

OVERALL SPLENECTOMY RATES STABLE DESPITE INCREASING
USAGE OF ANGIOGRAPHY IN THE MANAGEMENT OF HIGH GRADE
BLUNT SPLENIC INJURY

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REPRINTS: Reprints will not be available from the authors.

DISCLAIMERS: Dr.'s Dolejs, Savage, Hartwell, and Zarzaur have no conflicts of interest to disclose.

FUNDING: There is no funding for this paper

MEETING: This was a podium presentation at the American Association for the Surgery of Trauma on September 14-17, 2016 in Waikoloa, HI

WORD COUNT TEXT: 3,492/3,500

WORD COUNT ABSTRACT: 247/250

REFERENCES: 37/50

Figure/Table Limit: 6/7

RUNNING TITLE: Trends in splenectomy over time

INTRODUCTION:

Non-operative management (NOM) for blunt splenic injury (BSI) began over 30 years ago, and selective NOM is now the preferred method of treatment in BSI ¹⁻⁴. The use of angiography and embolization (ANGIO) in high-grade BSI began in 1979 and published in 1995 by Sclafani et al ². Trauma centers then developed protocols incorporating the use of ANGIO in the management of BSI. Some centers follow selective ANGIO strategies where patients with BSI and a vascular abnormality seen on admission computed tomography (CT) scan are referred for ANGIO ⁵⁻⁸. Other centers, based on evidence that CT may not be accurate at detecting vascular abnormalities that require embolization, advocate for the use of ANGIO for all patients with grades III-V or IV-V BSI, depending on the center ⁹⁻¹⁶. Utilizing non-selective ANGIO strategies, authors report improvements in the proportion of patients successfully managed with NOM after protocol implementation. However, not all studies show improved splenic salvage with ANGIO ¹⁷⁻²⁰. A recent multicenter prospective study showed no association between ANGIO utilization and splenic salvage in patients selected for NOM ¹⁷.

To further complicate matters, the use of angiography and embolization was introduced at a time when CT scanning in trauma was rapidly expanding and the rate of successful NOM of BSI was increasing across institutions, with or without ANGIO ^{14,21-23}. An increase in diagnosis of relatively minor spleen injuries could lead to confounding of the relationship between ANGIO and splenic salvage ^{14,21-23}. Additionally, selection bias may also confound the relationship between ANGIO and splenic salvage. Many studies of ANGIO in the setting of BSI only report success of non-operative management ⁵⁻¹⁵. Over time, changes in the use of urgent, or early splenectomy at a center could account for improvement in non-operative success. For example, if a center more accurately predicts which patients with BSI will ultimately fail observation and

require splenectomy, the surgeons at that center may become more aggressive with the use of early splenectomy and not refer patients to ANGIO. If this occurs, the population referred to ANGIO will be enriched with patients more likely to have successful splenic salvage, as the highest risk patients have already undergone splenectomy. Thus, rates of NOM will improve compared to historical controls, not because of ANGIO but because of better patient selection. A recent study using the National Trauma Data Bank found significant variability in the use of urgent splenectomy at the center level indicating that there may be selection bias at the center level ²⁴.

In this study we sought to exploit center level heterogeneity in the utilization of ANGIO to investigate nationwide trends in ANGIO and splenectomy in centers that utilized ANGIO compared to centers that did not utilize ANGIO from 2008 to 2014. We hypothesized that the overall rate of splenectomy would be stable from 2008 to 2014 with an increased rate of early splenectomy and decreased rate of late splenectomy. We further hypothesized that these trends would be similar in centers that utilized ANGIO and those that did not.

METHODS:

Study Sample:

The American College of Surgeons (ACS) National Trauma Data Bank (NTDB) from 2008-2014 was used for this study. Adults 18 years and older with a BSI and abbreviated injury scale (AIS) over II (classified as high-grade BSI in our study) treated at Level I or II trauma centers were included. Patients were only included if they were treated at trauma centers that managed over 20 patients with high-grade BSI during the study period. Patients were excluded if

they were dead on arrival, died in the emergency department (ED), or if they were transferred from another facility.

Study Variables:

Patient and facility level factors were examined. Patient characteristics included age, gender, race, admission systolic blood pressure (SBP), injury severity score (ISS), splenic injury severity (based on AIS), and the initial Glasgow coma scale (GCS) motor score with a priori defined cutoffs for continuous variables. Facilities were grouped based on ACS verification status, trauma level status, hospital region, number of beds, university status, and the usage of angiography at the facility level at any time during the study period.

Patients were classified as undergoing splenectomy if they had an International Classification of Diseases, Ninth Revision (ICD-9) procedure code of 41.5. Early splenectomy was defined as splenectomy within 6 hours of admission. Late splenectomy was defined as splenectomy over 6 hours from admission. ANGIO use was defined based on ICD-9 procedure codes of 88.47 (angiography) or 39.79 (angiography and embolization).

Statistical Methods:

Multiple imputation was performed for covariates with missing data. This included imputation for gender (0.2% missing), GCS motor score (2.4% missing), hospital region (0.4% missing), and hour to splenectomy (5.5% missing). Univariate and bivariate data analysis was then undertaken to compare unadjusted statistics over time. Statistical inference was performed with Chi-squared tests.

We then used the multiply imputed dataset to perform hierarchical logistic regression analysis, clustered on facilities, to adjust for patient and facility factors. The events of interest were splenectomy, angiography, and mortality. Using methods similar to those used by Abdelsattar et al and Cohen et al, expected event rates were determined for each outcome^{25,26}. Expected event rates were determined by the hierarchical logistic regression based on patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status). Observed to expected (O:E) event ratios were then calculated for each year stratified by whether a center utilized ANGIO or not. