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U.S. Department  
of Veterans Affairs

# Treatment Duration of Antibiotics for Sacral Osteomyelitis After Skin Flap Procedure

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## DISCLAIMER

- This material is the result of work supported with resources and the use of facilities at the VA St. Louis Health Care System.
- The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.
- This study was approved by the Institutional Review Board (IRB) at the VA St. Louis Health Care System.



# BACKGROUND

- Sacral Osteomyelitis
  - Common disease that can develop from an infection of deep pressure ulcers
  - Pressure ulcers are concern for patients with limited mobility
- Spinal cord injured patients are at high risk of pressure ulcers and risk factors should be minimized to prevent ulcers from forming
- Optimal treatment of sacral osteomyelitis often involves antibiotics and skin flap closure of the ulcer
  - Best practices for duration of antibiotic therapy are unknown



# STUDY OBJECTIVE & HYPOTHESIS

## Objective

- To determine if there is a difference in average antibiotic duration between spinal cord injured patients with resolution vs failure of sacral osteomyelitis after skin flap procedures

## Hypothesis

- There is a significant difference in average duration of antibiotic therapy between patients with resolution vs failure of sacral osteomyelitis after skin flap procedures



# METHODS

- Retrospective
- Cohort
- St. Louis VA Medical Center
- October 1, 2014 through March 31, 2019



# STUDY DESIGN

Spinal cord injured patient with sacral osteomyelitis & underwent a skin flap procedure between October 2014 to March 2019

Meet Inclusion Criteria

Do not meet Inclusion Criteria

Osteomyelitis Treatment Success

Osteomyelitis Treatment Failure

Antibiotic Duration

Antibiotic Duration



# INCLUSION AND EXCLUSION CRITERIA

## Inclusion

- Aged  $\geq 18$  to  $\leq 89$  years old
- Spinal cord injury
- Sacral osteomyelitis
- Skin flap procedure
- Antibiotic treatment between October 2014 to March 2019

## Exclusion

- Insufficient evidence to determine duration of antimicrobial therapy



## Primary Outcome

- Average duration of antibiotics
  - Total duration (pre-flap and post-flap)
  - Successful resolution versus treatment failure
- Treatment failure:
  - No resolution or recurrence of sacral osteomyelitis
  - Skin flap failure or breakdown of flap





## Secondary Outcomes

- Primary outcome at 6 months
- Average duration of antibiotic treatment
  - Pre-flap (successful treatment vs. failure)
  - Post-flap (successful treatment vs. failure)
- Compare success rates between treatment  $< 6$  weeks vs  $\geq 6$  weeks

