Three-Year Cost-effectiveness Model for Non–Animal Stabilized Hyaluronic Acid and Dextranomer Copolymer Compared With Sacral Nerve Stimulation After Conservative Therapy for the Management of Fecal Incontinence

Mitchell A. Bernstein, MD[1]; Christopher H. Purdy, MA[2]; Alison Becker, MS[2]; and Raf Magar, MBA[2]

[1]Department of Surgery, New York University Langone Medical Center, New York, New York; and [2]AHRM Inc, Buffalo, New York

ABSTRACT

Background: Two new therapies for fecal incontinence (FI) are now available: non–animal stabilized hyaluronic acid and dextranomer copolymer (NASHA/Dx) and sacral nerve stimulation (SNS).

Purpose: This study aimed to determine the cost-effectiveness of NASHA/Dx compared with SNS and conservative therapy (CT) for the treatment of FI after CT failure.

Methods: Decision tree models with Markov subbranches were developed to compare all direct costs and outcomes during a 3-year period from the viewpoint of the US third-party payer. Costs (in 2013 US dollars) of devices, medical and surgical care, and hospitalization were included. Outcomes included quality-adjusted life-years (QALYs) and incontinence-free days (IFDs). Both costs and outcomes were discounted at an annual rate of 3%. The incremental cost-effectiveness ratio was calculated for each outcome. One-way and probabilistic sensitivity analyses were performed to examine robustness of results and model stability. A budget impact analysis was also undertaken to estimate the potential cost and savings of NASHA/Dx for a payer with 1,000,000 covered lives.

Results: For the 3-year cost-effectiveness models, the expected cost was $9053 for CT, $14,962 for NASHA/Dx, and $33,201 for SNS. The numbers of QALYs were 1.769, 1.929, and 2.004, respectively. The numbers of IFDs were 128.8, 267.6, and 514.8, respectively. The incremental cost-effectiveness ratios per additional IFD gained were $42.60 for NASHA/Dx vs CT, $73.76 for SNS vs NASHA/Dx, and $62.55 for SNS vs CT. The incremental costs per QALY gained were $37,036 for NASHA/Dx vs CT, $244,509 for SNS vs NASHA/Dx, and $103,066 for SNS vs CT. The budget impact analysis evaluated the financial effect on the health care system of the use of NASHA/Dx and SNS. For the scenarios evaluated, when all of the patients receive NASHA/Dx, the net annual effect to the health care payer budget ranged from $571,455 to $2,857,275. When all of the patients receive SNS, the net annual effect to the health care payer budget ranged from $1,959,323 to $9,796,613.

Conclusion: Both NASHA/Dx and SNS have produced significant improvements in FI symptoms for affected patients. NASHA/Dx is a cost-effective and more efficient use of resources for the treatment of FI when compared with SNS. The budget impact analysis suggests that although reimbursement for NASHA/Dx treatment initially adds costs to the health care system, it is significantly less expensive than SNS for patients who are candidates for either treatment. (*Clin Ther.* 2014;▮:▮▮▮–▮▮▮)

Key words: budget impact analysis, cost-effectiveness, fecal incontinence, incontinence-free days, incremental cost-effectiveness ratio, InterStim, NASHA/Dx, sacral nerve stimulation, Solesta, quality-adjusted life-years.

INTRODUCTION

Fecal incontinence (FI) is a socially devastating condition of varied origin. Conservative therapy (CT) includes

