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# Surgeon Volume - Original

1 Military surgeon volume and stress incontinence surgery complications-a retrospective cohort study.

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

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47     Short title: Surgeon volume versus outcomes in the US military.

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## Abstract

Objective: To compare 12-month post-operative complication rates in women who underwent sling procedures by high-volume versus low-volume surgeons at US military treatment facilities.

Methods: This was a retrospective cohort study of women receiving slings in any US military treatment facilities from January 1, 2011, to December 31, 2012. The primary exposure was surgeon volume (high versus low). Surgeon volume was categorized as high or low based on the number of slings performed in the previous two years (January 1, 2009 - December 31, 2010). We used ICD-9 and CPT codes to identify post-operative complications that occurred in the 12 months following the index sling procedure. The primary outcome was a composite variable indicating at least one post-operative complication within 12 months.

Results: During the study period, 348 gynecologic and urologic surgeons performed 1,632 slings. The average patient age was 47.2 years. Based on our data distribution, we classified surgeons as high-volume (>12 slings /2 years) or low-volume (<4 slings/2 years). High-volume surgeons operated on patients that were older, more likely to have comorbidities, and more likely to receive concomitant prolapse surgery. The overall likelihood of at least one post-operative complication in 12 months for high-volume versus low-volume surgeons was 48.4% versus 42.2% (adjusted OR [95% CI]= 1.24 [0.99-1.54], p=0.06). There were no differences between high- and low-volume surgeons in the rate of almost all other post-operative complications.

Conclusion: No significant differences in 12-month complication rates after sling surgery, stratified by surgeon volume, were seen in a setting of overall low-volume military surgeons. The overall likelihood of at least one complication in 12 months was 45% indicating a need for more quality improvement efforts into reducing this rate.

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77    Keywords: sling; military beneficiary; military treatment facilities; post-operative complications; stress

78    incontinence; surgeon volume.

79

## Introduction

Slings are a common surgical treatment for stress urinary incontinence<sup>1</sup>. There are several modifications of sling surgery and can include pubovaginal slings with autologous fascia or graft and mid-midurethral slings placed via a transobturator or retropubic approach (ref). Investigators predict that the number of women receiving this treatment will increase by 47% and reach over 310,000 surgeries per year by 2050.<sup>2</sup>

Across all surgical fields there is a growing interest in the relationship between surgeon and hospital volumes and patient outcomes. Only two prior studies, with conflicting results, have looked at surgeon volume specifically in relation to surgical outcomes for sling surgery for stress urinary incontinence (SUI)<sup>3,4</sup>. One study looked at Medicare beneficiaries undergoing pubovaginal slings from 1999 to 2000 and found no difference in the rate of urological or non-urological post-operative complications within the first 12 months after surgery<sup>3</sup>. The second study looked at women in Ontario, Canada undergoing mesh sling implant for SUI between 2002 and 2012. The primary outcome was reoperation for SUI mesh-related complications and the authors found that patients of low volume surgeons experienced a higher rate of re-operation compared to patients of high volume surgeons. These studies used the 75<sup>th</sup> percentile as the cut point defining high-volume versus low-volume but did not suggest a minimum number that may be useful for surgeon privileging and credentialing. In the study that found no volume effect<sup>3</sup>, the cut point defining high versus low volume was 7 sling cases over a 2 year period while the median cut point was 16 cases per year in the study that did find a volume effect<sup>4</sup>. These two studies excluded patients younger than 65 years old and the large number of patients (active-duty service members, retirees, and dependents) receiving care in military treatment facilities.

The primary aim of this study was to compare 12-month post-operative complication rates in women who underwent sling procedures by high-volume versus low-volume surgeons at US military treatment facilities.

