

To stage or not to stage?—A cost minimization analysis of sacral neuromodulation placement strategies

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Abstract

Aims: Sacral neuromodulation (SNM) is a standard therapy for refractory overactive bladder (OAB). Traditionally, SNM placement involves placement of an S3 lead with 1–3 weeks of testing before considering a permanent implant. Given the potential risk of bacterial contamination during testing and high success rates published by some experts, we compared the costs of traditional 2-stage against single-stage SNM placement for OAB.

Methods: We performed a cost minimization analysis using published data on 2-stage SNM success rates, SNM infection rates, and direct reimbursements from Medicare for 2017. We compared the costs associated with a 2-stage vs single-stage approach. We performed sensitivity analyses of the primary variables listed above to assess where threshold values occurred and used separate models for freestanding ambulatory surgery centers (ASC) and outpatient hospital departments (OHD).

Results: Based on published literature, our base case assumed a 69% SNM success rate, a 5% 2-stage approach infection rate, a 1.7% single-stage approach infection rate, and removal of 50% of non-working single-stage SNMs. In both ASC (\$17 613 vs \$18 194) and OHD (\$19 832 vs \$21 181) settings, single-stage SNM placement was less costly than 2-stage placement. The minimum SNM success rates to achieve savings with a single-stage approach occur at 65.4% and 61.3% for ASC and OHD, respectively.

Conclusions: Using Medicare reimbursement, single-stage SNM placement is likely to be less costly than 2-stage placement for most practitioners. The savings are tied to SNM success rates and reimbursement rates, with reduced costs up to \$5014 per case in centers of excellence ($\geq 90\%$ success).

KEYWORDS

costs and cost analysis, electrodes, implanted, Medicare, overactive, urinary bladder

Abbreviations: SNM, sacral neuromodulation; OAB, overactive bladder; ASC, ambulatory surgery center; OHD, outpatient hospital department.

This work has not been published before and is not under consideration for publication elsewhere.

1 | INTRODUCTION

Sacral neuromodulation (SNM) is a standard therapy for urinary frequency, urinary urgency, urge urinary incontinence, nonobstructive urinary retention, and fecal

incontinence. It is standard for patients being considered for SNM placement to have an initial trial with placement of an S3 lead that is externally powered for 1 to 3 weeks. If a 50% or greater improvement in symptoms is seen, a permanent generator is placed. The success rate of the two-stage method (trial followed by implant) can vary based on the indication for surgery and surgeon experience. Most success rates of SNM for overactive bladder (OAB) are 60% to 70%,¹⁻³ but centers of excellence have reported conversion to a full device in nearly 90% of patients.⁴⁻⁶

A risk of the staged testing approach is lead infection. The leads, which are externalized during the testing phase, are at risk of bacterial contamination (20% of tined leads),⁷ which can result in device infection requiring explant (5% to 13.5% of cases).^{2,8,9} Given the high success rates of SNM trials for OAB in the hands of some practitioners, and the potential for increased infection with a staged procedure, the need for any testing phase before complete SNM placement has been questioned. In addition to decreasing infection rates, a single-stage procedure would also be expected to reduce the time and cost associated with a two-stage surgery.

Only one study has performed a cost comparison of a single-stage vs two-stage approach to SNM. While it suggested that a single-stage approach would reduce costs at particularly high success rates, it was limited by not specifically accounting for infection rates and relied on institution-specific charges.⁶ The aim of the study was to evaluate the conditions under which a single-stage approach to SNM for refractory OAB, becomes economically advantageous compared to the standard two-stage approach, using generalizable reimbursement rates and other common SNM variables. We hypothesized that under current conditions, single-stage SNM placement would be less costly than two-stage placement for most practitioners.

