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SUI Sling Study - Final

1 Complications of Sling Surgery for Stress Urinary Incontinence among Female Military
2 Beneficiaries.

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32 Short title: Sling surgery among female military beneficiaries

33 Abstract

34

35 Background: Between 2010 and 2050, the number of women undergoing surgery for stress
36 urinary incontinence (SUI) is projected to increase by 47%. Prior studies of complications after
37 sling surgery excluded the large number of women in military treatment facilities (MTFs).

38

39 Objective: To characterize the post-operative complication rates after sling surgery for SUI
40 within MTFs in the United States.

41

42 Methods: This was a retrospective cohort study of women, aged 18 years and older, who were
43 enrolled in the U.S. military healthcare system, TRICARE Prime, between January 1, 2011, and
44 December 31, 2013. Women aged 18 and older, with SUI, and who underwent either an
45 outpatient or inpatient mid-urethral sling placement for SUI in any MTF in the United States
46 between January 1, 2011, and December 31, 2012, were included.

47

48 Results: During the study period, 348 surgeons performed 1,632 slings. The average patient age
49 was 47.2 years. In terms of surgical characteristics, 22.4% of the patients had a concomitant
50 pelvic organ prolapse procedure. Overall, 45.5% of subjects had at least one post-operative
51 complication. Of the specific complications, urologic infectious complications were the most
52 frequent, occurring in 25.2% of patients. Overall, only 0.9% of patients underwent a repeat
53 incontinence procedure. In multivariate analyses, concomitant pelvic organ procedure was
54 associated with an increased risk of bladder outlet obstruction and non-infectious urologic
55 complications. Those with a Charlson comorbidity index (CCI) score of 1 or more were more

56 likely to have an infectious complication and a new diagnosis of pelvic pain. Women older than
57 the median age were less likely than those below to experience treatment failure and a new
58 diagnosis of pelvic pain.

59

60 Conclusion: The population of TRICARE beneficiaries undergoing sling surgery for SUI is a
61 much younger population compared to Medicare beneficiaries. Complication rates after sling
62 surgery among TRICARE beneficiaries at MTFs compare favorably with documented rates
63 among Medicare beneficiaries. However, the absolute rates of complications (particularly for
64 infectious complications) are still high, indicating opportunities for quality improvement
65 measures.

66

67 Keywords: Mid-urethral sling; military beneficiary; military treatment facilities; post-operative
68 complications; stress incontinence; surgeon volume.

69

70 Introduction

71

72 Urinary incontinence (UI) has been shown to cause deterioration in quality of life, poor care
73 seeking, lifestyle restrictions, limitations in work and social relationships, and a higher
74 prevalence of psychological morbidity¹⁻⁶. Stress urinary incontinence (SUI), involuntary leakage
75 of urine on effort, exertion, or with coughing and laughing⁷ affects 15-80% of women and is
76 commonly treated with surgery⁸. Limited data suggest that the prevalence of UI is higher in
77 active duty service women^{9,10} than in similarly-aged community-dwelling women¹¹. Between
78 2010 and 2050, as a result of projected demographic changes, the prevalence of UI is projected
79 to increase 55% from 18.3 to 28.4 million women¹², and the number of women undergoing
80 surgery for SUI is projected to increase by 47% (from 210,700 to 310,050) over the same time
81 period¹³. These figures illustrate the public health burden of SUI and the importance of reducing
82 complications after sling surgery.

83 In 1999, the National Institutes of Health (NIH) sponsored a workshop to address the state of
84 research addressing female pelvic floor disorders. One of the recommendations made by the NIH
85 for outcomes research on SUI was that outcomes should not only focus on SUI symptoms, but
86 should also include unwanted effects resulting from any intervention. These include new urinary
87 symptoms such as urge incontinence, frequency, and urinary urgency; changes in sexual
88 function; onset of urinary tract infections; adverse effect on bowel function; surgical
89 complications; and the development or worsening of pelvic organ prolapse¹⁴.

90

91 Following the NIH recommendation, Anger et al.¹⁵ looked at short-term complications among
92 Medicare beneficiaries undergoing sling surgery for SUI between January 1999 and July 2000.

93 They found that, in the first post-operative year, almost 50% of women experienced a urinary
94 tract infection, 7% experienced bladder outlet obstruction, 9.4% experienced a new diagnosis of
95 pelvic pain, 8% experienced treatment failure requiring a repeat incontinence procedure, and
96 15% developed urge incontinence.

97

98 Between 2011 and 2013 there were over two million women, aged 18 years and older, who were
99 enrolled in the U.S. military healthcare system, TRICARE Prime. This population does not
100 include female veterans treated within the Department of Defense (DoD) Veteran's
101 Administration system, and civilian databases do not capture this large population of women
102 treated at military bases across the United States. The primary aim of this study was to
103 characterize the post-operative complication rates after sling surgery for SUI among TRICARE
104 beneficiaries within military treatment facilities (MTFs) in the United States.

105

106

107 **Materials and Methods**

108

109 *Study design:* Retrospective cohort study.