Accepted for publication April 9, 2014.
http://dx.doi.org/10.1016/j.clinthera.2014.04.010
0149-2918/$ - see front matter

dietary changes, bulking agents, antidiarrheal medications, enemas, and biofeedback. Contingent on the severity of the incontinence, these noninvasive measures are often initial options. Conservative therapy can successfully improve FI in >30% to 50% of affected individuals.[1–4] When CT is unsuccessful, other therapies may be considered. Anal sphincter repair, artificial bowel sphincter, muscle transfers, radiofrequency, and stomas are other treatment options for FI available in the United States. Historically, repair of anterior defects was favored; however, more recent research has revealed poor long-term results.[5,6] Although an attractive alternative with often impressive long-term functional results, artificial bowel sphincter was found to have a 40% major infection rate, limiting its appeal.[7,8] Muscle transfers are complex and associated with a high morbidity; thus, they have not been widely popularized. Radiofrequency collagen reformation is a promising modality but requires an anesthetic and an operating room or endoscopy suite for its application. A diverting stoma allows affected patients to function away from the toilet but interferes with their overall quality of life.

More recently, 2 therapies for FI have been approved by the US Food and Drug Administration (FDA), including non–animal stabilized hyaluronic acid and dextranomer copolymer (NASHA/Dx*), approved in May 2011, and sacral nerve stimulation (SNS†), approved in March 2011. NASHA/Dx is a bulking agent that consists of dextranomer microspheres in stabilized hyaluronic acid, which are injected into the submucosa. In the prospective randomized study conducted for FDA approval of NASHA/Dx, 52% of patients had a >50% reduction of FI versus 31% of sham-treated patients after 6 months ($P = 0.009$).[4] These results were sustained in the NASHA/Dx treatment group at 36 months.[9] A separate 24-month follow-up study evaluated the effectiveness of NASHA/Dx for FI under open-label conditions; 62.7% of the patients were treatment responders and experienced at least a 50% reduction in the total number of FI episodes.[10]

SNS has also produced major clinical benefits for patients with FI.[11–15] This therapy involves the administration of long-term low-level electrical impulses to stimulate the sacral sensory and motor fibers. The SNS procedure is a staged process in which the patient first undergoes insertion of an electrode attached to an external pulse generator to assess benefit. If there is a >50% reduction in FI, a permanent electrode is inserted and connected to an implanted pulse generator. The mechanism of action of SNS includes local sensory improvement, probably secondary to cortical stimulation.[16] In the 12-month study conducted for FDA approval of SNS, 90% of patients passed test stimulation and proceeded to long-term implantation; for those patients who received permanent implantation, 83% had therapeutic success, with 41% achieving complete continence.[15] In a long-term study of SNS, Hull et al[17] found sustained success, with 89% having a >50% reduction in FI at ≥5 years and 36% having complete resolution of FI.

Considering the various treatment interventions for individuals in whom CT fails and the associated cost burden, a number of studies of the cost-effectiveness of interventions with SNS for FI have been performed.[18–24] In most cases, SNS was cost-effective, dominating in one Markov analysis from the Netherlands.[24] A simulation model evaluating the cost-effectiveness of SNS treatment for FI in patients with an intact anal sphincter estimated an incremental cost-effectiveness ratio (ICER) of €38,662 per quality-adjusted life-year (QALY) gained in the Italian health care system.[18] A similar simulation model developed to assess the cost-effectiveness of SNS treatment for a comparable patient population in the Spanish health care system yielded an ICER of €16,181 per QALY gained with minimal budget impact.[21] This latter model was validated using a prospective comparison of 2 patient cohorts.[23] The exception was a study from France comparing 2 patient cohorts; that study found significantly higher ICERs.[22] Patients with FI who underwent implantation with sacral nerve modulation experienced improved disease-related quality of life when compared with patients without implants, but at an increased cost. For the FI patients, the 12- and 24-month ICERs were €90,082 and €185,160, respectively.

Although studies have investigated the cost-effectiveness of SNS, there is no published literature evaluating the cost-effectiveness of NASHA/Dx. In addition, no comparison has been made between these 2 treatment options to guide health care professionals in choosing one treatment option over the other for

*Trademark: Solesta® (Salix Pharmaceuticals, Raleigh, North Carolina)

†Trademark: InterStim® (Medtronic Inc, Minnetonka, Minnesota).