2 | MATERIALS AND METHODS

2.1 | Decision model

We performed a cost minimization analysis using TreeAge Pro Healthcare (TreeAge Software, Inc, Williamstown, MA). A literature review was performed to determine two-stage SNM success and infection rates as well as direct

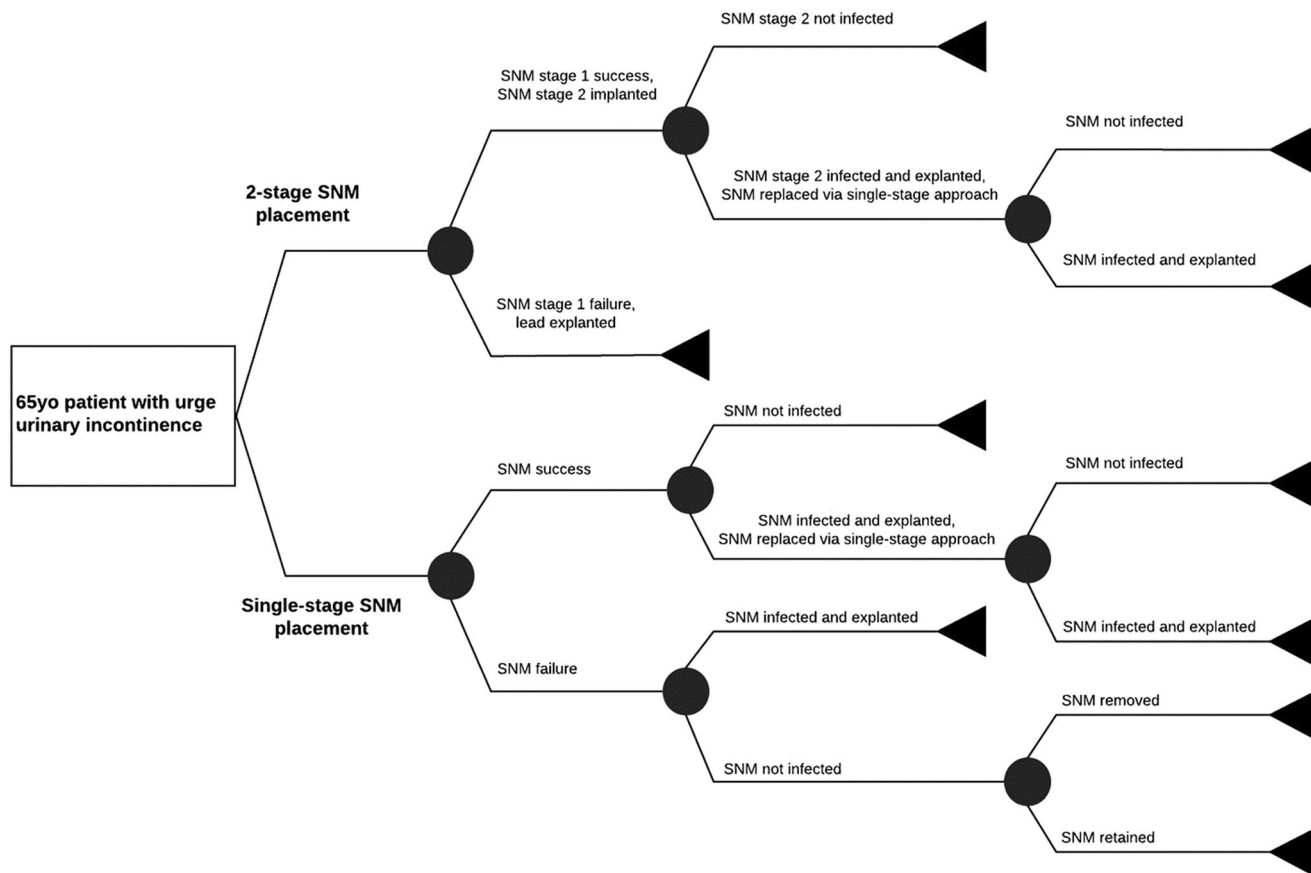


FIGURE 1 Decision tree model for a 65-year-old patient with overactive bladder (OAB) and no other comorbidities undergoing sacral neuromodulation (SNM) placement after failure of medical therapy. The model evaluates outcomes after each procedure in regard to both success and infection

reimbursements from Medicare (the most common payer for SNM procedures¹⁰) for the fiscal year 2017. We compared the costs associated with a two-stage approach (external lead testing and subsequent generator placement if successful), against a single-stage approach (simultaneous lead and generator placement). Because payment amounts vary based on the surgical setting, separate models were used for a freestanding ambulatory surgery center (ASC) and an outpatient hospital department (OHD).¹¹ We included branch points based on the likelihood of success

or failure of each treatment pathway, the possibility of device infection, and SNM explant for nonfunctional systems. Sensitivity analyses were performed to assess where threshold values occurred (Figure 1).

