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Surgeon Volume - Final

1 **Original Article**

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3 **Military Surgeon Volume and Stress Incontinence Surgery Complications—a**
4 **Retrospective Cohort Study**

5

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22

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37

38 **Precis**

39 No significant differences in complication rates after sling surgery, stratified by surgeon volume,
40 are seen in a setting of overall low-volume military surgeons.

41

42 **Abstract**

43 **Study Objective:** To compare 12-month post-operative complication rates in women who
44 underwent sling procedures by high-volume versus low-volume surgeons at US military
45 treatment facilities (MTFs).

46 **Design:** Retrospective cohort study (Canadian Task Force classification II-2)

47 **Setting:** US military treatment facilities

48 **Patients:** Female military beneficiaries enrolled in TRICARE

49 **Interventions:** Sling surgery for stress urinary incontinence (SUI) between January 1, 2011,
50 and December 31, 2012.

51 **Measurements and Main Results:** The primary exposure was surgeon volume (high versus
52 low). Surgeon volume was categorized as high or low based on the number of slings performed
53 in the previous 2 years at US MTFs (January 1, 2009, to December 31, 2010). The primary
54 outcome was a composite variable indicating at least 1 post-operative complication within 12
55 months. We used ICD-9 and CPT codes to identify post-operative complications that occurred in
56 the 12 months following the index sling procedure. During the study period, 348 gynecologic
57 and urologic surgeons performed 1,632 slings. The average patient age was 47.2 years. Based
58 on our data distribution, we classified surgeons as high-volume (>12 slings/2 years) or low-
59 volume (<4 slings/2 years). High-volume surgeons operated on patients who were older, more
60 likely to have comorbidities, and more likely to receive concomitant prolapse surgery.

61 The overall likelihood of at least 1 post-operative complication in 12 months for high-volume
62 versus low-volume surgeons was 48.4% versus 42.2% (adjusted OR [95% CI]=1.24 [0.99-1.54],
63 p=.06). There were no differences between high- and low-volume surgeons in the rate of
64 almost all other post-operative complications.

65 **Conclusion:** No significant differences in 12-month complication rates after sling surgery,
66 stratified by surgeon volume, were seen in a setting of overall low-volume military surgeons.

67

68 *Keywords:* Military Beneficiary; Military Treatment Facilities; Post-operative Complications; Sling

69

70 Introduction

71

72 Slings are a common surgical treatment for stress urinary incontinence (SUI) [1]. Several
73 modifications of sling surgery exist: pubovaginal slings, midurethral slings placed via
74 transobturator or retropubic approaches, and mini-slings [21]. Investigators predict that the
75 number of women receiving this treatment will increase by 47%, reaching over 310,000
76 surgeries per year by 2050 [2].

77

78 Across all surgical fields there is a growing interest in the relationship between surgeon volumes
79 and patient outcomes. Only 2 prior studies, with conflicting results, have looked at surgeon
80 volume in relation to sling surgical outcomes for SUI [3,4]. In Medicare beneficiaries undergoing
81 pubovaginal slings from 1999 to 2000, no difference in the rate of urological or non-urological
82 post-operative complications within the first 12 months after surgery was seen [3]. A Canadian
83 study evaluated mesh-related complications and surgeon volume between 2002 and 2012. The
84 primary outcome was reoperation for SUI mesh-related complications. The authors found that
85 patients of low-volume surgeons experienced higher re-operation rates compared to patients of
86 high-volume surgeons. Both studies used the 75th percentile as the cut point defining high-
87 volume, but the results were different; no volume effect was seen with 7 sling cases over a 2-
88 year period [3], while 16 cases per year demonstrated a volume effect [4]. These studies
89 excluded patients younger than 65 years old and patients receiving care in military treatment
90 facilities (MTFs).

91

92 Our primary aim was to compare 12-month post-operative complication rates in women who
93 underwent sling procedures by high-volume versus low-volume surgeons at US MTFs.

