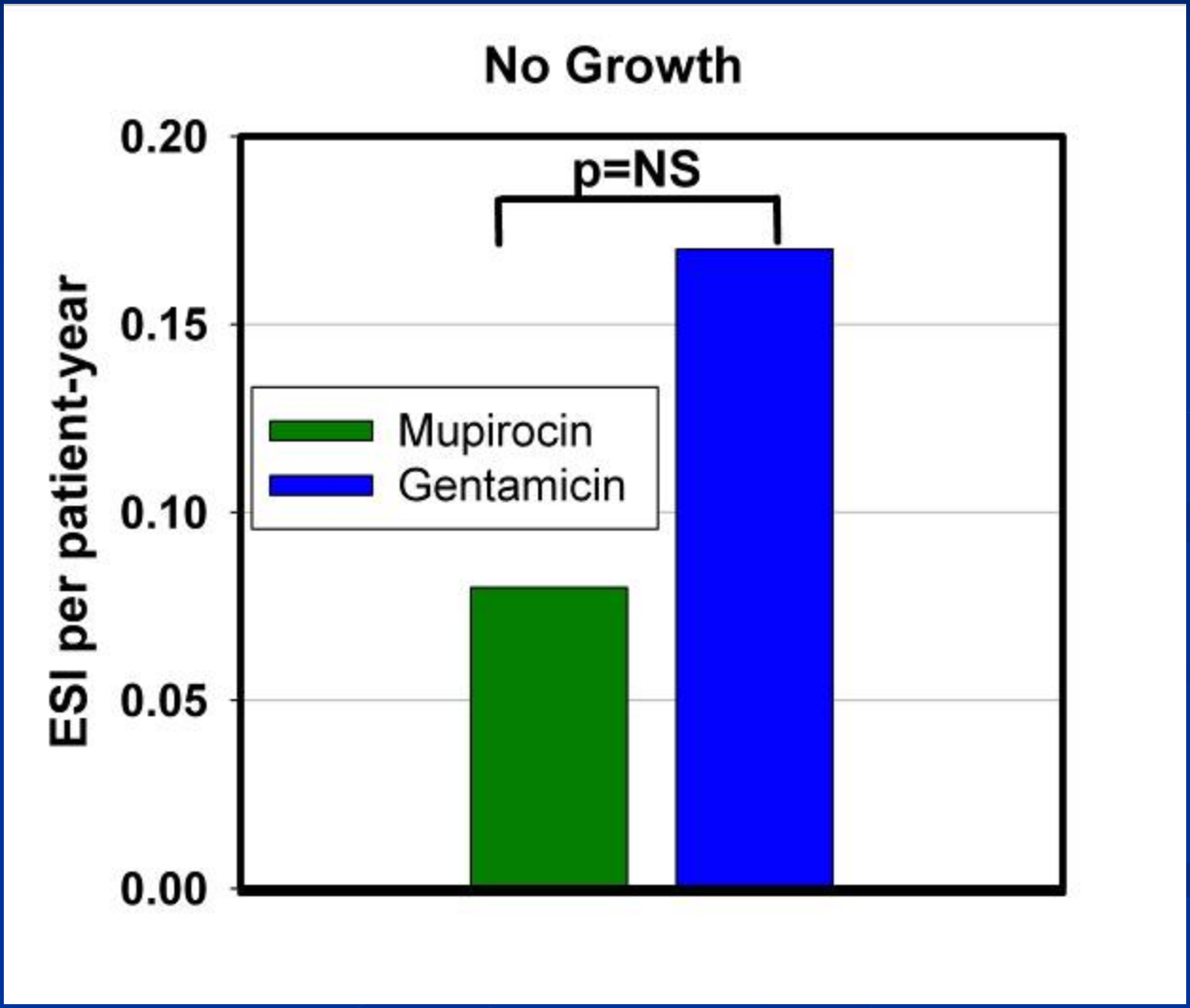
Etiology of ESI



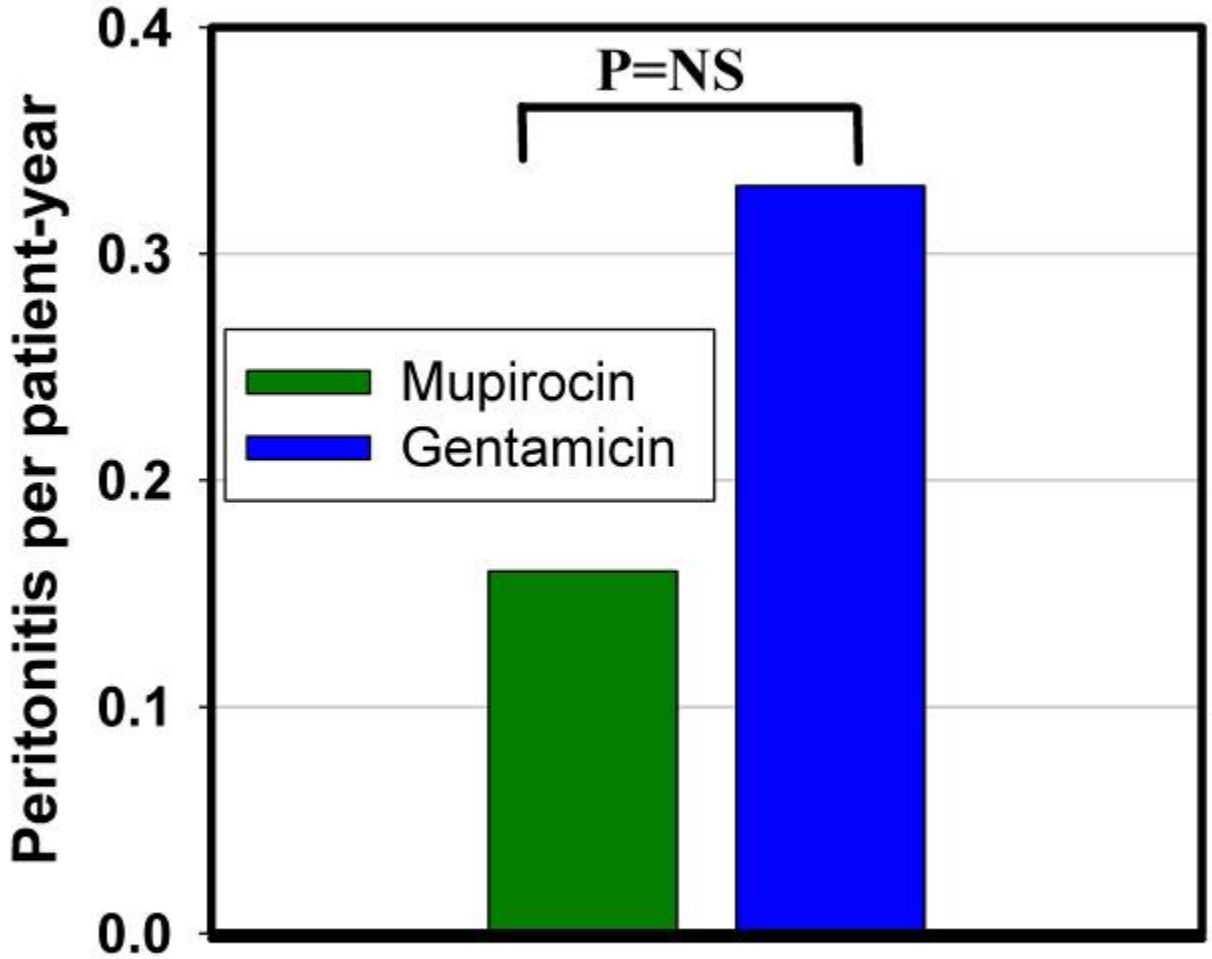




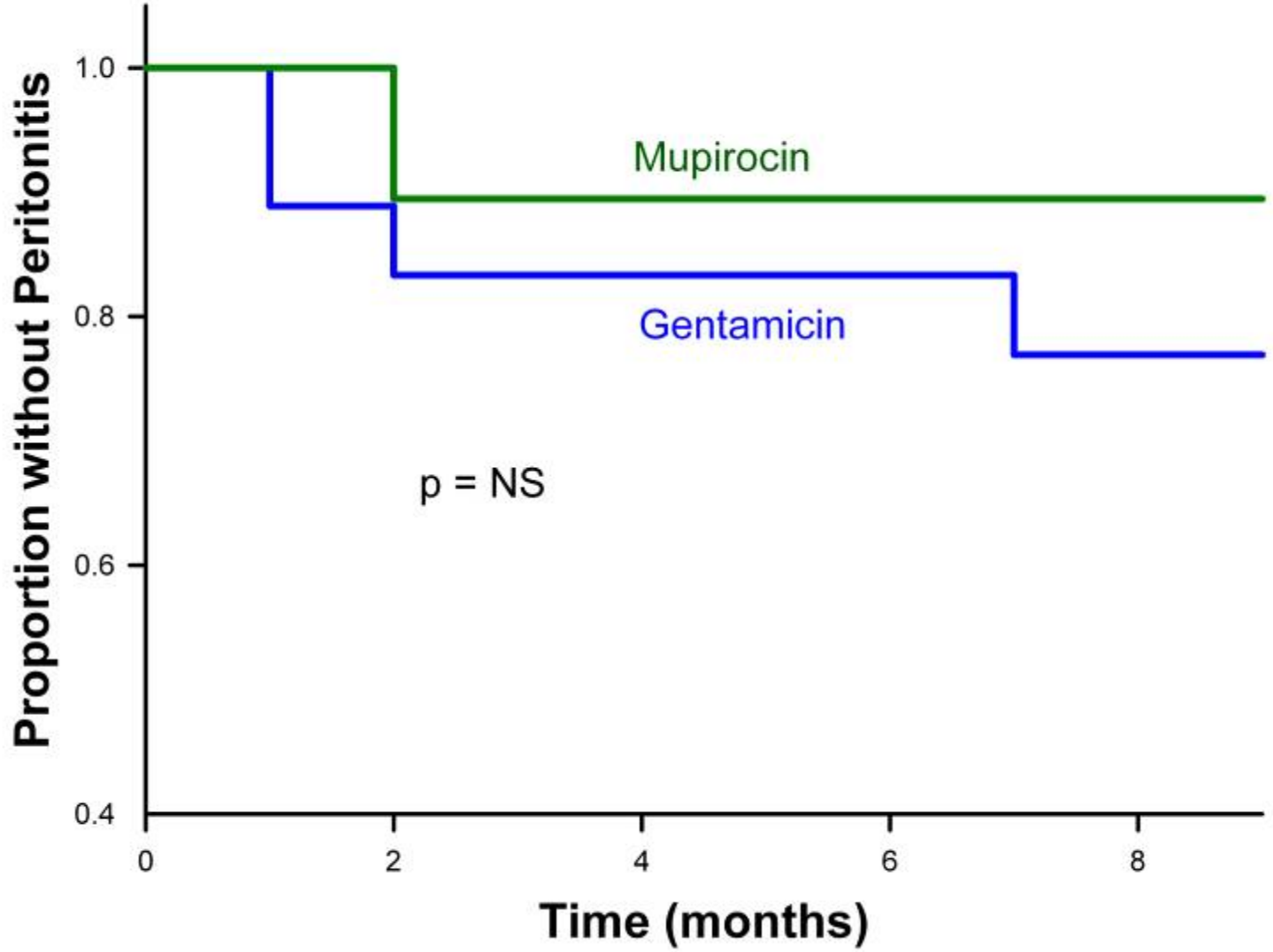
Etiology of ESI



Peritonitis Rates



Peritonitis Survival Analysis



Summary

- The ESI rate with mupirocin (0.48/year) was lower when compared to gentamicin (1.32/year).
- Time to first ESI was lower with mupirocin.
- More gram positive infections occurred with gentamicin, while more gram negative infections occurred with mupirocin.
- Peritonitis rates were not different between mupirocin (0.16/year) and gentamicin (0.33/year).
- Time to first peritonitis was not different between mupirocin and gentamicin.

Conclusions

- This study demonstrates that despite the nearly 20-fold increased cost, mupirocin is superior in the prevention of ESI.
- These results differ from previous adult studies and thus emphasize the need for studies in pediatric patients where infectious complications remain a significant problem.
- Further follow up is needed to assess the impact on the rate of peritonitis.

Acknowledgement

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