2.2 | Base case

We defined our base case as a 65-year-old patient with OAB who undergoes SNM placement after failure of medical therapy.

TABLE 1 Rates and costs used in models

Rate/Cost	Base case	Reported range	Range tested in models
Stage-1 SNM success rate, %	69	59-100 ^{1,2,4,5,10,18}	0-100
Single-stage SNM success rate, %	Same as SNM 1 success rate	–	0-100
Two-stage SNM infection rate, %	5	0-13.5 ^{2,8,9,13,14}	0-20
Single-stage SNM infection rate, %	1.7*	–	0-20
Explant rate after infection, %	100	42.3-100 ^{8,13,19,20}	100
Explant rate after single-stage SNM failure, %	50**	–	0-100
Physician fee, \$			
Stage-1 SNM placement	687	–	–
Stage-2 SNM placement	166		
Single-stage SNM placement	770		
Fluoroscopy for lead placement	9		
Lead removal	148		
Lead and generator removal	213		
Facility fee—ASC, \$			
Stage-1 SNM placement	4681	–	–
Stage-2 SNM placement	16 004		
Single-stage SNM placement	16 004		
Fluoroscopy for lead placement	39		
Lead removal	1455		
Lead and generator removal	1455		
Facility fee—OHD, \$			
Stage-1 SNM placement	5745	–	–
Stage-2 SNM placement	17 803		
Single-stage SNM placement	17 803		
Fluoroscopy for lead placement	226		
Lead removal	2690		
Lead and generator removal	2690		
Anesthesia fee, \$***			
Stage-1 SNM placement	287	–	–
Stage-2 SNM placement	198		
Single-stage SNM placement	287		
Lead removal	176		
Lead and generator removal	176		

Abbreviations: SNM, sacral neuromodulation; ASC, ambulatory surgery center; OHD, outpatient hospital department.

*On the basis of implantable cardiac defibrillator data.¹⁵⁻¹⁷

**No data exists, 50% used in base case with accompanying sensitivity analyses for 0% to 100%.

***Calculated using anesthesia base unit, previously reported procedure times,⁶ and 2017 conversion factor.

2.3 | Model description (Table 1)

We assumed that success during the trial period of stage 1 equates to long-term device success. For this reason, we assigned equal success rates for single-stage SNM placement and the first stage of two-stage SNM placement. A base-case success rate of 69% was used¹⁰ as it falls within published values¹⁻³ and is likely more generalizable than the high success rates reported by certain centers of excellence.^{4,5,12} All second-stage procedures (pulse generator implantation) of two-stage SNM placement were assumed to be successful with no drop off in device efficacy. While 100% of failed first-stage SNM leads are removed, the rate of SNM removal (lead and generator) after a failed single-stage approach is unknown. Given the paucity of data, we assumed a base-case rate of 50%. (Table 1)

A base-case infection rate of 5% after the second-stage of two-stage SNM placement was utilized, consistent with published literature.^{2,8,9,13,14} As there is no data on infection rates after single-stage SNM placement, we extrapolated data from infection rates of implantable cardiac defibrillators. These devices include a generator and leads that are placed in a single operation, making them somewhat analogous to single-stage SNM placement. On the basis of the available literature on implantable cardiac defibrillators, a base-case infection rate of 1.7% for single-stage SNM placement was estimated.¹⁵⁻¹⁷ We felt that the lower infection rate was justified, as the single-stage approach omits the testing phase with an exposed lead.

If an infection occurred in either the single-stage or two-stage approaches, we assumed that the infected device would be explanted in all cases. This reflects our practice and that of others.¹³ After explant for infection and a period of antibiotic treatment, we modeled that the patient would then be given a replacement device in a single-stage fashion. As all patients would have either had a successful stage-1 SNM trial or had several weeks with an implanted device to assess success (infections are typically seen >4 weeks after implantation⁹), we modeled all replaced SNMs to have a 100% success rate. For reimplanted devices, we assigned the same infection rate associated with first-time single-stage SNM placement (1.7%). If an infection occurred again, we modeled explanation of the second device without any further attempts at SNM placement.

