
AdVance sling use decreasing relative to artificial urinary sphincters

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Introduction: To evaluate the percent of AdVance male sling usage relative to artificial urinary sphincters (AUS) over a 9 year period since its introduction in order to assess trends across the United States.

Materials and methods: As a surrogate for procedures performed, we reviewed device utilization trends of the AdVance sling and AUS broken down by American Urological Association (AUA) section. ANOVA testing between years was used to determine purchasing trends with p values of < 0.05 considered statistically significant.

Results: Relative to AUS, AdVance sling percentage significantly increased from 36% in 2007 to 48% in 2008 ($p = 0.032$). Sling percentage then remained stable over the next 3 years from 2008-2011 with no significant

percent change between years ($p = \text{NS}$). Compared with 2008-2011, AdVance usage decreased in 2012 to 29% ($p = 0.002$) and remained stable at this decreased relative level through 2015 ($p = \text{NS}$, difference between years 2012-2015). Comparing incontinence procedures across AUA sections, the Southeast section performed the highest percentage of male stress urinary incontinence procedures, including 27% of all AdVance slings and 25% of all artificial sphincters.

Conclusion: Proportion of AdVance sling usage relative to AUS increased after its introduction through 2008. Usage remained stable at an increased level for the next 3 years. More recent years have found decreased AdVance usage and a resurgence of the artificial urinary sphincter. Reasons for these trends remain speculative.

Key Words: urinary incontinence, artificial urinary sphincter, AdVance male sling, trends

Introduction

Incontinence after treatment of prostate cancer is potentially long term with significant burden to the quality of life among survivors.^{1,2} The prevalence of incontinence in elderly prostate cancer survivors is two to five fold greater depending on treatment type. Additionally, the prevalence increases with time since treatment, regardless of age at diagnosis.³ It is expected that about 5% of men will undergo surgical treatment for incontinence within 15 years of radical prostatectomy.⁴

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The artificial urinary sphincter (AUS) and AdVance male sling are the two most commonly performed male incontinence procedures in the United States. AUS implantation has increased dramatically in the United States since it became available in 1975.⁵ The AUS has been well established as the gold standard for the treatment of postprostatectomy urinary incontinence (PPI) even in patients with history of prior incontinence procedures, pelvic radiation, and neurogenic bladders.⁶ The AUS has proven durability, but is associated with infection rates of 5%-6%, erosion rates of 6%-8% and mechanical failure rates of 6%-23% over 7-13 years.^{7,8} Additionally, rates of urethral atrophy and reoperation have been reported to be as high as 7.9% and 26%.⁹

The AdVance retrourethral transobturator male sling is an option for men with mild to moderate PPI.^{10,11} It is thought to improve continence by repositioning

and lengthening the membranous urethra.¹² Studies have shown it to be effective, safe,¹³ and durable.¹⁴ Success rates have been reported to be as high as 76%-91% with low explantation rate.¹⁵ We aimed to evaluate the percent of AdVance male sling usage relative to AUS over a 9 year period since its introduction in order to assess trends across the United States.

Materials and methods

Industry purchasing data was provided by American Medical Systems (AMS, Division of Boston Scientific, Natick, MA, USA) for the sale of AdVance male slings and AUS devices. This data included the percentage of each device purchased by state and American Urological Association (AUA) section from 2007-2015. Actual purchased amounts were not provided as this is proprietary. We used the purchasing data as a surrogate for procedures performed. The New York AUA Section was included in the Mid-Atlantic Section utilization data. ANOVA testing between years was

used to determine purchasing trends with p values of < 0.05 considered statistically significant.

Results

Relative to AUS, AdVance sling percentage significantly increased from 36% in 2007 to 48% in 2008 ($p = 0.032$), Figure 1. Sling percentage then remained stable over the next 3 years from 2008-2011 with no significant percent change between years ($p = \text{NS}$). Compared with 2008-2011, AdVance usage decreased in 2012 to 29% ($p = 0.002$) and remained stable at this decreased relative level through 2015 ($p = \text{NS}$, difference between years 2012-2015). The Mid-Atlantic AUA section utilized proportionally more AdVance slings relative to AUS at nearly every time point compared to the other sections. Comparing incontinence procedures across AUA sections, the Southeast section performed the highest percentage of male stress urinary incontinence procedures, including 27% of all AdVance slings and 25% of all artificial sphincters, Table 1.

