

Abstract (revised)

Background: Physician Office Infusion Centers (POICs) provide a safe and effective treatment site for patients with severe infections, including osteomyelitis (OSTEO) and complicated skin and skin structure infections (cSSSI), as noted in our previous findings from 2008¹. The purpose of the current study was to evaluate and compare 2 years of data, to expand upon previous findings, and further evaluate cost savings.

Methods: A retrospective database and chart review was conducted of all patients receiving intravenous antibiotics (IVAB) in 2009. Those without immediate prior hospitalization, defined as >72 hrs prior, with either OSTEO or cSSSI were evaluated. The primary outcome measured was clinical success rate, defined as cure + improving, with a secondary outcome of AEs. Costs were evaluated by comparing those from a nation wide database for mean inpatient length of stay (LOS) to the actual reimbursement for the same LOS in the POIC for both years. Analyses and comparisons were made of all data collected in 2009 with that of 2008.

Results: 518 pts were treated with IVAB in 2008-9, of which 162 (32%) were treated with IVAB without prior hospitalization. Of these, 53 pts (33%) had OSTEO and 109 (67%) cSSSI. Diabetes was the most common co-morbidity present and predominant site of infection was the foot. MRSA was the most commonly reported organism. Overall clinical success was 89% for both diagnoses (77% cure + 12% improving), with 86% for OSTEO (including 4 non-evaluables) and 91% for cSSSI. Those with initial cure and relapse within 90 days were considered failed. The total number of AEs was 35 (22%). Daily costs for both diagnoses and years were comparable among OSTEO and cSSSI patients. However, daily costs were significantly higher when patients were treated in a hospital setting (p < 0.05).

Characteristic	2008 (n=89)	2009 (n=73)	Cost Savings	p value
Success-OSTEO	88%	72%		1.0
Success-cSSSI	89%	94%		1.0
Adverse Events	21%	22%		1.0
MRSA Prevalence	37%	40%		1.0
POIC Daily Cost-OSTEO	\$314	\$245	\$1,038	<0.05
Hospital Daily Cost-OSTEO	\$1,242	\$1,283		
POIC Daily Cost-cSSSI	\$211	\$219	\$1,090	<0.05
Hospital Daily Cost-cSSSI	\$1,225	\$1,309		

Conclusion: Treatment of serious OSTEO and cSSSI infections with IVAB in an Infectious Disease POIC without prior hospitalization is safe and effective, with demonstrated, reproducible results over a 2-year period. Daily costs are significantly less when care is provided in the POIC as compared with hospitalization.

Introduction

With the rates of hospital-acquired infections on the rise as well as associated costs, the prospect of treating patients requiring IV antibiotic therapy (IVAB) without requiring hospitalization poses significant merit. This study was initiated in 2008 to assess the safety, efficacy and cost benefit of IVAB for cSSSI and osteomyelitis when the therapy is initiated in a POIC.¹ This is a continuation of the 2008 study to compare two years of data.

Methods

- Retrospective database and chart review of Infectious Disease Associates (IDA) POIC patients.
- Electronic reporting form used to record demographic, clinical, and safety data.
- Inclusion Criteria**
 - IVAB initiated in the IDA POIC between January 1, 2008 and December 31, 2009.
 - Receipt of POIC-provided IVAB for a minimum of 48 hours.
 - Age 18 years and older.
 - One of the following documented diagnoses:
 - Osteomyelitis (with and without hardware).
 - Complicated skin and skin structure infections.
 - Deep soft tissue infection, major abscess, surgical wounds, diabetic infections/ulcers, necrotizing fasciitis, infections with underlying vascular insufficiency, gastrointestinal or urogenital site infections, traumatic wounds, and animal bites.
 - POIC-initiated treatment, defined as no inpatient hospitalization within 72 hours of receiving IVAB in the POIC.

- Demographic Data**
 - Age, gender, weight, ethnicity.
 - Concurrent disease states: diabetes, renal failure, immunosuppression.

- Clinical Data**
 - Infection diagnosis.
 - IVAB name, dose, duration of therapy.
 - Oral antibiotic use (pre-POIC and concurrent).
 - Culture results, pre-POIC and during POIC treatment.
 - Adverse events (AEs):
 - Mild: Resolution with or without discontinuation of IVAB, use of medication or short term treatment allowed.
 - Serious: Results in IVAB-related hospital admission and/or permanent change in patient status and/or requires IVAB discontinuation to prevent patient status change.
 - Adverse event rate defined as (Mild + Serious events)/(total # of patients).
 - IVAB efficacy at time of POIC discharge:
 - Cure: Clinical signs/symptoms resolved, and/or no additional antibiotic therapy needed, and/or negative culture at end of therapy.
 - Improved: Partial resolution of clinical signs/symptoms, and/or additional antibiotic therapy necessary.
 - Failed: Resistant, worsening, or new clinical signs/symptoms, recurrence of same infection within 90 days, and/or the need to change antibiotic therapy, and/or hospital admission due to worsening infection.

- Success rate defined as (Cure + Improved)/(total # of patients).
- POIC costs were calculated as a mean reimbursement rate per day. Inpatient costs, also calculated as a mean reimbursement rate were obtained from inpatient reimbursement rates from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample for the OSTEO and cSSSI diagnostic related group (DRG) and mean inpatient LOS.²

- Data Analysis**
 - Descriptive statistics (mean, standard deviation, min/max) were used for demographic data.
 - Percentages were used for efficacy and safety data; chi square was used for two-year comparisons.
 - Cost savings were calculated by comparing differences in the mean daily reimbursement for inpatients to the daily reimbursement in the POIC. The total savings were calculated based upon days of inpatient stay saved over two years.

Results

Patient Demographics and Characteristics:

Characteristics	2008 (n=89)	2009 (n=73)	Total (n=162)
Gender (%)			
Female	46 (52%)	38 (52%)	84 (52%)
Male	43 (48%)	35 (48%)	78 (48%)
Mean Age in years (range)	52 (20-80)	54 (29-80)	53 (20-80)
Mean Weight in kg (range)	99 (37-182)	96 (48-182)	98 (37-182)
Ethnicity (%)			
Caucasian	53 (59%)	39 (53%)	92 (57%)
African American	30 (34%)	12 (16%)	42 (26%)
Other	6 (7%)	2 (3%)	8 (5%)
Unknown	0 (0%)	20 (27%)	20 (12%)
Comorbidities (%)			
Diabetes	41 (46%)	29 (40%)	69 (43%)
Chronic Kidney Disease	21 (24%)	5 (7%)	23 (14%)
Immune Disorders (non-HIV)	12 (13%)	1 (1%)	12 (7%)
Immunosuppressive Drugs	10 (11%)	4 (5%)	10 (6%)
Comorbidities Per Patient (%)			
None	34 (39%)	30 (41%)	64 (40%)
One	28 (31%)	33 (45%)	61 (38%)
Two	25 (28%)	10 (14%)	35 (22%)
Third	2 (2%)	0 (0%)	2 (1%)

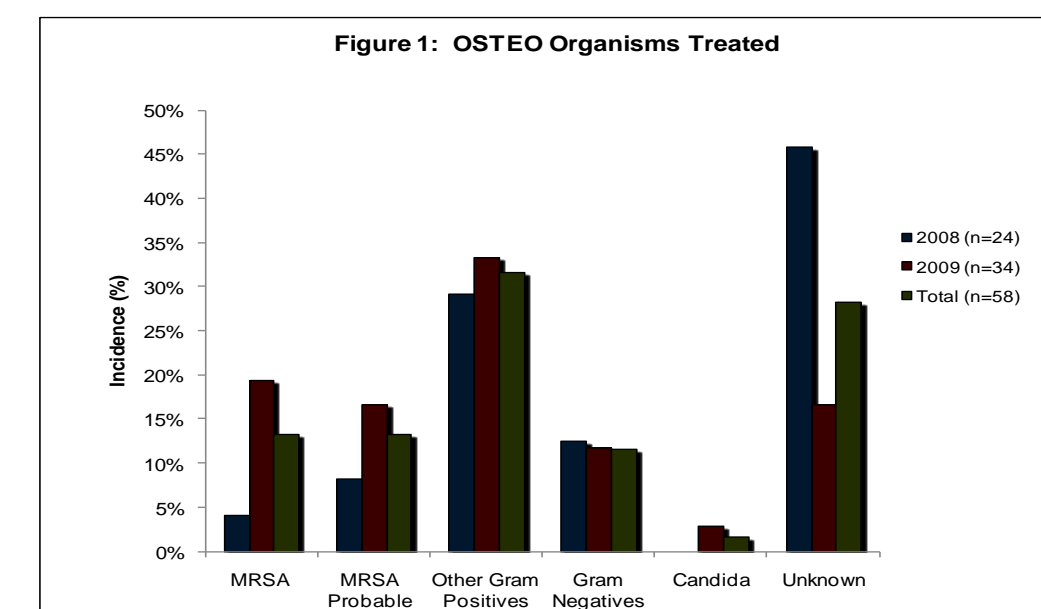
- The POIC treated 518 patients with IVAB in 2008-9, of which 162 (32%) were treated with IVAB without prior hospitalization, meeting study criteria. Of these, 53 (33%) had OSTEO and 109 (67%) cSSSI.
- Diabetes was the most common comorbidity present and predominant site of infection was the foot.
- 96 patients (59%) failed oral antibiotics prior to POIC admit.

Location	Foot	Lower Leg	Toe	Finger	Multi-Site	Other*
OSTEO 2008	11	n/a	8	n/a	2	3
OSTEO 2009	11	1	6	4	1	6
cSSSI 2008	14	12	2	4	5	28
cSSSI 2009	8	7	n/a	4	2	23
TOTAL	44	20	16	12	10	60

*Other includes: ear, face, back, thigh, buttocks, genitals, abdomen, ankle, arm, chest, knee, spine, and head

Drug Therapy:

OSTEO:



cSSSI:

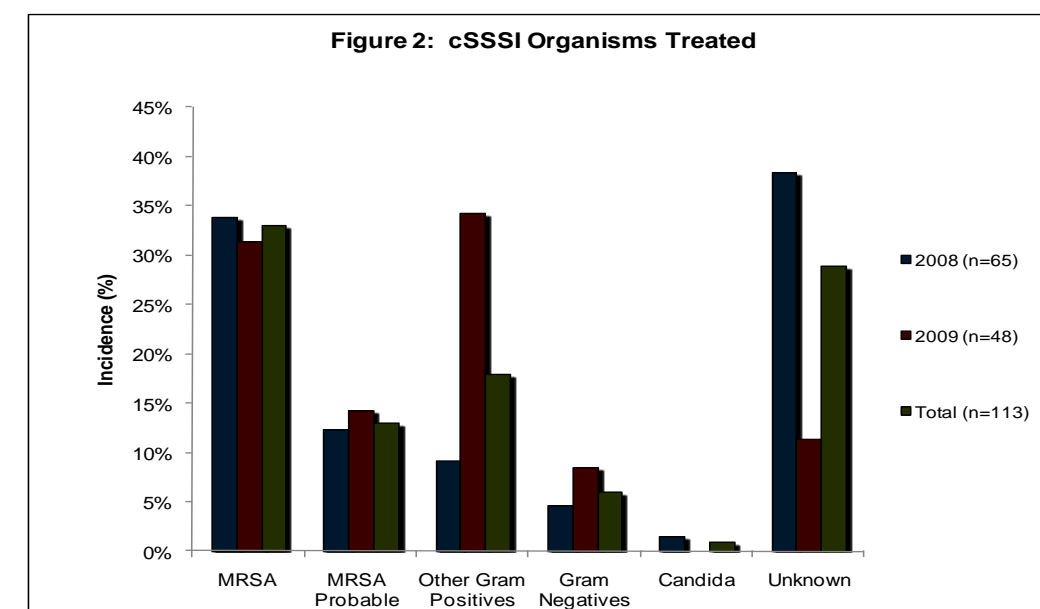


Figure 3. IVAB Selection for OSTEO

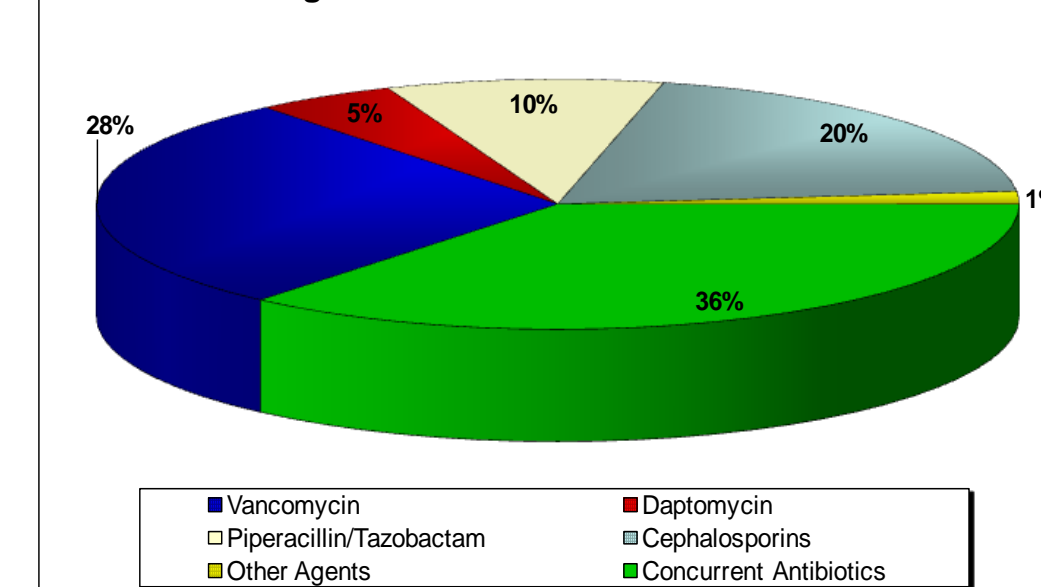
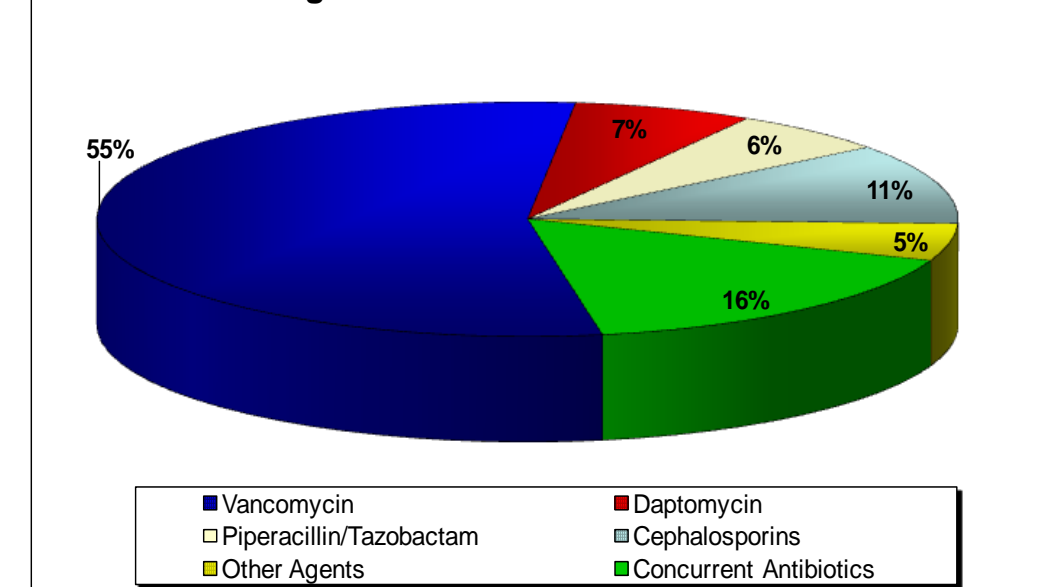


Figure 4. IVAB Selection for cSSSI



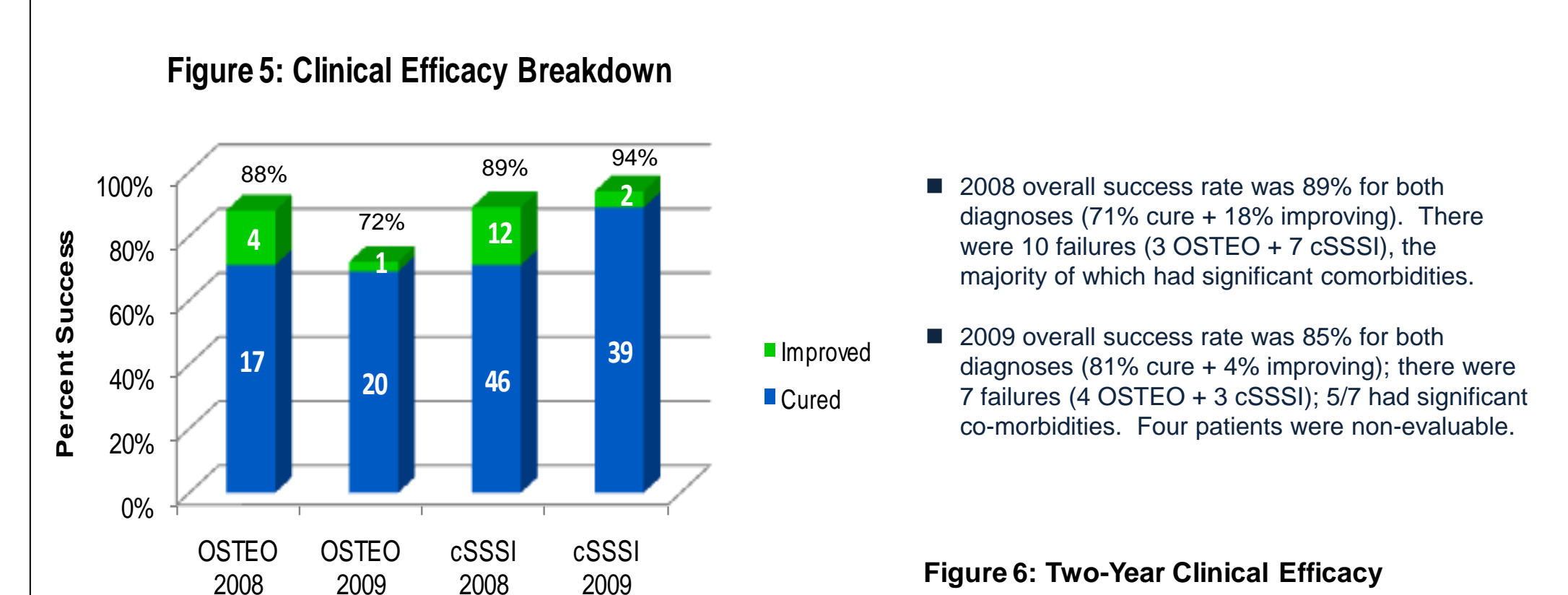
- Across both diagnoses, MRSA was the most common identified or treated pathogen (62 total patients, 38%).
- Dual IVAB therapy was frequent (24% overall; 35% OSTEO, 18% cSSSI).
- Drug doses were all within recommended guidelines. OSTEO patients receiving daptomycin had a mean dose of 6mg/kg /day; cSSSI patient doses ranged between 4mg/kg and 6mg/kg.
- 2009 mean IVAB therapy duration was 41 days for OSTEO; 20 days for cSSSI; 2008 mean IVAB therapy duration was 33 days for OSTEO; 21 days for cSSSI.