94

95

96 Materials and Methods

97

98 These methods were previously published in Howard, McGlynn, and Greer 2018. This was a
99 retrospective cohort study of women aged 18 years and older; who were enrolled in the US
100 military healthcare system, TRICARE Prime, between January 1, 2011, and December 31,
101 2013; who had SUI; and who underwent either an outpatient or inpatient sling placement for SUI
102 in any MTF in the United States between January 1, 2011, and December 31, 2012. SUI was
103 defined as the presence of the ICD-9 code for SUI (625.6), intrinsic sphincter deficiency
104 (599.81), and/or urethral hypermobility (599.82) as a primary or secondary diagnosis in the
105 electronic medical record. Sling placement was defined by the CPT code 57288 or the ICD-9
106 procedure codes 59.4, 59.71, and 59.79. The dataset did not allow discrimination based on sling
107 type or approach.

108

109 We excluded women who disenrolled from TRICARE within 12 months of their procedure, as the
110 database only captured that care was billed to TRICARE, regardless of whether it was performed
111 within military or civilian facilities. Other exclusions included women for whom 12-month follow-up
112 data was not available; women who had a procedure for pelvic organ prolapse within 30 days of the
113 sling procedure; women with a diagnosis of pelvic pain within the 12 months prior to the procedure;
114 and women with slings placed laparoscopically, as such procedures are never performed by general
115 gynecologists in the military. We did not exclude women with concomitant pelvic reconstruction
116 procedures performed at the same time as the index sling procedure.

117

118 The primary exposure of interest was surgeon volume. The Health Analysis Department at the
119 Naval Medical Center Portsmouth identified all surgeons who performed mid-urethral slings for SUI
120 during the study period, and then, for each surgeon, they determined the number of sling
121 procedures performed over the 2 years preceding the study period (January 1, 2009, to December

122 31, 2010). The Health Analysis Department subsequently created a patient level data set, and, for
123 each patient undergoing a mid-urethral sling during the study period who was eligible for inclusion, a
124 variable was created that indicated the number of cases that the performing surgeon had done in
125 the 2 years prior to the study period. This is displayed graphically in Figure 1.

126
127 We initially stratified surgeons by quartiles according to the volume of procedures they performed.
128 As Figure 1 shows, however, a large proportion of our surgeons did fewer than 4 sling procedures in
129 this 2-year period. In our initial analyses, the cut point for the 75th percentile for surgeon sling
130 volume was just 4. Conceptually, we could not rationalize treating a surgeon with 4 sling cases over
131 2 years as a high-volume surgeon. We subsequently divided up the highest quartile into tertiles and
132 used the highest tertile as our high-volume surgeon group. The cut point defining the highest tertile
133 of the highest quartile was 13 sling cases over 2 years. We combined the bottom 3 quartiles into a
134 single group, and this was our low-volume group. The cut point that defined low-volume was 3 or
135 fewer cases over 2 years. The bottom 2 tertiles of the top quartile represented our intermediate-
136 volume group. By defining our high-volume group as 13 or more cases in 2 years and our low-
137 volume group as 3 or fewer cases over 2 years, we clearly separated our high-volume and low-
138 volume groups.

139
140 Our primary outcome was a composite outcome of “any post-operative complication” identical to
141 that used by Suskind and colleagues [5]. We extracted data on post-operative complications,
142 identified by CPT-4 codes and ICD-9 codes (see Table 1), during the 12 months after the sling
143 placement procedure date for all women included in the final sample. Our definitions for both the
144 composite outcome of “any post-operative complication” and specific post-operative complications,
145 in addition to the ICD-9 codes and CPT-4 codes used to identify these complications, were
146 identical to prior studies to enable a direct comparison to published literature [5,6].

147

148 In addition to our primary exposure and outcome, we obtained data on age, race, surgeon
149 specialty, comorbid diseases, and concomitant pelvic surgery. A priori, we planned to control for
150 these potential confounders: age, race, surgeon specialty, Charlson comorbidity index score [7],
151 and concomitant pelvic organ prolapse surgery.