We calculated all costs based on Medicare national averages for the year 2017. Separate models were used to calculate costs for both ASC and OHD operative settings, as costs are substantially different. The total cost of each model included facility fees, physician fees, and anesthesia fees. The procedure codes used included 64 581 (lead

implantation), 64 590 (generator implantation), 64 585 (lead removal), 64 595 (generator removal), and 76 000 (fluoroscopy). Anesthesia charges were calculated by adding anesthesia base units to previously published procedure times,⁶ and multiplying by the Medicare conversion factor. Per Medicare guidelines, physician fees were calculated as the cost of the most expensive procedure plus half of the cost of additional procedures. In the case of a single-stage procedure, the facility reimbursement only covered the more expensive of the two procedures being done (ie, cost of generator placement > cost of tined-lead placement).

2.4 | Model variations—sensitivity analyses

To account for potential variation in the explant rates for failed single-stage device placement and facility reimbursement patterns we performed sensitivity analyses. While our base case assumed that 50% of failed single-stage SNMs would be explanted, we examined explant rates from 0% to 100% to account for different theoretical practice patterns and patient preference. Additionally, a large amount of the potential savings related to the single-stage approach is tied to Medicare reimbursing only the most expensive facility fee if multiple procedures are done concurrently. As noted above, for SNM placement, stage 2 is costlier than stage 1, so for single-stage placement only the cost of stage 2 is reimbursed. As this may not represent the reimbursements of payors distinct from Medicare, we examined the outcomes if 0% to 100% of the stage-1 SNM facility costs were additionally reimbursed in those undergoing single-stage SNM placement.

3 | RESULTS

3.1 | Base case—ASC

In an ASC setting, single-stage SNM placement (\$17 613) was less costly than two-stage SNM placement (\$18 194). The SNM success threshold point was 65.4%, with any higher success rate exhibiting a cost savings for the single-stage approach. When varying infection rates for SNM, if an infection rate of 0.6% or less is achieved for double-stage SNM placement, the double-stage approach would be less costly. Similarly, an infection rate of 6.0% or higher with a single-stage approach would result in a two-stage approach being less costly (Figure 2).

3.2 | Base case—OHD

In an OHD setting, single-stage SNM placement (\$19 832) was again less costly than a two-stage SNM placement