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## 105   Materials and Methods

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107   These methods were previously published in Howard, McGlynn and Greer 2018. This was a retrospective  
108   cohort study of women, aged 18 years and older, who were enrolled in the U.S. military healthcare  
109   system, TRICARE Prime, between January 1, 2011, and December 31, 2013, with SUI, and who  
110   underwent either an outpatient or inpatient sling placement for SUI in any MTF in the United States  
111   between January 1, 2011, and December 31, 2012. SUI was defined as the presence of the presence of the  
112   ICD-9 code for SUI (625.6), intrinsic sphincter deficiency (599.81), and/or urethral hypermobility  
113   (599.82) as a primary or secondary diagnosis in the electronic medical record. Sling placement was  
114   defined by the CPT code 57288 or the ICD-9 procedure codes 59.4, 59.71, and 59.79 . The dataset did not  
115   allow discrimination based on sling type or approach.

116

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

124

125   The primary exposure of interest was surgeon volume. The Health Analysis department at the Naval Medical  
126   Center Portsmouth identified all surgeons who performed mid-urethral slings for SUI during the study period,  
127   and then, for each surgeon, they determined the number of sling procedures performed over the two years  
128   preceding the study period (January 1, 2009 – December 31, 2010). The Health Analysis department



subsequently created a patient level data set, and for each patient undergoing a mid-urethral sling during the study period, and eligible for inclusion, a variable was created that indicated the number of cases that the performing surgeon had done in the 2 years prior to the study period. This is displayed graphically in figure 1.

We initially stratified surgeons by quartiles according to the volume of procedures they performed. As Figure 1 shows, however, a large proportion of our surgeons did less than four sling procedures in this two-year period. In our initial analyses, the cut point for the 75<sup>th</sup> percentile for surgeon sling volume was just four. Conceptually, we could not rationalize treating a surgeon with four sling cases over two years as a high-volume surgeon. We subsequently divided up the highest quartile into tertiles and used the highest tertile as our high-volume surgeon group. The cut point defining the highest tertile of the highest quartile was 13 sling cases over two years. We combined the bottom three quartiles into a single group and this was our low-volume group. The cut point that defined low-volume was three or fewer cases over two years. The bottom two tertiles of the top quartile represented our intermediate-volume group. By defining our high-volume group as 13 or more cases in two years and our low-volume group as three or fewer cases over two years, we clearly separated our high-volume and low-volume groups.

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

In addition to our primary exposure and outcome, we obtained data on age, race, surgeon specialty, comorbid diseases, and concomitant pelvic surgery. A priori, we planned to control for these potential confounders: age, race, surgeon specialty, Charlson comorbidity index score<sup>7</sup>, and concomitant pelvic organ prolapse surgery.

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

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

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

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

*Sample size calculations:* Based on data from Suskind et al.<sup>5</sup>, we assumed the composite post-sling 12-month complication rate would be 70% for high-volume surgeons and 85% for low-volume surgeons. Assuming a power of 80% with a type 1 error rate of 5%, we calculated that we would need approximately 95 patients in each group. In the study by Suskind et al., the prevalence of the most uncommon individual post-operative complication was approximately 6% (new diagnosis of pelvic pain). If we assumed that the prevalence of the most uncommon individual complication in our study would also be 6% among high-volume surgeons and 11% among low-volume surgeons, we calculated we would need 384 patients in each group to detect that difference with a power of 80% and a type 1 error rate of

5%. In the end we had significantly more patients than we calculated we would need during our a priori sample-size calculations.

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

## Results

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

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

The mean age of our study population was  $47.2 \pm 11.3$  years. The characteristics of our study population, stratified by surgeon volume, are shown in Table 2, and the distribution of individual surgeon volume is illustrated in Figure 1. The patients of high-volume surgeons were five years older on average and

significantly more likely to have a Charlson score of one or greater. High-volume surgeons were also significantly more likely to perform concomitant pelvic organ repair at the same time as the index sling procedure.

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

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

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

Comment

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

This study has important strengths and limitations. In terms of strengths, this is a large-scale study of surgeon volume versus surgical outcomes within the military health care system in the United States. Within the military beneficiary population, SUI is a common diagnosis, and sling surgery is a procedure

performed by both general and fellowship-trained gynecologists and urologists. We were able to control for the impact of individual surgeon practice by using a robust cluster analysis using a randomly-generated surgeon identifier.