152

153 During the process of data abstraction, we realized that race was a self-reported variable and
154 not present for all subjects, whereas the other variables were administratively coded variables
155 from the medical record. We did not include race in our final data set. Age was kept as a
156 continuous variable with the caveat that anyone above the age of 90 had their age recoded to
157 90 to comply with HIPAA rules. Physician specialty was coded as a binary variable for our
158 analyses (gynecologist versus non-gynecologist). However, the dataset did not permit
159 identification of fellowship-trained gynecologists or urologists. For the Charlson comorbidity
160 index, we extracted data on comorbidities for 1 year prior to the sling placement procedure date
161 for all women included in the final study sample.

162

163 We computed 12-month post-operative complication rates for high-volume and low-volume
164 surgeons. We then computed unadjusted and adjusted odds ratios via logistic regression and
165 used a robust cluster analysis to control for clustering at the level of individual surgeons. In our
166 multivariate logistic regression models, our initial approach was to adjust for age (continuous),
167 Charlson score (0,1-2, 3 or more), surgeon specialty (gynecologist versus non-gynecologist),
168 and whether or not there was a concomitant procedure for pelvic organ prolapse. When we
169 constructed our logistic regression model (for our composite outcome) with our covariates
170 defined in this manner, there was poor model fit due in large part to age defined as a continuous
171 variable. We subsequently redefined age in several ways and eventually settled on a binary
172 recoding with the cut point at the median age for our cohort (46 years). With age defined this
173 way our multivariate logistic regression model had better fit, but age and physician specialty

174 were not statistically significant. For our composite outcome we thus decided to remove age and
175 physician specialty and only adjust for Charlson score and whether or not there was a
176 concomitant procedure for pelvic organ prolapse. In this iteration there was still a small number
177 of cells with 0 frequencies for the outcome, so we further refined our covariates by collapsing
178 the Charlson score into a binary variable (0 versus 1 or more). In this final iteration there were
179 no cells with 0 frequencies. For 3 of our individual post-operative complications with low
180 frequencies, a model adjusting for Charlson score and concomitant pelvic organ repair
181 produced cells with 0 frequencies and overall poor model fit. Thus, we had to adjust our
182 modeling strategy for these outcomes (see footnotes in Table 3).

183
184 Because there is no consensus as to how to define a high-volume surgeon within the specialty of
185 gynecology, we performed our multivariate logistic regression analyses with surgeon volume
186 modeled as a binary variable (as described above) for our primary analysis. To ensure our results
187 were not simply due to our choice of cut-points for high- and low-volume surgeons, we performed a
188 sensitivity analysis and redefined these categories in a more extreme way. We redefined low-
189 volume as 0 cases in 2 years and high-volume as 20 or more cases in 2 years. We then repeated
190 our analyses using this more extreme definition. We also modeled surgeon volume as a continuous
191 variable (with a range of 0 to 158 cases in 2 years).

192
193 *Sample size calculations:* Based on data from Suskind et al [5], we assumed the composite
194 post-sling 12-month complication rate would be 70% for high-volume surgeons and 85% for low-
195 volume surgeons. Assuming a power of 80% with a type 1 error rate of 5%, we calculated that
196 we would need approximately 95 patients in each group. In the study by Suskind et al [5], the
197 prevalence of the most uncommon individual post-operative complication was approximately 6%
198 (new diagnosis of pelvic pain). If we assumed that the prevalence of the most uncommon
199 individual complication in our study would also be 6% among high-volume surgeons and 11%

200 among low-volume surgeons, we calculated we would need 384 patients in each group to detect
201 that difference with a power of 80% and a type 1 error rate of 5%. In the end we had
202 significantly more patients than we calculated we would need during our a priori sample-size
203 calculations.

204

205 Data were analyzed and manipulated through Statistical Analysis Software (SAS), STATA SE
206 version 15 (College Station, TX), SPSS version 17 (Armonk, NY, IBM Corp), and Microsoft
207 Office Excel.

208

209

210 Results

211

212 There were 1,935 women, aged 18 and older, who had a sling procedure for SUI at US MTFs
213 between January 1, 2010, and December 31, 2011. After excluding women for whom 12-month
214 follow up data was not available (n=26), women who had a procedure for pelvic organ prolapse
215 within 30 days of the index sling procedure (n=6), and women with a diagnosis of pelvic pain
216 within 12 months prior to the procedure (n=280), our final analysis dataset consisted of 1,632
217 patients.

218

219 There were 348 surgeons who performed the sling surgeries during the study period. In our
220 primary analysis, high-volume was defined as 13 or more cases in 2 years, while low-volume
221 was defined as 3 or fewer cases in 2 years. Of the 348 surgeons, 256 (73%) performed 3 or
222 fewer slings, and 30 (8.6%) performed 13 or more slings in the 2 years preceding the study
223 period. During the study period, these 30 high-volume surgeons performed almost as many
224 slings (638) as the 256 low-volume surgeons (664). The surgeon with the highest volume prior
225 to the study period did 158 sling procedures during this time.

226

227 The mean age of our study population was 47.2±11.3 years. The characteristics of our study
228 population, stratified by surgeon volume, are shown in Table 2, and the distribution of individual
229 surgeon volume is illustrated in Figure 1. The patients of high-volume surgeons were 5 years
230 older on average and significantly more likely to have a Charlson score of 1 or greater. High-
231 volume surgeons were also significantly more likely to perform concomitant pelvic organ repair
232 at the same time as the index sling procedure.

233

234 Overall, 45.5% of subjects had at least 1 post-operative complication. Of the specific
235 complications, urologic infectious complications were the most frequent, occurring in 25.2% of
236 patients.

237

238 In unadjusted analyses, the overall likelihood of at least 1 post-operative complication in 12
239 months for high-volume versus low-volume surgeons was 48.4% versus 42.2% (OR [95%
240 CI]=1.29 [1.00-1.66]). There were no statistically significant differences between high- and low-
241 volume surgeons in the rate of other post-operative complications (Table 3).

242

243 In adjusted analyses, there was no statistically significant difference, by volume, in the odds of
244 at least 1 post-operative complication. There were no statistically significant differences
245 between high- and low-volume surgeons in the rate of other post-operative complications in our
246 adjusted analyses (Table 3). In our sensitivity analyses, regardless of how surgeon volume was
247 modeled, the results and the conclusions were unchanged.

248

249

250 Discussion

251

252 There was no statistically significant association between surgeon sling volume and 12-month
253 post-operative complications within US MTFs when we adjusted for clinically relevant
254 confounding factors including cluster analysis using a randomly generated surgeon identifier.
255

256 The study that most closely mirrors our study, by Anger et al [3], examined the same outcomes
257 in the context of the Medicare population. They defined surgeon volume as being high if greater
258 than or equal to the 75th percentile (greater or equal to 7 slings in 2 years) and low if less than
259 the 75th percentile. Overall, their results were similar to ours in that they found no systematic
260 differences in outcomes after sling surgery between high-volume versus low-volume surgeons.
261

262 In the study by Welk et al [4], done in Canada, the median value for the 75th percentile for
263 surgeon volume across the 10 years studied was 16 cases per year. The surgeon population in
264 this study had much higher individual annual volume than in our study and in the study by Anger
265 et al [3]. This study only looked specifically at re-operation for mesh related complications after
266 sling surgery but did find that higher surgeon volume correlated with lower re-operation rates.
267 This specific complication was not abstracted in our database.
268

269 This study has important strengths and limitations. In terms of strengths, this is a large-scale
270 study of surgeon volume versus surgical outcomes within the military health care system in the
271 US. Within the military beneficiary population, SUI is a common diagnosis, and sling surgery is a
272 procedure performed by both general and fellowship-trained gynecologists and urologists. We
273 were able to control for the impact of individual surgeon practice by employing a robust cluster
274 analysis using a randomly-generated surgeon identifier. We also chose to use the same ICD-9
275 and CPT codes as previously reported by Suskind, et al [5] in order to enable a direct
276 comparison of our results with published data.
277

278

279 Another strength relates to the way we modeled surgeon volume. Recognizing the conceptual
280 problems with defining surgeon volume by a single approach, we intentionally modeled surgeon
281 volume to ensure there was a clear delineation between high- and low-volume (13 or more
282 versus 0-3 cases over 2 years). Furthermore, we used a more extreme definition of high- and
283 low-volume surgeons (20 or more versus 0 cases over 2 years) and modeled surgeon volume
284 as a continuous variable in our sensitivity analysis without any impact on our primary outcome.

