

ADOPTION OF AND INDICATIONS FOR THE ARTIFICIAL URINARY SPHINCTER OVER TIME IN THE UNITED STATES OF AMERICA

Hypothesis / aims of study

The artificial urinary sphincter (AUS) represents an effective means of treating incontinence, but current practice trends for its use in the United States remain poorly defined [1]. Few studies have systematically examined the evolution of AUS utilization over time[2,3] We examined temporal trends in AUS use, specifically focusing on adoption of AUS over time, surgeon volume, indications for AUS placement, and differences in application by gender.

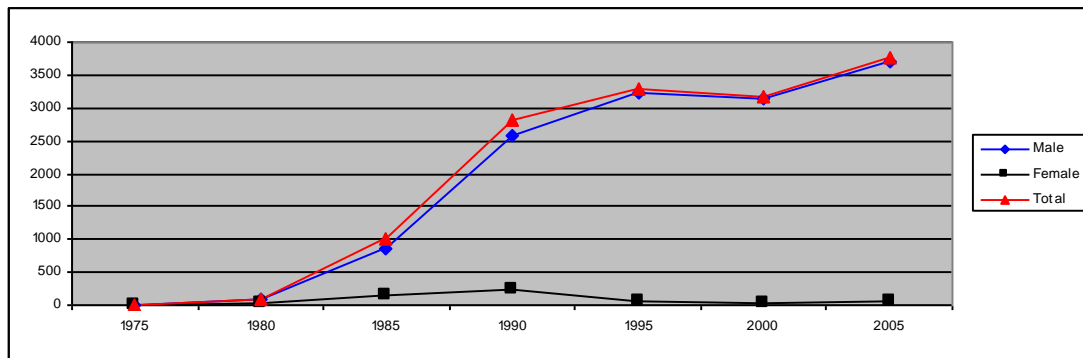
Study design, materials and methods

Data from voluntary physician-reported Patient Information Forms (PIF) regarding AUS related operations performed in the United States were provided by American Medical Systems, Inc. (Minnetonka, MN). Surgeons were identified by a unique identification number. Demographic data from each patient were recorded, as were the date and indication for each procedure. Data from 1975 onwards were analyzed in five year intervals to demonstrate the number of AUS procedures performed and individual surgeon volume. Indications for original AUS implants were also studied and recorded in five year increments.

Results

The compliance rate for PIF completion was estimated to be 89.2% (3948 responses for 4426 AUS units sold in 2005 [2]). AUS use increased dramatically from 1975 (n=11 cases), circa the time of device introduction, to 2005 (n=3762) (See Figure 1). Most of the increase in volume stemmed from an increase in device utilization for men, with comparatively low use of AUS in women throughout the timeframe analyzed. Female AUS volume appears to have peaked in 1990 (n=231 cases) and then fallen.

Figure 1: AUS Case Volume by Gender over Time



Note: Data is for ALL types of cases (original, revisions, replacements, etc.)

The majority (>90%) of surgeons performed 5 or fewer AUS-related cases per annum in most years (See Table 1). Only a small number achieved high-volume (>20 cases per annum) status. The mean number of cases performed per surgeon ranged from 2.0 to 4.4 cases per year; the median number of cases ranged from 1 to 2, with a median of 1 since 1985.

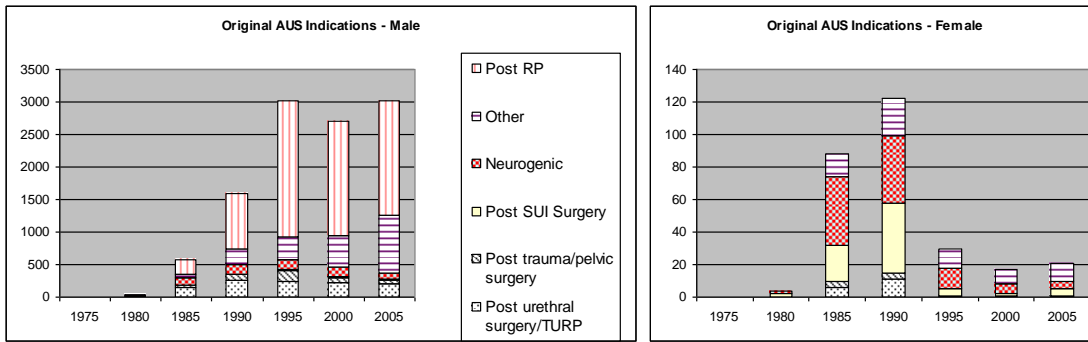
Table 1: Individual Surgeon Annual Volume over Time

Annual Volume	1975	1980	1985	1990	1995	2000	2005
≥21	0 (0%)	1 (4%)	3 (0.8%)	7 (0.5%)	9 (0.6%)	4 (0.3%)	8 (0.5%)
11-20	0 (0%)	0 (0%)	10 (3%)	7 (0.5%)	14 (1%)	13 (0.8%)	30 (2%)
6-10	1 (25%)	4 (13%)	25 (7%)	41 (3%)	70 (5%)	58 (4%)	82 (5%)
2-5	0 (0%)	12 (40%)	116 (31%)	503 (38%)	594 (42%)	594 (38%)	625 (40%)
1	3 (75%)	13 (43%)	223 (59%)	778 (58%)	720 (51%)	889 (57%)	813 (52%)
Total Surgeons	4 (100%)	30 (100%)	377 (100%)	1336 (100%)	1407 (100%)	1558 (100%)	1558 (100%)

Note: Table data is for ALL types of cases (original, revisions, replacements, etc.)

The most prevalent indication for original AUS implantation in men was neurogenic, post-urethral/TURP or trauma/post pelvic surgery prior to 1985; from 1985 onwards, post radical prostatectomy (RP) incontinence represented the most common indication (peak=69%, 1995) (See Figure 2a). In contrast, neurogenic disease consistently represented the most common indication for first-time AUS placement in women (See Figure 2b).

Figure 2: Indications for original AUS implantation - Male (a), Female (b)



Note: Table data refers to original AUS implant cases only.

Interpretation of results

Overall AUS utilization has increased since 1975, and appears to have reached a plateau in recent years; with approximately 3700 cases performed annually. AUS utilization is predominantly skewed toward men. Despite not being approved for use in females by the Food and Drug Administration, AUS have been implanted in women, peaking in 1990 and subsequently falling, likely due to the introduction of other treatments for female incontinence. Indications for AUS placement differ between men and women, with post-radical prostatectomy incontinence most common for the former and neurogenic disease for the latter. Most surgeons perform 5 or fewer AUS-related procedures per year.

Concluding message

AUS utilization has grown dramatically in the United States since 1975. AUS placement is primarily performed in men with post radical prostatectomy incontinence. Its use in women has peaked and then fallen, likely due to the introduction of other surgical treatments for stress urinary incontinence in females. The number of surgeons performing AUS surgery in the United States has also grown since 1975 and appears to have stabilized over the last decade with only a small minority performing a high volume of cases. As shown previously [3], given the estimated number of men who would likely benefit from AUS, it appears that AUS remains underutilized.

References

- ¹Urology (2000) 56; 353-9.
- ²Urology (2000) 56; 116-20.
- ³J Urol (2007) 178; 578-83.

Specify source of funding or grant	None
Is this a clinical trial?	No
What were the subjects in the study?	NONE