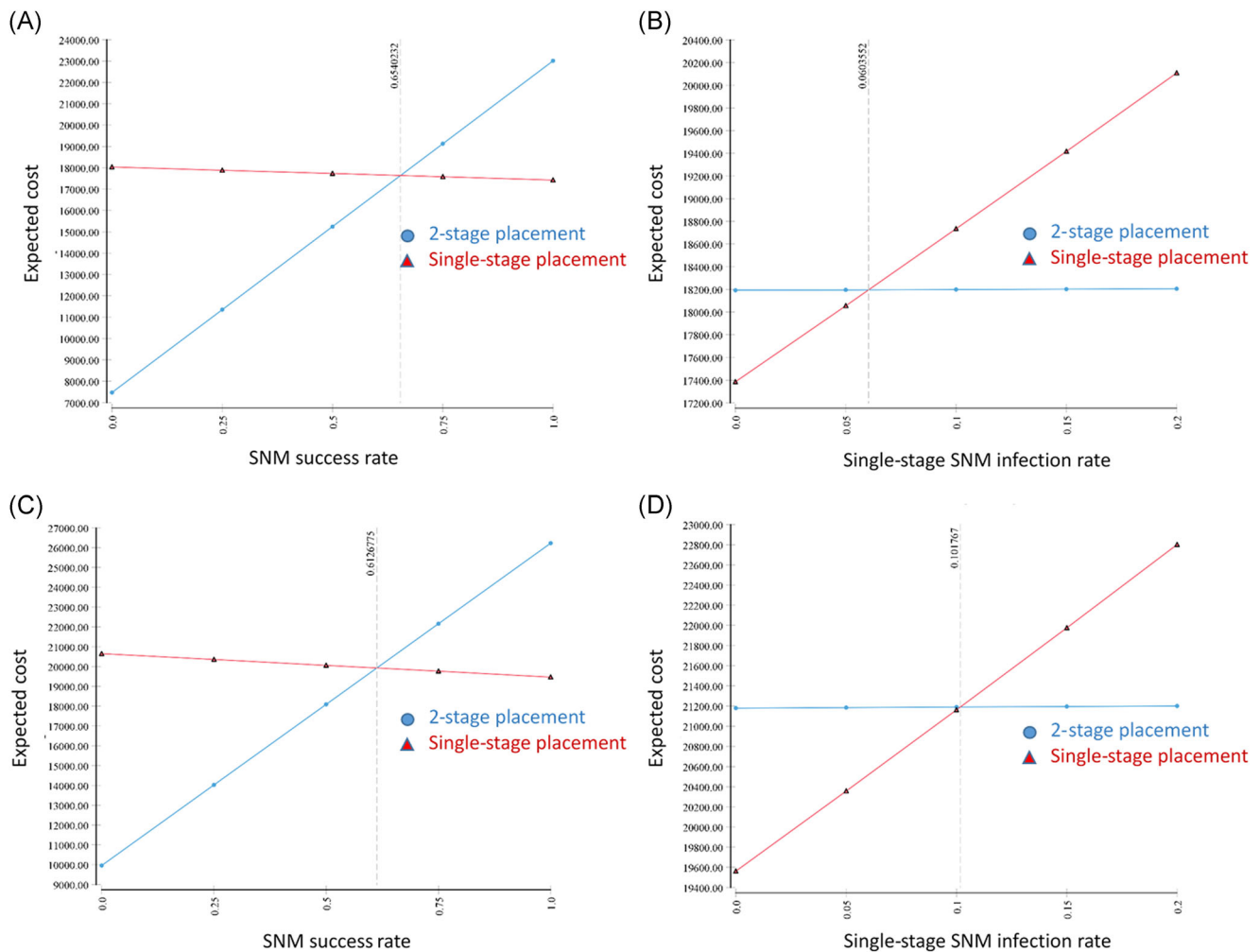


FIGURE 2 Two-stage vs single-stage SNM placement for ASC (A, B) and OHD (C, D). A, Expected cost for each approach in ASC when varying SNM success rate. Success rates above 65.4% have less cost with a single-stage approach. B, Expected cost for each approach in ASC when varying single-stage SNM infection rate. Infection rates below 6.0% have less cost with a single-stage approach. C, Expected cost for each approach in OHD when varying SNM success rate. Success rates above 61.3% have less cost with a single-stage approach. D, Expected cost for each approach in OHD when varying single-stage SNM infection rate. Infection rates below 10.2% have less cost with a single-stage approach. ASC, ambulatory surgery center; OHD, outpatient hospital department; SNM, sacral neuromodulation

(\$21 181). The SNM success threshold point occurred at 61.3% with higher success rates leading to more cost savings for a single-stage approach. When examining infection rates, even when assuming a 0% rate for the two-stage approach, a single-stage approach was still less costly. Only when the infection rate was 10.2% or higher for the single-stage approach, did the single-stage approach become costlier (Figure 2).

3.3 | Sensitivity analysis: single-stage SNM removal rates

As there is no data on SNM removal after a failed single-stage SNM placement, we used a 50% value for our base case. However even if 100% of devices were assumed to be removed, a single-stage approach would still be less

costly than a two-stage approach for our base cases in both the ASC and OHD settings. In an ASC setting, if a 0% removal rate is assumed, an SNM success rate of 64% or higher is needed to make a single-stage approach less costly. If a 100% removal rate is assumed, the threshold success rate increases to 68%. In an OHD setting, if a 0% removal rate is assumed, an SNM success rate of 58% or higher is needed to make a single-stage approach less costly, while if a 100% removal rate is assumed, the threshold success rate increases to 65% (Figure 3).