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

In the study by Welk et al<sup>4</sup>, done in Canada, the median value for the 75<sup>th</sup> percentile for surgeon volume across the 10 years studied was 16 cases per year. The surgeon population in this study had much higher individual annual volume than in our study and in the study by Anger et al (ref 7). This study only looked specifically at re-operation for mesh related complications after sling surgery but did find that higher surgeon volume correlated with lower re-operation rates. This specific complication was not abstracted in our database.

Both the study by Welk et al and the study by Anger et al defined volume in a binary manner using the 75<sup>th</sup> percentile as a cut point. Everyone above the cut point was defined as high-volume and everyone below was low volume. Most comparable studies of surgeon volume and surgical outcomes use a single method for defining volume. One such method is a binary approach with the cut-point at the 75<sup>th</sup> percentile<sup>3,4</sup>. Another approach is to use a predetermined number of surgeries as a cutoff<sup>9-15</sup>. Finally, other studies have used an ordinal approach categorizing volume into tertiles or quartiles<sup>16-19</sup>. Recognizing the conceptual problems with defining surgeon volume by a single approach, we intentionally modeled surgeon volume to ensure there was a clear delineation between high- and low-volume (13 or more versus 0-3 cases over two years). Furthermore, we used a more extreme definition of high- and low-volume

surgeons (20 or more versus 0 cases over two years) and modeled surgeon volume as a continuous variable in our sensitivity analysis without any impact on our primary outcome.

The limitations of this study are similar to any study using a large administrative database as subjective and objective measures of efficacy are not included<sup>20</sup>. We recognize potential for information bias through inaccurate coding or use of codes not captured in our data abstraction. In this study, we were not able to differentiate between the different types of slings, surgical approach, or graft material used and we recognize that some differences in adverse events do exist based on these factors<sup>27</sup> but surgeon volume has not been demonstrated to impact these adverse events to date.

We also included subjects with concomitant pelvic organ prolapse surgery as we were not certain of our initial population size or surgeon volume. We did not want to report a falsely low number for surgeon volume as slings can be performed as isolated procedures or as a concomitant procedure. We did not want to exclude a potential group of subjects or surgeons that may add more insight and explanation to complication rates. Furthermore, concomitant prolapse surgery has been reported to have an uncertain impact on complications, increasing bladder outlet obstruction but decreasing treatment failure<sup>8</sup>. Therefore, we planned a priori to control for this variable in our analysis.

Furthermore, a large proportion of our surgeons were classified as having done zero cases in the two years prior to the study period. The database we used only captured cases at US military treatment facilities performed by attending physicians. We were not able to capture surgeon volume from overseas military treatment facilities, cases done at civilian hospitals during the study period or in the previous two years, or cases done in residency or fellowship training. Recognizing these limitations, we chose to use the

same ICD-9 and CPT codes as previously reported by Suskind, et al,<sup>5</sup> in order to enable a direct comparison of our results with published data. Future analyses in this database and others should investigate all complications as reported by Schimpf et al (ref) and attempt to delineate the type of sling, approach and graft material if that information can be obtained.

In terms of the meaning of the results of this study, there are several broad themes. Including this study there are now three large population based studies specifically looking at surgeon volume and post-operative complications after sling surgery for SUI<sup>3,4</sup>. In two of these studies the overall surgeon volume was low with the 75<sup>th</sup> percentile being 4-7 cases over 2 years. Both of these failed to show a volume effect. In the third study<sup>4</sup> the surgeon volume was much higher with the 75<sup>th</sup> percentile being 16 cases per year. This study did find a volume effect. This trend points to the fact that it may be hard to see a relationship between surgeon volume and outcomes if the overwhelming majority of the surgeons are low-volume surgeons.

Two large-scale US based studies (conducted in very different populations) that have failed to show a statistically significant association between surgeon volume and surgical outcomes after sling surgery for SUI in overall low-volume surgeon populations. While one out of every 30 women will experience a mesh related complication within 10 years after a mid-urethral sling<sup>4</sup>, this is not the only complication related to mid-urethral slings as reported by Schimpf et al (Schimpf 2014). As higher surgeon volume is linked to improved outcomes in other studies, perhaps our threshold for defining high-volume surgeons is too low. We need to continue to investigate a wide variety of complications and the threshold at which point individual complications decrease. These studies will likely need to be carried out using other national bases that capture data from an increased number of high volume and low volume surgeons as most randomized-controlled trials set a minimum surgeon volume but do not track surgeon volume over the course of the trial.