285

286 The limitations of this study are similar to any study using a large administrative database.
287 Information bias through inaccurate coding or use of codes not captured in our data abstraction
288 may exist. In this study, we were not able to differentiate between the different types of slings,
289 surgical approach, or graft material used, and we recognize that some differences in adverse
290 events do exist based on these factors [21]. However, surgeon volume has not been
291 demonstrated to impact these adverse events to date.

292

293 We also included subjects with concomitant pelvic organ prolapse surgery. We did not want to
294 report a falsely low number for surgeon volume, as slings can be performed as isolated
295 procedures or as a concomitant procedure. In support, a large proportion of our surgeons were
296 classified as having done 0 cases in the 2 years prior to the study period. The database we
297 used only captured cases at US MTFs performed by attending physicians. We were not able to
298 capture surgeon volume from overseas MTFs or cases done at civilian hospitals during the
299 study period or in the previous 2 years. Therefore, we did not want to exclude a potential group
300 of subjects or surgeons that may add more insight and explanation to complication rates.

301 Concomitant prolapse surgery has been reported to have an uncertain impact on complications,
302 increasing bladder outlet obstruction but decreasing treatment failure [8]. We planned a priori to
303 control for this variable in our analysis.

304

305 While 1 out of every 30 women will experience a mesh-related complication within 10 years
306 after a mid-urethral sling [4], this is not the only complication related to mid-urethral slings, as
307 reported by Schimpf et al [21]. Future analyses in this database and others should investigate
308 all complications reported by Schimpf et al [21] and attempt to delineate the type of sling,
309 approach, and graft material, if that information can be obtained.

310

311

312 Conclusion

313

314 Including this study there are now 3 large population-based studies specifically looking at
315 surgeon volume and post-operative complications after sling surgery for SUI [3,4]. In 2 of these
316 studies the overall surgeon volume was low, with the 75th percentile being 4-7 cases over 2
317 years. Both of these failed to show a volume effect. In the third study [4] the surgeon volume
318 was much higher, with the 75th percentile being 16 cases per year. This study did find a volume
319 effect. This trend points to the fact that it may be hard to see a relationship between surgeon
320 volume and outcomes if the overwhelming majority of the surgeons are low-volume surgeons.
321 As higher surgeon volume is linked to improved outcomes in other studies, perhaps our
322 threshold for defining high-volume surgeons is too low. We need to continue to investigate a
323 wide variety of complications and the threshold at which point individual complications
324 decrease. These studies will likely need to be carried out using other national bases that
325 capture data from an increased number of high-volume and low-volume surgeons, as most
326 randomized-controlled trials set a minimum surgeon volume but do not track surgeon volume
327 over the course of the trial.

328

329

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335

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337

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390 e71-71 e27.
391

392 Table 1. Procedure and Diagnosis Codes Used to Define Specific Complications.

Variable	ICD-9/CPT codes used
Infectious complications	590.10, 590.80, 590.9, 595.0, 595.3, 595.89, 595.9, 599.0, 599.7x, 996.31, 996.64, 996.65, 998.5x
Urologic complications	565.1, 568.81, 593.3, 596.x, 597.0, 608.83, 619.x, 665.7x, 996.3x, 997.5, 998.1x, 998.2, 998.4, 998.6, 998.7
New diagnosis of urgency	596.51, 788.31
New diagnosis of pelvic pain	625.8, 625.9, 788.9x, 789.9
New diagnosis of bladder outlet obstruction	596.0, 599.6x, 788.2x, 788.38, 788.62
Management of bladder outlet obstruction	51010, 51040, 51701, 52270, 52281, 52285, 53500, 53620,

53660, 57287 (CPT)

Cytoscopy 52000, 52204, 52281 (CPT)

Urodynamics 51725, 51726, 51795 (CPT)

Repeat incontinence 57288 (CPT),
procedure 59.4, 59.71,
59.79 (ICD-9 Procedure)