3.4 | Sensitivity analysis: increased reimbursement

As insurers may reimburse differently, despite similar surgeries, we performed sensitivity analyses assuming

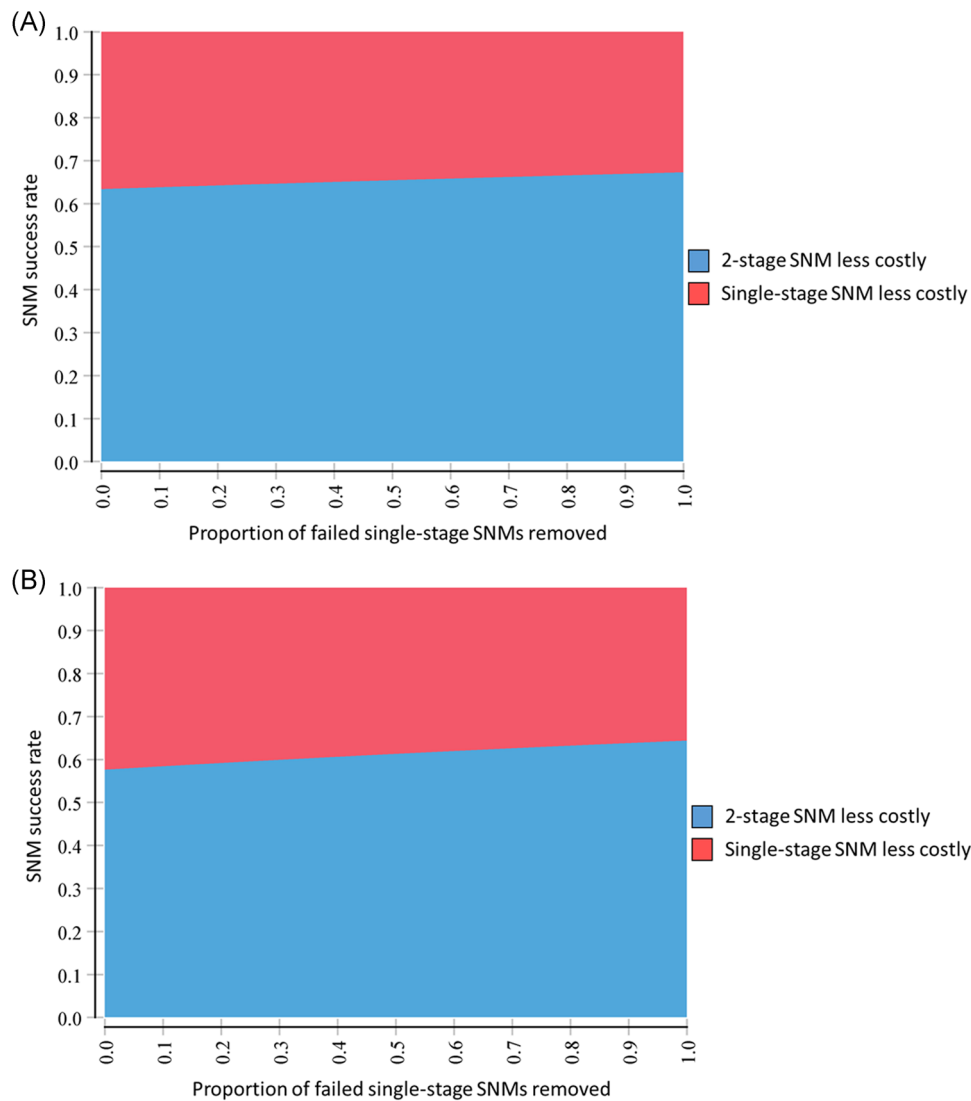


FIGURE 3 Two-way sensitivity analysis comparing SNM success rate and failed single-stage SNM removal rate in ASC (A) and OHD (B). In an ASC setting, if a 0% removal rate is assumed, an SNM success rate of 64% or higher is needed to make a single-stage approach less costly, while if a 100% removal rate is assumed, the threshold success rate increases to 68%. In an OHD setting, if a 0% removal rate is assumed, an SNM success rate of 58% or higher is needed to make a single-stage approach less costly, while if a 100% removal rate is assumed, the threshold success rate increases to 65%. ASC, ambulatory surgery center; OHD, outpatient hospital department; SNM, sacral neuromodulation

additional reimbursement of 0% to 100% of the cost of the stage-1 facility fee during single-stage SNM placement (Figures 4 and S1). If 50% reimbursement is assumed, SNM success rates of at least 79.5% (ASC) and 77.3% (OHD) are needed to make a single-stage approach less costly. If 100% reimbursement is assumed, SNM success rates must further increase to 93.5% (ASC) and 93.2% (OHD).