Safety:

Adverse Event	2008 No. (n=89)	2009 No. (n=73)	Relevant IVAB	Serious	Outcome	Drug Changed
CPK Increase*	3	0	Daptomycin	No	Resolved	Yes (1)
Diarrhea	3	5	Clindamycin; Meropenem; Pip/Tazo**;	No	Resolved	Yes (1)
			Vancomycin; Vancomycin + Pip/Tazo			
Genital Yeast	1	0	Vancomycin + Cefepime	No	Resolved	No
Itching	6	1	Vancomycin; Vancomycin + Pip/Tazo	No	Resolved	No
Rash	4	3	Cefazolin; Cefepime;	Yes (2)	Resolved	Yes (5)
			Daptomycin; Vancomycin;			
			Vancomycin + Cefepime			
Renal Insufficiency†	1	0	Vancomycin	No	Resolved	No
Vomiting	1	1	Vancomycin	No	Unknown (1)	Yes (1)
Other‡	0	2	Vancomycin;	No	Resolved	No
			Vancomycin + Cefazidime			
Total	19 (21%)	16 (22%)				

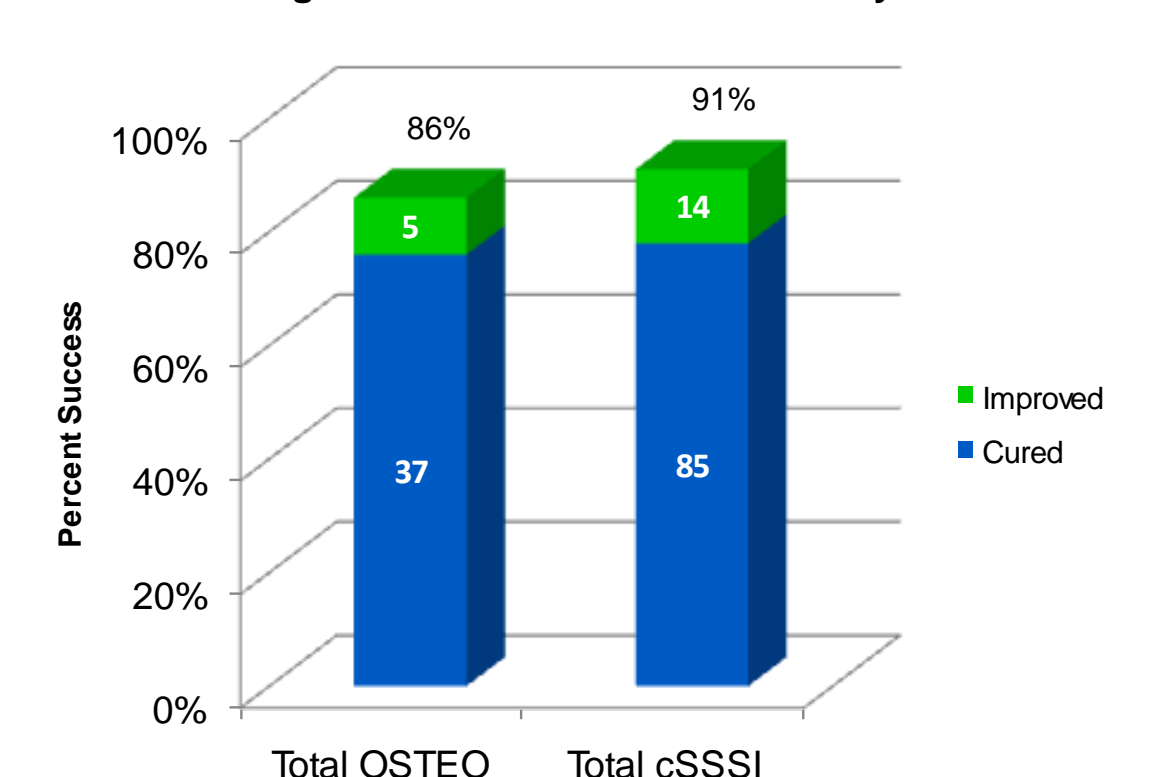
- Two-year total study AEs were 35 (22%), with 19 (36%) for OSTEO and 16 (15%) for cSSSI.
- Two-year serious AEs were 2 (1%), both occurring in 2008 OSTEO patients.
- All AEs resolved without residual effects; one patient with an AE was lost to follow-up.
- Two-year total study catheter-related infections were 2 (0.47 days per 1,000 catheter days), both growing yeast.