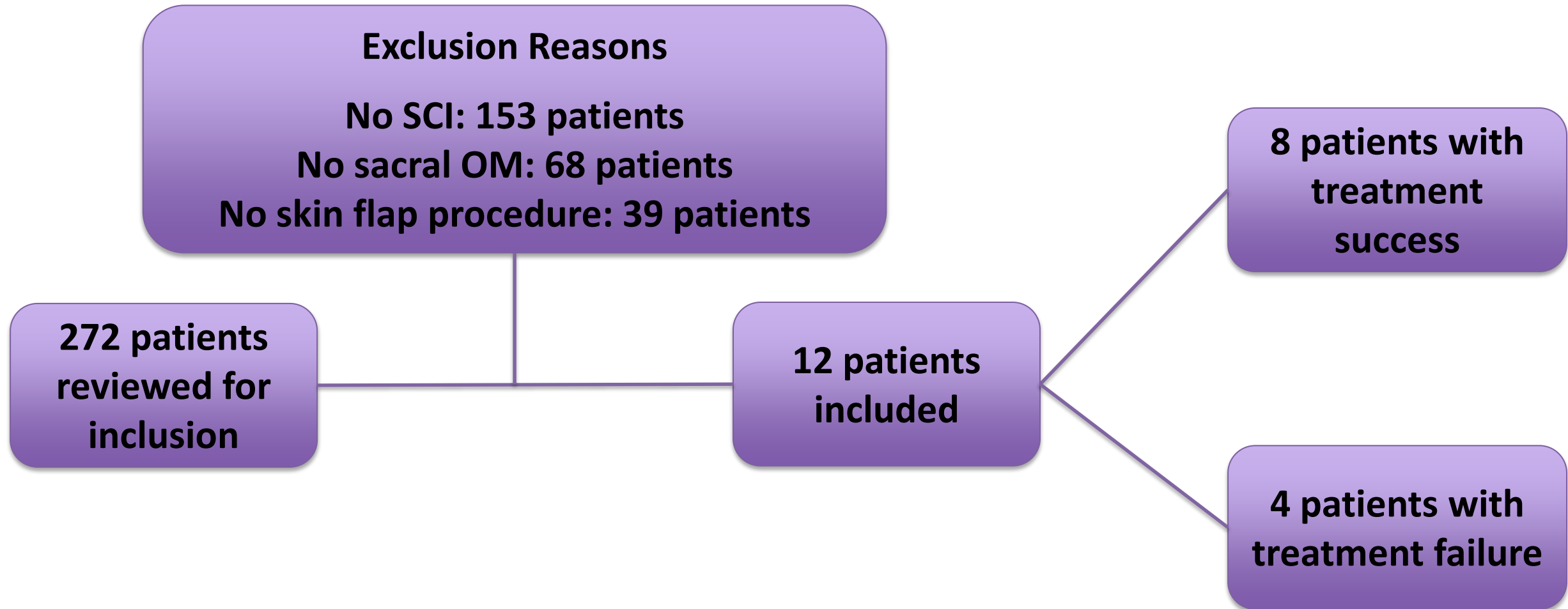


# STATISTICAL ANALYSIS

- Baseline Characteristics
  - Descriptive statistics
  - Chi-square/Fisher's exact for categorial variables
  - Independent t-test for continuous variables
- Outcomes
  - Primary
    - Two sided alpha of 0.05
    - 45 patients per group to give 80% power
    - t-test
  - Secondary
    - Chi-square
    - t-test
- Sub-analysis
  - Multivariate analysis for any variables with  $p < 0.2$  in univariate analysis
  - Variables considered for inclusion:
    - ESR
    - Diabetes
    - Albumin
    - Smoking status
    - Peripheral vascular disease
    - Coronary artery disease
    - Setting of care