4 | DISCUSSION

In this cost minimization analysis, we examined the conditions needed to make single-stage SNM placement less costly than traditional two-stage placement.

Considering contemporary reports of success, infection, and Medicare reimbursements, we found that a single-stage approach is likely to yield cost savings. This was true in the setting of either an independent ASC (\$581 savings per case) or OHD (\$1349 savings per case). If a 90% success rate is considered, as reported by centers of excellence,^{4-6,12} the savings increase to \$3973 and \$5014 per case for ASC and OHD settings, respectively. In addition to these direct cost savings, there are indirect cost savings associated with omitting a second trip to the operating room such as, facility resources, surgeon time, and patient time. From both a societal and financial perspective, single-stage SNM placement should strongly be considered as a standard approach.

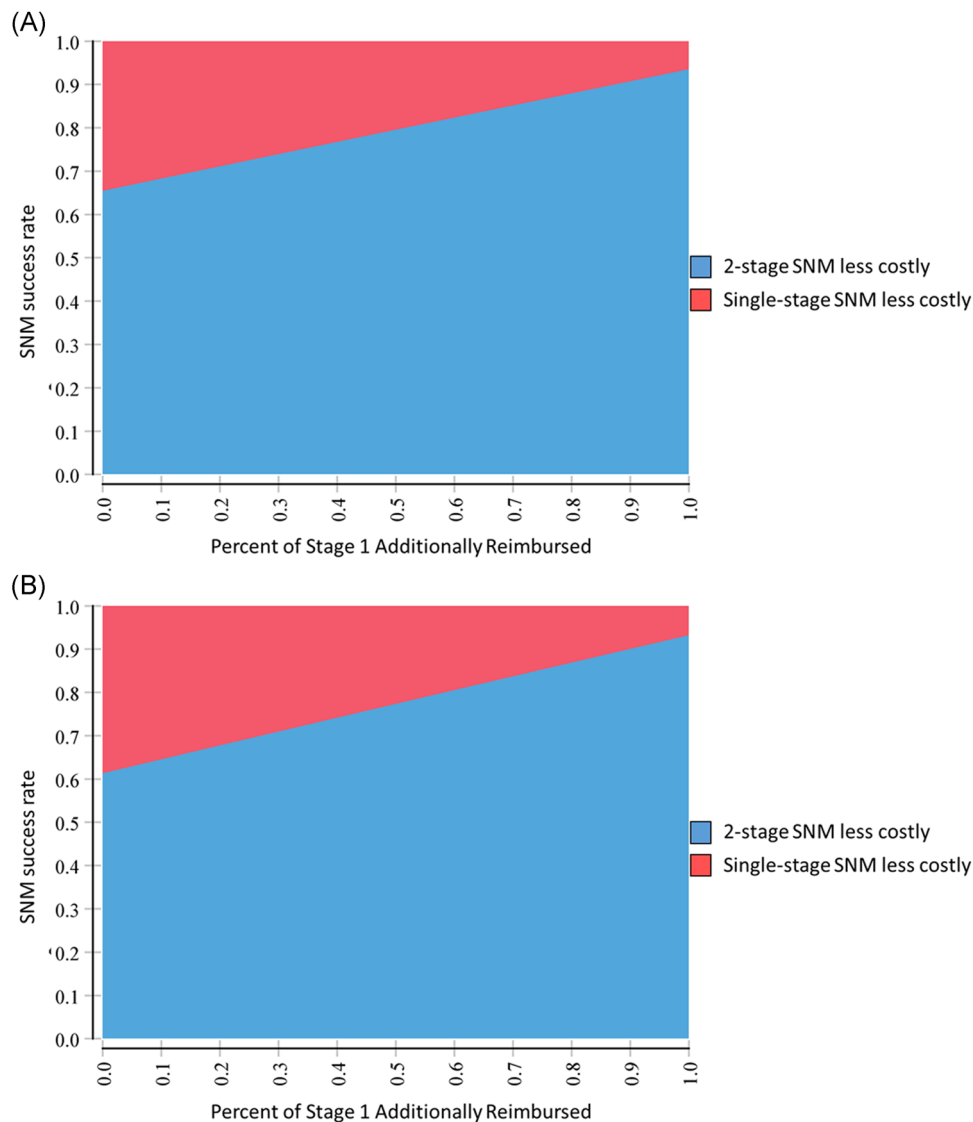


FIGURE 4 Two-way sensitivity analysis comparing SNM success rate and proportion of the traditional stage-1 SNM facility fee additionally reimbursed in ASC (A) and OHD (B). At 50% reimbursement a success rates of 80% (ASC) and 77% (OHD) are needed to make a single-stage approach less costly. At 100% reimbursement, required rates increase to 94% (ASC) and 93% (OHD). ASC, ambulatory surgery center; OHD, outpatient hospital department; SNM, sacral neuromodulation

As Medicare is the most common payor for SNM placement,¹⁰ we based our primary model on their costs and methods for reimbursements. However, not all payors reimburse equally. To account for this, we performed companion analyses assuming that 50% or 100% of the cost of stage-1 SNM placement would be reimbursed in addition to what Medicare currently reimburses for a single-stage SNM placement. Under these circumstances, the success rates required to make single-stage SNM placement less costly ranged between 77.3% to 79.5% and 93.2% to 93.5% for 50% and 100% reimbursement schemes, respectively. These rates are higher than those seen at the national level,¹⁰ but are still within those reported by centers of excellence^{4,5,12} and suggest that at the very least, insurers consider individual

physician success rates when considering SNM testing phase policies.

Nikolavsky et al⁶ previously examined the costs of single-stage SNM placement using institution-specific data. In their analysis, Blue Cross/Blue Shield would save \$3655 per case, if all SNMs were placed using a single-stage approach at their center (>90% success rate). This study was primarily limited by only utilizing institutional data, which may not be generalizable to other centers. Additionally, they did not directly account for or examine infection rates. By using national Medicare averages and considering infection rates, our models are more likely to provide realistic and generalizable findings.