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394

395 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)

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Cytoscopy	52000, 52204, 52281 (CPT)
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Urodynamics	51725, 51726, 51795 (CPT)
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Repeat incontinence procedure	57288 (CPT), 59.4, 59.71, 59.79 (ICD-9 Procedure)
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398 Table 2. Summary of demographic and comorbidity characteristics of women undergoing a sling<sup>a\*</sup> within  
 399 military treatment facilities in the U.S., Jan 1, 2011, to Dec 31, 2012.

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	Surgeon volume		p-value
	Low-volume	High-volume	
	(0-3 slings in 2 years)	(13 or more slings in 2 years)	
	N=664	N=638	
Patient age <sup>b</sup>	44.64±0.42	50.12±0.45	0.001 <sup>c</sup>
Concomitant pelvic organ prolapse procedure at time of index sling <sup>d</sup>	128(19.3)	166(26.0)	0.004 <sup>e</sup>
Provider specialty <sup>d</sup>			0.001 <sup>e</sup>
Gynecologist	473(71.2)	450(70.5)	
Urogynecologist	146(22)	186(29.2)	
Other	45(6.8)	2(0.3)	
Charlson Score <sup>d</sup>			0.001 <sup>e</sup>
0	507(76.4)	442(69.3)	
1-2	140(21.1)	155(24.3)	
3 or more	17(2.6)	41(6.4)	

401

<sup>a</sup>Defined by the combination of CPT code 57288 and ICD-9 procedure codes 59.4 (suprapubic sling operation); 59.71 (levator muscle operation for urethrovesical suspension), 59.79 (other repair of stress urinary incontinence), and ICD-9 diagnosis codes 625.6 (stress incontinence female); and 599.81 (urethral hypermobility) and 599.82 (intrinsic sphincter deficiency). This captured both inpatients and outpatients.

<sup>b</sup>Data presented is mean $\pm$ standard error

<sup>c</sup>P-value computed by Student's t-test

<sup>d</sup>Data presented is N(%)

<sup>e</sup>P-value computed by chi-square test



414  
 415 Table 3. Twelve-month post-operative complications after sling surgery within military treatment  
 416 facilities in the U.S. by surgeon volume with clustering for each surgeon  
 417

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

outlet obstruction	55(8.3)	40(6.3)	0.74(0.41-1.32)	0.72(0.40-1.28) <sup>b</sup>
Management of bladder outlet				
obstruction	72(10.8)	703(16.1)	1.58(.89-2.81)	1.58(.89-2.80) <sup>b</sup>
Cystoscopy	49(7.4)	43(6.7)	0.91(.51-1.61)	0.93 (0.51- 1.70) <sup>d</sup>
Urodynamics	11(1.7)	8(1.3)	0.75(.29-1.93)	0.76(0.29-1.99) <sup>e</sup>
Repeat incontinence procedure	6(.9)	7(1.1)	1.22(.24-6.08)	1.17(.23-5.89) <sup>f</sup>

418 Because patients can have more than one complication, the percentages in the column do not total

419 100%.

420 <sup>b</sup>Adjusted for Charlson comorbidity score (0 versus 1 or more) and concomitant pelvic organ

421 prolapse repair

422 <sup>d</sup>Adjusted for age (greater than or equal to median [46] versus less than median) and concomitant

423 pelvic organ prolapse repair

424 <sup>e</sup>Adjusted for concomitant pelvic organ prolapse repair

425 <sup>f</sup>Adjusted for Charlson comorbidity score (0 versus 1 or more)

426

427

428

429

430 Figure Legend

431

432 Figure 1. Number of sling procedures performed by military surgeons within the United States (January 1,

433 2009 - December 31, 2010)