Clinical Outcomes:

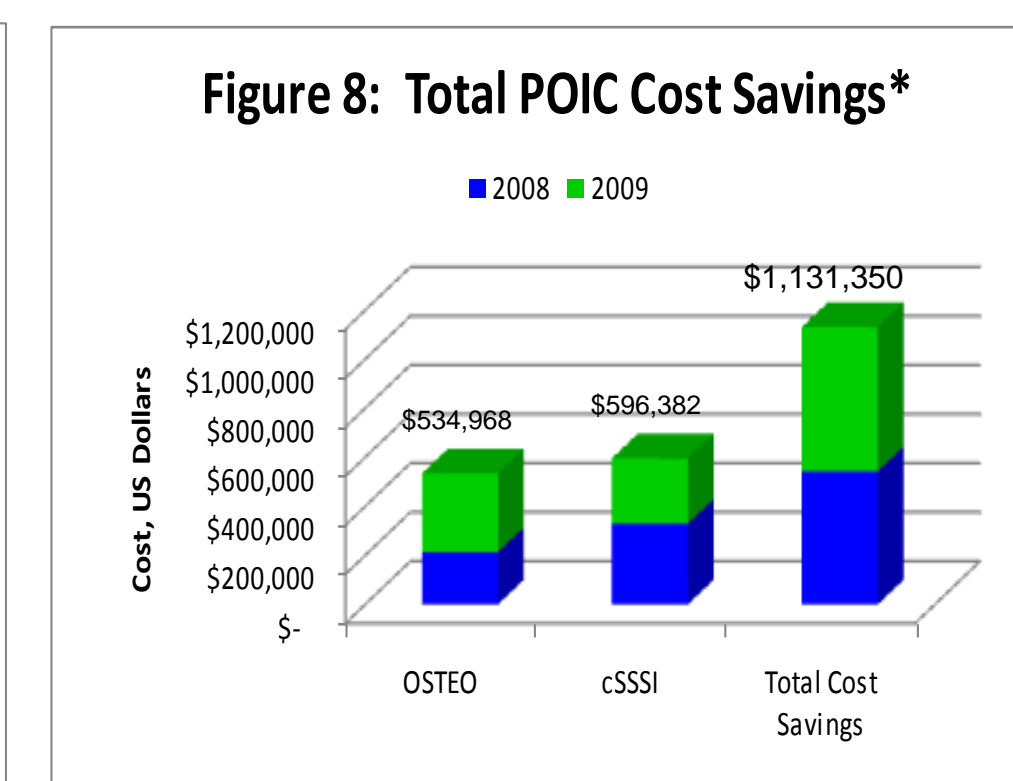
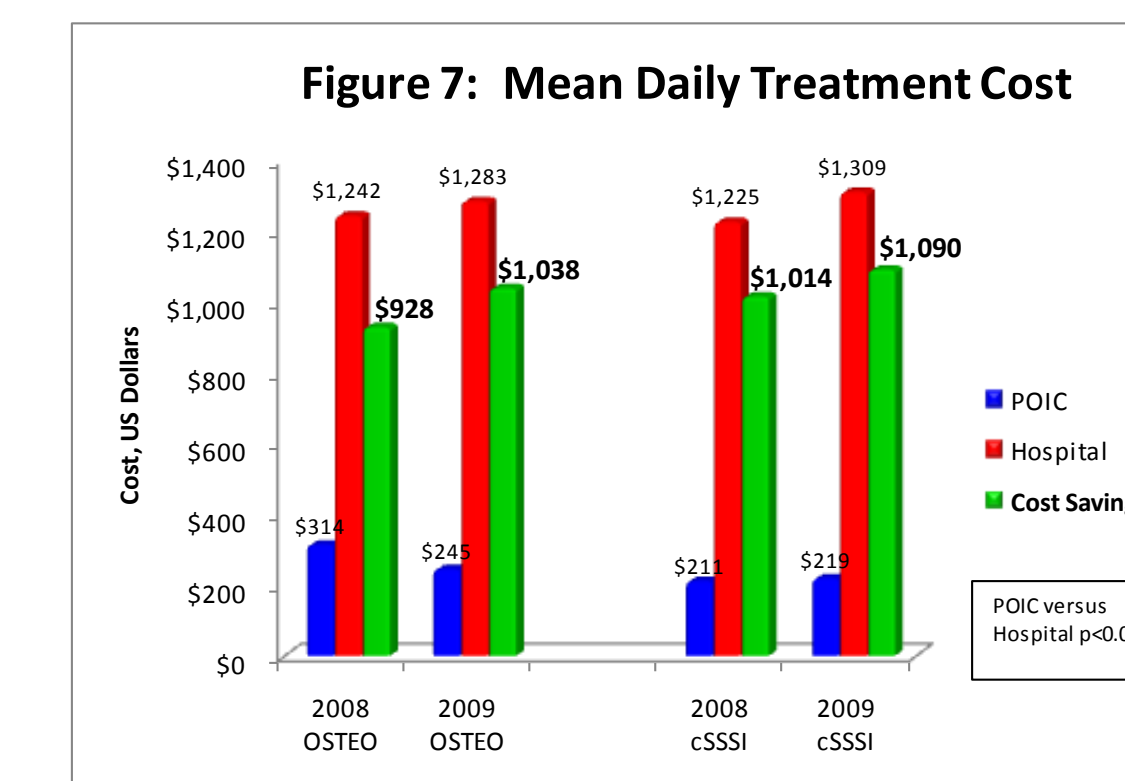