110

111 *Study population:* Women, aged 18 years and older, who were enrolled in the U.S. military
112 healthcare system, TRICARE Prime, between January 1, 2011, and December 31, 2013.

113

114 *Inclusion criteria:* Women aged 18 and older, with SUI, and who underwent either an outpatient
115 or inpatient sling placement for SUI in any MTF in the United States between January 1, 2011,

116 and December 31, 2012, were included. Women were identified based on the presence of the
117 ICD-9 code for SUI (625.6), intrinsic sphincter deficiency (599.81), and/or urethral
118 hypermobility (599.82) as a primary or secondary diagnosis. Sling placement was defined by the
119 CPT code 57288 or the ICD-9 procedure codes 59.4, 59.71, and 59.79 (Table 1).

120
121 *Exclusion criteria:* We excluded women who left the military system after their procedure; women
122 for whom 12-month follow-up data was not available; women who had a procedure for pelvic organ
123 prolapse within 30 days of the sling procedure; women with a diagnosis of pelvic pain within the 12
124 months prior to the procedure; and women with slings placed laparoscopically, as such procedures
125 are never performed by general gynecologists in the military. We did not exclude women with
126 concomitant pelvic reconstruction procedures performed at the same time as the index sling
127 procedure.

128
129 *Data source:* The Military Health System Management and Analysis Reporting Tool and the
130 Military Health System Data Repository (MDR) database were our primary data sources. The
131 MDR is the centralized data repository that captures, archives, validates, integrates, and
132 distributes Defense Health Agency (DHA) corporate health care data worldwide. It receives and
133 validates data from the DoD's worldwide network of more than 260 health care facilities and
134 from non-DoD data sources. The MDR applies data quality edits to maximize the value of DHA
135 corporate data. It also provides online and near-line data storage and supports health care data
136 transfers. The Military Health System Management Analysis and Reporting Tool (M2) is an ad-
137 hoc query tool used for viewing population, clinical, and financial MHS data. All administrative
138 data for those seen in MTFs or in outside facilities when the TRICARE benefit was used reside

139 in the MDR. It is commonly referred to as "cradle to grave" data, because, through this data
140 source, one can see longitudinal data for people, where most large insurance companies cannot.

141

142 From these databases, we identified women who underwent sling placement during the study
143 period. As noted above, ICD-9 and CPT-4 codes were used to identify eligible patients. The
144 codes used to identify subjects are listed in detail in Table 1.

145

146 *Outcome variables:* Our primary outcome was a composite outcome of “any post-operative
147 complication” identical to that used by Suskind and colleagues¹⁶. We extracted data on post-
148 operative complications, identified by CPT-4 codes and ICD-9 codes (see Table 1), during the 12
149 months after the sling placement procedure date for all women included in the final sample. Our
150 definitions for both the composite outcome of “any post-operative complication” and specific post-
151 operative complications, in addition to the ICD-9 codes and CPT-4 codes used to identify these
152 complications, were identical to prior studies^{15,16}.

153

154 *Primary exposure variables:* We obtained data on age, surgeon specialty, comorbid diseases, and
155 concomitant pelvic surgery.

156

157 Age was initially abstracted as a continuous variable, with the caveat that anyone above the age
158 of 90 had their age recoded to 90 to comply with HIPAA rules. In our exploratory analyses we
159 tested differing ways to model age and, in the end, we categorized age as a dichotomous variable
160 using the median age as the cut point.

161

162 Using taxonomy codes, physician specialty was coded as a categorical variable for our analyses
163 (gynecologist versus urologist versus other). The taxonomy codes used to classify surgeons by
164 specialty are shown in Table 1. During the study period, there were not yet any taxonomy codes
165 for urogynecology, so we were not able to separately identify fellowship-trained
166 urogynecologists.

167

168 To compute the Charlson comorbidity index (CCI) score for each patient, we extracted data on
169 comorbidities for one year prior to the sling placement procedure date for all women included in
170 the final study sample. We used the CCI score to quantify comorbidity severity because it has
171 shown been shown to be a valid predictor of mortality even when computed from administrative
172 databases.¹⁷⁻¹⁹

173

174 Data were analyzed and manipulated through Statistical Analysis Software (SAS), STATA
175 versions 8 and 14 (College Station, TX), SPSS version 17 (Armonk, NY, IBM Corp), and
176 Microsoft Office Excel.

177

178 This retrospective cohort study was approved by the Naval Medical Center Portsmouth (NMCP)
179 Institutional Review Board.

180

181

182 Results

183

184 There were 1,935 women, aged 18 and older, who had a sling procedure for SUI at U.S. MTFs
185 between January 1, 2010, and December 31, 2011. After excluding women for whom 12-month
186 follow up data was not available (n=26), women who had a procedure for pelvic organ prolapse
187 within 30 days of the index sling procedure (n=6), and women with a diagnosis of pelvic pain
188 within 12 months prior to the procedure (n=271), our final analysis dataset consisted of 1,632
189 patients.