# PATIENT ENROLLMENT

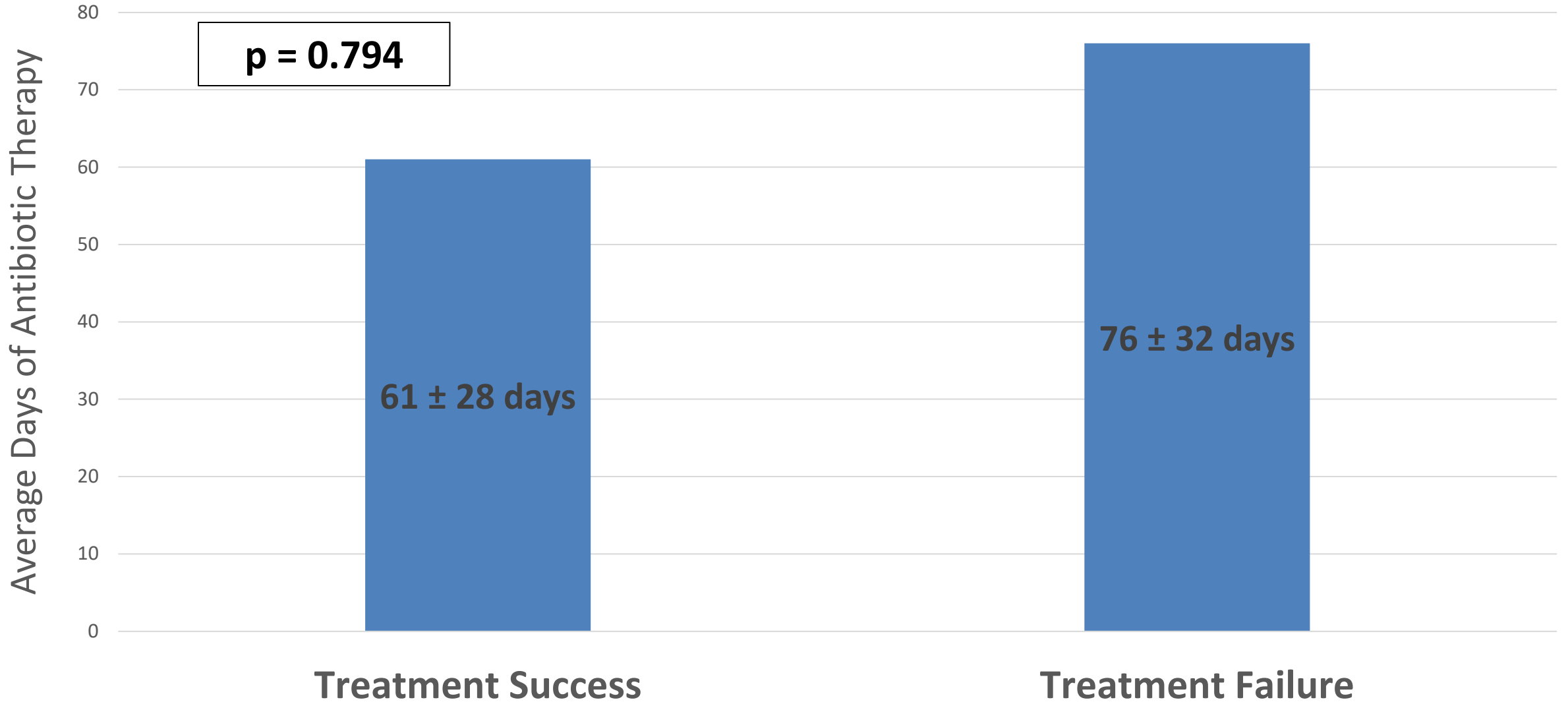


Baseline Characteristics	Treatment Success Group (n=8)	Treatment Failure Group (n=4)	p value
Age (years) ± SD	64 ± 16.5	62 ± 8.5	0.82
White, n (%)	8 (100%)	4 (100%)	1.0
Male, n (%)	8 (100%)	4 (100%)	1.0
Body Mass Index (kg/m <sup>2</sup> )	30.54 ± 3.58	30.08 ± 5.46	0.86
Serum Creatinine (mg/dL)	0.81 ± 0.17	0.64 ± 0.14	0.13
Creatinine Clearance (mL/min)	116 ± 49	133.5 ± 38.1	0.56
Albumin (g/dL)	3.48 ± 0.3	3.23 ± 0.3	0.19
Baseline ESR (mm/hr)	38.8 ± 20.7	57.75 ± 50.7	0.36
History of Skin Flap Procedures, n (%)	4 (50%)	2 (50%)	1.0
ASIA A Score, n (%)	5 (62.5%)	4 (100%)	0.491
ASIA B Score, n (%)	1 (12.5%)	0 (0%)	1.0
ASIA C Score, n (%)	2 (25%)	0 (0%)	0.515

<b>Baseline Characteristics</b>	<b>Treatment Success Group (n=8)</b>	<b>Treatment Failure Group (n=4)</b>	<b>p value</b>
<b>History of Treatment Failure for Sacral Osteomyelitis, n (%)</b>	8 (100%)	3 (75%)	0.333
<b>History PVD, n (%)</b>	0 (0%)	1 (25%)	0.333
<b>History CAD, n (%)</b>	4 (50%)	1 (25%)	0.576
<b>History Tobacco Use, n (%)</b>	2 (25%)	2 (50%)	0.547
<b>Current Tobacco Use, n (%)</b>	0 (0%)	1 (25%)	0.333
<b>History Pressure Ulcers, n (%)</b>	8 (100%)	4 (100%)	1.0
<b>History of Diabetes, n (%)</b>	3 (37.5%)	1 (25%)	1.0
<b>Baseline A1c (%)</b>	6.36 ± 0.97	5.5 ± 0.64	0.21