In our analysis, a single-stage approach would save Medicare a substantial amount of money and save

patients time and discomfort. In addition, the single-stage approach could increase physician productivity by reducing clinic visits and optimizing operative time. Employed patients would similarly realize a reduction in lost productivity associated with staged surgery. However, a single-stage approach would reduce the reimbursements paid to ASC and OHD facilities and physicians. In a fee-for-service model, these unrealized professional and facility fees may present significant barriers to implementation. As a result, Medicare and other payors may need to increase reimbursements for the single-stage approach to make it more financially acceptable to physicians and facilities.

One limitation of our model is that the Medicare payment model may not be generalizable to other insurers. However, Medicare is the most common payor for SNM placement (>60%)¹⁰ and our companion analyses have attempted to address these differences, specifically by increasing the facility and physician reimbursements for a one-stage procedure. A further limitation is that there is a paucity of robust data regarding single-stage SNM infection and explant rates, requiring us to estimate their prevalence. Additionally, there is no published data on how a previous SNM infection and explant would change the infection rate for the second implantation, requiring us to use our base-case single-stage infection rate. Finally, our practice of explanting all infected devices may not be generalizable to all practitioners, as some literature supports the possibility of salvage with antibiotics alone in certain cases.^{2,8}

Despite these limitations, our study is the first to assess single-stage SNM placement using national cost data from the most common SNM payor. Further, after an extensive literature review we were able to create a base case founded on the best-available data and consider not only SNM success rates, but also infection rates. Last, we use separate models to assess costs in ASC and OHD settings, which can differ substantially. Given these considerations, our models are likely to be generalizable to most practitioners in the United States.

5 | CONCLUSION

Using Medicare reimbursement cost data, single-stage SNM placement is less costly than two-stage placement for most practitioners and should be considered as a standard approach. The savings are tied to SNM success rates and reimbursement rates, with the success in centers of excellence (~90%) saving up to \$5014 per case. Further, a single-stage procedure optimizes utilization of healthcare and patient resources.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTION

All authors contributed to the conception and design, drafting and revising the manuscript for important intellectual content, and gave final approval for submission.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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