190

191 In Table 2 we present the overall characteristics of our study population. The mean age of our
192 study population was 47.2 ± 11.3 years. Only 14.5% of our population was 60 years old or older.
193 In terms of comorbidities, 25.6% of our population had a CCI score of 1 or more. In terms of
194 surgical characteristics, 22.4% of the patients in our study had a concomitant pelvic organ
195 prolapse procedure at the time of the index sling procedure. The slings were placed by 348
196 surgeons, the majority of whom were gynecologists (70.8%).

197

198 Overall, 45.5% of subjects had at least one post-operative complication (Table 3). Of the specific
199 complications, urologic infectious complications were the most frequent, occurring in 25.2% of
200 patients. Less than 10% of the patients experienced a new diagnosis of urgency, a new diagnosis
201 of bladder outlet obstruction, or a new diagnosis of pelvic pain. Less than 1% of patients
202 underwent a repeat incontinence procedure.

203

204 Multivariate analyses are described in Table 4. Age was not independently associated with any
205 specific post-operative complication. CCI score of 1 or more was associated with increased risk
206 of urologic infectious complications and new diagnosis of pelvic pain. Concomitant pelvic organ

207 procedure was associated with an increased risk of bladder outlet obstruction and an increased
208 risk of non-infectious urologic complications.

209

210

211 Discussion

212

213 We describe the first large-scale examination of the surgical management of SUI within the very
214 large military healthcare system in the United States in this study. We examined 1,632 sling
215 procedures and found that the average patient age was only 47. Slightly less than one out of
216 every four patients had a concomitant pelvic organ procedure. Overall, 45.5% of subjects had at
217 least one post-operative complication. Less than 1% had a repeat anti-incontinence procedure
218 within 12 months after the index surgery.

219

220 The characteristics of our study population are different from the Medicare population, which
221 has been extensively studied. Anger et al.^{15,20-24} published a series of studies focused on
222 complications after sling surgery for SUI among Medicare beneficiaries. In their study of 1,356
223 procedures, 34% of patients were aged 65 to 69, compared to only 10% of our population who
224 were between 60 and 69 years old. In their study, 53.5% of the patients were between 70 and 79
225 years old, compared to just 3% in our study population. We hypothesize that the significant
226 difference in the age distribution within the military population versus the Medicare population
227 may at least partially account for the lower complication rates and reduced need for repeat anti-
228 incontinence procedures in our study population.

229

230 In our study, we did not find a significant association between age and specific post-operative
231 complications after sling surgery for SUI. This contrasts with data from the Medicare population.
232 Anger et al.²⁰ found, in bivariate analyses, that women aged 65 to 74 were significantly less
233 likely than women older than 75 to have post-operative urge incontinence, treatment failure, and
234 outlet obstruction. With the entire age distribution of the military beneficiaries in our study
235 skewed to the left, this could potentially explain why, in multivariate analyses, we did not see an
236 association between age and post-operative complication rates after sling surgery.

237
238 In our study population, 22.4% had a concomitant pelvic organ procedure. This is lower than in
239 the Medicare population where, in the seminal series by Anger et al., 34.4% of sling cases were
240 accompanied by concomitant prolapse repair²¹. In the Medicare population, women undergoing
241 concomitant prolapse repair were more likely to be diagnosed with post-operative outlet
242 obstruction and less likely to undergo a repeat procedure for SUI within 12 months than those
243 who had an isolated sling procedure. We found a similar association between concomitant pelvic
244 organ procedure and increased risk of bladder outlet obstruction. However, the overall rate of 12-
245 month repeat incontinence procedures in our study population was less than 1%, and there was
246 no association in our population between this outcome and concomitant pelvic organ procedure.

247
248 This study has important strengths and limitations. One strength is our sample size. We studied
249 1,632 sling procedures over a two-year time span. Anger et al. studied a 5% random sample of
250 sling procedures among Medicare beneficiaries over an 18-month span, and this included 1,356
251 sling procedures. Another important strength is that our population is the most recent and
252 modern of all the large-scale population-based studies of complications after sling surgery for

253 SUI within the United States. The series by Anger et al.^{15,20-23} looked at sling surgeries that were
254 performed between 1999 and 2000. In contrast, we looked at sling surgeries performed between
255 2011 and 2012. Civilian researchers doing population-based studies using claims/administrative
256 databases do not have access to military data, so large scale studies using administrative
257 databases typically exclude the very large military health care system (which is separate from the
258 Veteran's Administration system). This is the only large-scale examination of complications
259 after sling surgery for SUI within the military health care system. One of the striking findings is
260 that the population of women undergoing sling surgery for SUI in the military health care system
261 is a much younger population, with an average age of less than 50 years old.

262

263 In terms of limitations, this study has the same limitations as any study using an administrative
264 or claims database. In this study, we were not able to differentiate between the different types of
265 slings, surgical approach, or graft material used. In spite of these limitations, our complication
266 rates compare favorably to other civilian database studies^{15,16}.

267

268 In conclusion, the population of women with SUI undergoing sling surgery at MTFs is a young
269 population with post-operative complication rates that compare favorably with documented rates
270 among Medicare beneficiaries. However, the absolute overall complication rate is still high,
271 suggesting that significant opportunities exist for quality improvement.

272

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274

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279

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281

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360 Author Disclosure Statement

361

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365 Disclaimer

366

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