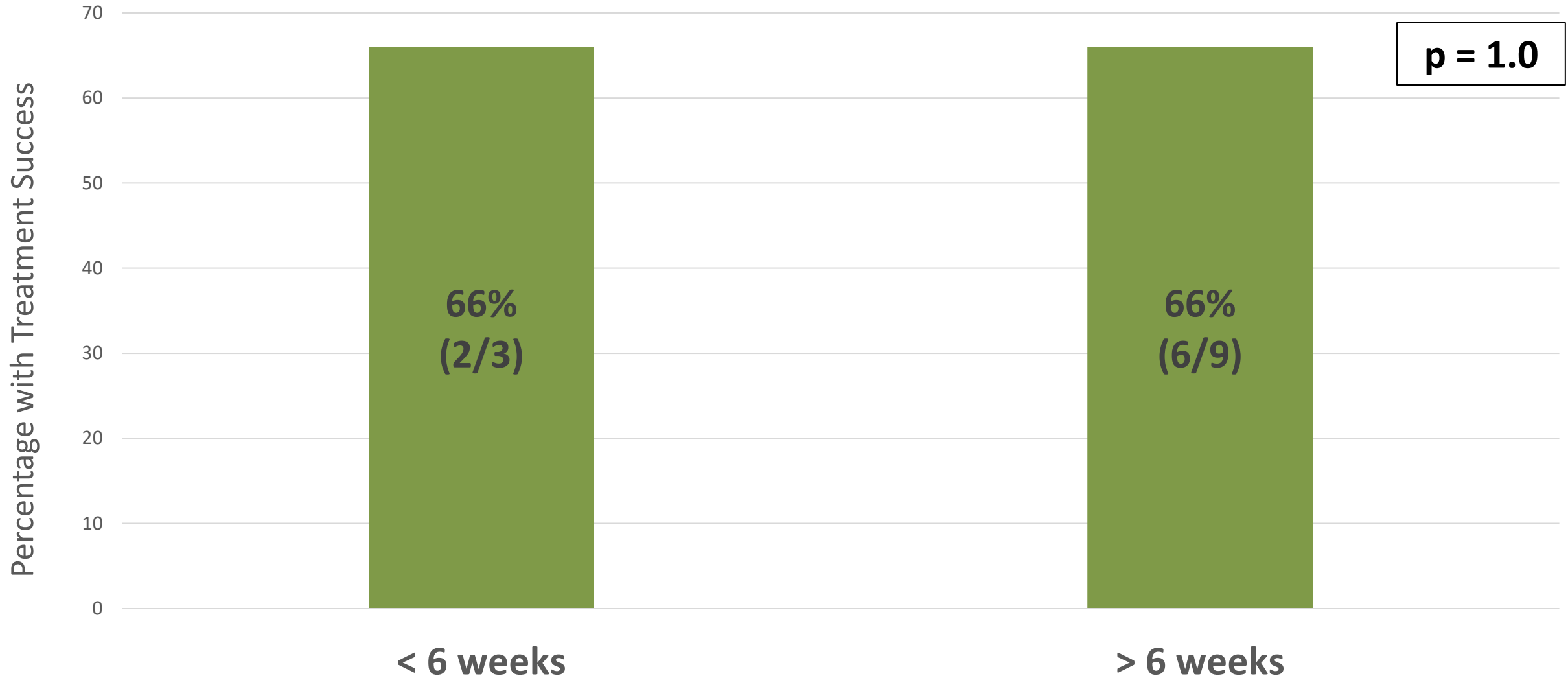


# AVERAGE TOTAL DAYS OF THERAPY, SUCCESS VERSUS FAILURE





# PERCENTAGE OF PATIENTS WITH SUCCESSFUL OUTCOME





# AVERAGE DURATION OF ANTIBIOTICS AT 12 MONTHS

	Treatment Success Group (n=8)	Treatment Failure Group (n=4)	p value
Duration antibiotics pre-flap (days) $\pm$ SD	23 $\pm$ 24	33 $\pm$ 23	0.712
Duration antibiotics post-flap (days) $\pm$ SD	40 $\pm$ 12	43 $\pm$ 22	0.381





# AVERAGE DURATION OF ANTIBIOTICS AT 6 MONTHS

	Treatment Success Group (n=10)	Treatment Failure Group (n=2)	p value
<b>Total duration of antibiotics (days) ± SD</b>	<b>66 ± 29</b>	<b>70 ± 39</b>	<b>0.883</b>
<b>Duration antibiotics pre-flap (days) ± SD</b>	<b>26 ± 23</b>	<b>25 ± 35</b>	<b>0.915</b>
<b>Duration antibiotics post-flap (days) ± SD</b>	<b>39 ± 16</b>	<b>45 ± 4</b>	<b>0.651</b>



# DISCUSSION

- Overall, 75% of patients had successful treatment outcome at 12 months
- Average duration of antibiotics
  - Total: no difference
  - Pre-flap: no difference
  - Post-flap: no difference
- Less than 6 weeks versus 6 weeks or more
  - No significant difference noted in success rates
- Multivariate Regression
  - No significant predictors identified



# DISCUSSION

## Strengths

- Demographics evenly matched
- Pathogen directed therapy

## Weaknesses

- Retrospective study
- Single center
- Limited sample size
- One year follow up period
- Generalizability



# CONCLUSION

- In spinal cord injured patients with sacral osteomyelitis who underwent a skin flap procedure, no difference was found in:
  - Total antibiotic duration
  - Pre-procedure antibiotic duration
  - Post-procedure antibiotic duration
- Additional research with National VA data and longer follow up periods would be beneficial

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