TABLE 1. Percentage of total incontinence procedures by American Urological Association (AUA) section

	2007	2008	2009	2010	2011	2012	2013	2014	2015	Grand total
Mid-Atlantic section										
Advance %	56%	55%	58%	58%	48%	33%	50%	39%	41%	50%
AUS %	44%	45%	42%	42%	52%	67%	50%	61%	59%	50%
North Central section										
Advance %	39%	50%	51%	49%	44%	23%	37%	31%	27%	40%
AUS %	61%	50%	49%	51%	56%	77%	63%	69%	73%	60%
Northeastern section										
Advance %	28%	48%	49%	47%	46%	34%	41%	34%	30%	41%
AUS %	72%	52%	51%	53%	54%	66%	59%	66%	70%	59%
South Central section										
Advance %	37%	44%	46%	44%	41%	29%	35%	28%	26%	38%
AUS %	63%	56%	54%	56%	59%	71%	65%	72%	74%	62%
Southeastern section										
Advance %	35%	50%	52%	51%	49%	33%	39%	34%	31%	43%
AUS %	65%	50%	48%	49%	51%	67%	61%	66%	69%	57%
Western section										
Advance %	28%	43%	40%	42%	42%	24%	40%	30%	33%	36%
AUS %	72%	57%	60%	58%	58%	76%	60%	70%	67%	64%
New England section										
Advance %	37%	56%	53%	51%	42%	29%	38%	34%	35%	43%
AUS %	63%	44%	47%	49%	58%	71%	62%	66%	65%	57%
Total Advance %	36%	48%	49%	48%	45%	29%	39%	32%	31%	41%
Total AUS %	64%	52%	51%	52%	55%	71%	61%	68%	69%	59%

AUA = artificial urinary sphincters

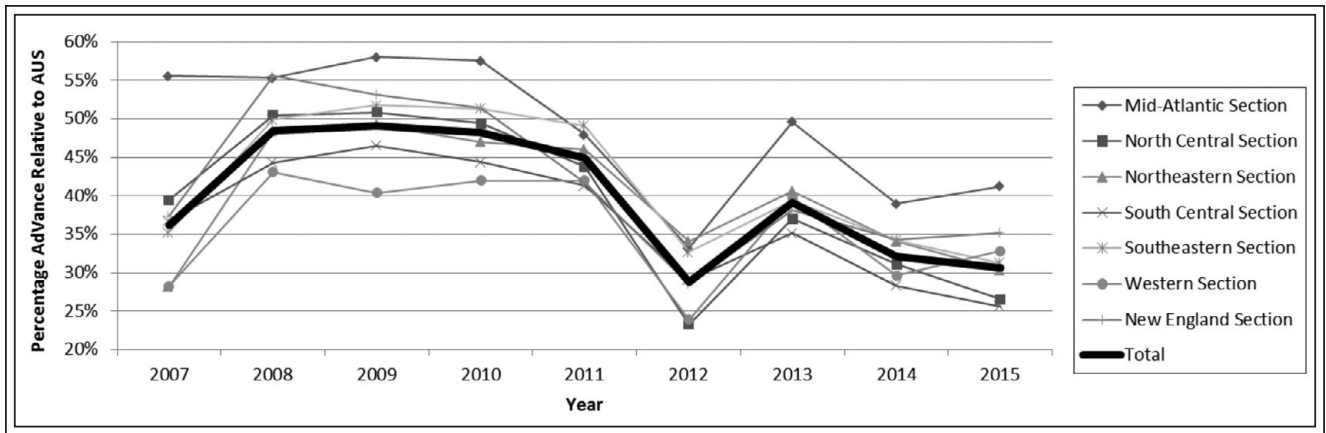


Figure 1. Trends in AdVance sling utilization by American Urological Association (AUA) section.

Discussion

AUS, slings, and bulking agents are safe options for management of stress urinary incontinence (SUI) in men.¹⁶ The operative device selected should be based on the degree of leakage, history of radiation, previous incontinence surgery, and bladder contractility. These domains can be evaluated based on physical exam with post void residual, voiding diary, pad weight, and in some cases urodynamics. History of pelvic radiation or previous AUS explantation may result in decreased compressibility of the urethra making a sling procedure less effective.¹⁷

Kim et al evaluated trends in utilization of incontinence procedures after radical prostatectomy by matching Surveillance, Epidemiology, and End Results (SEER) and Medicare claims data. They assessed that only 6% of elderly patients underwent surgical intervention to correct incontinence. Similar to our study, they report that residence in the South was independently associated with an increased likelihood of incontinence surgery. They concluded that incontinence procedures for PPI may be underused in the PPI patient.¹⁸

Recently, MacDonald et al report in their cross sectional study of 32,416 male anti-incontinence operations performed from 2000-2012 that there was a significant downtrend in the total number of incontinence procedures over that time period ($p=0.03$). They go on to stratify the data by procedure type in which they report a significant decline in AUS placement with a significant increase in sling procedures. The authors do note a potential bias given that the data was extracted from the National Inpatient Survey (NIS) database which does not capture same day and ambulatory surgery.¹⁹

A contemporary systematic review of surgical treatment for PPI suggests that while the AUS has the highest success rate, it is also associated with the highest complication rate.²⁰ Two studies assessed 3 year outcomes after AdVance placement in patient sizes of 156 and 30 respectively.^{13,21} They report cure or improved rates of 76.8% and 73% in their populations with most improvement in patients with mild to moderate SUI. Both studies report low grade complication rates mostly consisting of mild perineal pain and transient urinary retention with no serious complications.

A recent review of surgical procedures for male SUI suggests that the degree of urinary leakage, proximal urethral mobility, and detrusor contractility should be considered to determine the best procedure. In patients with daily pad weights of < 200 g, sling procedures are the preferred treatment while AUS would be optimal in patients with pad weights of > 400 g. AUS implantation is the treatment of choice for patients with persistent incontinence despite prior incontinence surgery due to its circumferential urethral compression.²² In light of this, there may have been an overutilization of AdVance male slings after its introduction in 2007. Patients with higher degree of PPI may have received AdVance slings when an AUS would have been more appropriate. As our understanding of patient selection grew, the trend towards AUS implantation increased.

Kumar and colleagues report a series of 133 men with PPI of whom 84 (63%) underwent AUS and 63 (47%) underwent AMS AdVance sling placement. They found that men who were initially offered male sling placement chose to undergo sling placement. Additionally, when given the option of AUS or sling, nearly all the men chose sling as a first line treatment option even if they were counselled that the sling

procedure was less likely to be effective. They attribute this preference to men not wanting mechanical devices implanted.²³

A review of 1615 American Board of Urology case logs from 2003-2013 found that male slings and AUS implantation was nearly equal over that period of time. There was steady increase in the overall amount of male incontinence procedures performed. Similar to our study, they note a decline in the percent of slings after 2011 with 62% of SUI managed with a sling procedure in 2011 and 40.6% in 2012.²⁴ Poon et al performed a similar review from 2004 to 2010 in which they report a steady increase in sling procedures from 2007-2010 (14% to 23% respectively).²⁵

The learning curve for AUS surgery is long and may take hundreds of implants to become proficient. Sandhu and colleagues assessed the learning curve in one study by measuring reoperative rates compared to experience level. They assessed patient and procedure characteristics of 65,602 men who had undergone AUS placement after 1987. Surgeons with five or fewer prior cases had a 24% reoperation rate where surgeons with > 200 cases had a 13.2% reoperation rate.²⁶ Conversely, there is evidence to suggest that the learning curve for the AdVance sling is far less dramatic.²⁷

The midurethral sling is a well established surgical intervention for the management of SUI in women. As with the Advance sling, synthetic polypropylene mesh is commonly used as the implant material for midurethral slings. In 2011, the Food and Drug Administration (FDA) released a Public Health Notification on Serious Complications of Transvaginal Mesh.²⁸ In today's society, advertisements of transvaginal mesh lawsuits have had a high penetration into the patient population.²⁹ There is evidence in the female literature to suggest that patients may avoid anti-incontinence procedures using mesh follow the FDA notification.³⁰ This suggests that there is a stigma within the general population regarding the use of mesh in surgery. While it is a leap to explain the decline in AdVance slings in 2011 by the FDA notification, the temporal relationship is worth noting.

Our study does have limitations. We were only able to analyze percentage purchase data and not device numbers. We also used purchase data as a surrogate for devices implanted which has the potential to misrepresent the amount of devices that were actually implanted. Finally, we were unable to breakout the New York AUA Section secondary to the way the industry data is stored. For this reason it was reported as part of the Mid-Atlantic Section. These limitations notwithstanding, this data adds to the body of literature that suggests AUS usage is maintaining its hold as the

gold-standard procedure for male urinary incontinence. Following initial exuberance with the male sling this data and others suggest that the AUS continues to make up the majority of incontinence procedures performed.

Conclusion

Proportion of AdVance sling usage relative to AUS increased after its introduction through 2008. Usage remained stable at an increased level for the next 3 years. More recent years have found decreased AdVance usage and a resurgence of the artificial urinary sphincter. Reasons for these trends remain speculative.

Disclosure

The views expressed in this manuscript are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government. □

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