393

394

395 Table 2. Summary of Demographic and Comorbidity Characteristics of Women Undergoing a
 396 Sling^{a*} within Military Treatment Facilities in the US, January 1, 2011, to December 31, 2012.
 397

	Surgeon volume		P-value
	Low-volume (0-3 slings in 2 years) N=664	High-volume (13 or more slings in 2 years) N=638	
Patient age ^b	44.64±0.42	50.12±0.45	.001 ^c
Concomitant pelvic organ prolapse procedure at time of index sling ^d	128(19.3)	166(26.0)	.004 ^e
Provider specialty ^d			.001 ^e
Gynecologist	473(71.2)	450(70.5)	
Urogynecologist	146(22)	186(29.2)	
Other	45(6.8)	2(0.3)	
Charlson Score ^d			.001 ^e
0	507(76.4)	442(69.3)	
1-2	140(21.1)	155(24.3)	
3 or more	17(2.6)	41(6.4)	

398

399 ^aDefined by the combination of CPT code 57288 and ICD-9 procedure codes 59.4
400 (suprapubic sling operation); 59.71 (levator muscle operation for urethrovesical
401 suspension), 59.79 (other repair of stress urinary incontinence), and ICD-9 diagnosis
402 codes 625.6 (stress incontinence female); and 599.81 (urethral hypermobility) and 599.82
403 (intrinsic sphincter deficiency). This captured both inpatients and outpatients.

404 ^bData presented is mean±standard error

405 ^cP-value computed by Student's t-test

406 ^dData presented is N(%)

407 ^eP-value computed by chi-square test

408

409

410

411 Table 3. Twelve-month Post-operative Complications after Sling Surgery within Military
 412 Treatment Facilities in the US by Surgeon Volume with Clustering for Each Surgeon.
 413

Complications	Surgeon volume			
	Low-volume (0-3 slings in 2 years) N=664 N(%)	High-volume (13 or more slings in 2 years) N=638 N(%)	Unadjusted odds ratio OR (95% CI)	Adjusted odds ratio OR (95% CI)
Any complication	280(42.2)	309(48.4)	1.29(1.00-1.66)	1.24(0.95-1.60) ^a
Infectious complication	154(23.2)	177(27.7)	1.27(0.95-1.69)	1.22(0.92-1.63) ^a
Urologic complication	74(11.1)	72(11.3)	1.01(.63-1.64)	0.92(0.54-1.57) ^a
New diagnosis of urgency	36(5.4)	35(5.5)	1.01(.58-1.78)	0.96(0.54-1.70) ^a
New diagnosis of pelvic pain	67(10.1)	48(7.5)	0.72(0.47-1.12)	0.69(.44-1.06) ^a
New diagnosis of bladder outlet obstruction	55(8.3)	40(6.3)	0.74(0.41-1.32)	0.72(0.40-1.28) ^a

Management of bladder outlet obstruction	72(10.8)	703(16.1)	1.58(.89-2.81)	1.58(.89-2.80) ^a
Cystoscopy	49(7.4)	43(6.7)	0.91(.51-1.61)	0.93 (0.51- 1.70) ^b
Urodynamics	11(1.7)	8(1.3)	0.75(.29-1.93)	0.76(0.29-1.99) ^c
Repeat incontinence procedure	6(.9)	7(1.1)	1.22(.24-6.08)	1.17(.23-5.89) ^d

414 Because patients can have more than 1 complication, the percentages in the column do
415 not total 100%.

416

417 ^aAdjusted for Charlson comorbidity score (0 versus 1 or more) and concomitant pelvic
418 organ prolapse repair

419 ^bAdjusted for age (greater than or equal to median [46] versus less than median) and
420 concomitant pelvic organ prolapse repair

421 ^cAdjusted for concomitant pelvic organ prolapse repair

422 ^dAdjusted for Charlson comorbidity score (0 versus 1 or more)

423

424

425 Figure Legend

426

427 Figure 1. Number of Sling Procedures Performed by Military Surgeons within the US (January 1,

428 2009, to December 31, 2010).