- 2008 overall success rate was 89% for both diagnoses (71% cure + 18% improving). There were 10 failures (3 OSTEO + 7 cSSSI), the majority of which had significant comorbidities.
- 2009 overall success rate was 85% for both diagnoses (81% cure + 4% improving); there were 7 failures (4 OSTEO + 3 cSSSI); 5/7 had significant co-morbidities. Four patients were non-evaluable.
- Two-year success rate was 86% OSTEO (76% cure + 10% improving) and 91% cSSSI (78% cure + 13% improving).
- 2008 recurrence rates were OSTEO 1 (4%) and cSSSI 3 (5%); 2009 recurrence rates were OSTEO 4 (12%) and cSSSI 3 (6%).
- Total recurrence rates were 9% for OSTEO and 5% for cSSSI.

Figure 6: Two-Year Clinical Efficacy



Cost Savings:



*Based upon a 2008-09 mean LOS for OSTEO of 9.6-9.1 days and cSSSI of 5.5-1.1 days.

Discussion

- This POIC treated 162 patients in 2008-9 with IVAB without hospitalization, representing 32% of the total patients requiring IVAB.
- This study focused on a two-year analysis of cSSSI and OSTEO treated without hospitalization. Methicillin-resistant *S. aureus* was the most common pathogen. The majority of patients had failed oral antimicrobial therapy and had one or more significant comorbidities.
- Adverse event rates were low and comparable to other retrospective studies.^{3,4} AEs were higher in OSTEO patients, possibly due to longer therapy duration and higher antibiotic doses.
- There were no long-term sequelae for any AE, including the two serious events.
- Catheter-related infection rates were low, below nationally reported data.⁵
- Costs per day were significantly lower for patients treated in a POIC versus the hospital, with savings in two years of over \$1.3 million.
- Limitations: Lack of comparator group, not able to evaluate surgical interventions or continued clinical success after 90 days. HCUP hospital costs reflected 2006-2007 data, respectively.

Conclusion

- Patients requiring intravenous antibiotics for serious infections, including OSTEO and cSSSI can be treated with IVAB entirely in a POIC, allowing for prompt evaluation and treatment, including first dosing, catheter placement and drug therapy.
- IVAB in this setting for OSTEO and cSSSI treatment appears to be safe, efficacious and cost-effective. This was reproduced over a two year period.
- Initiation and treatment of OSTEO and cSSSI in a POIC versus hospital saves significant health care dollars and costs associated with potential hospital-acquired infections.

References

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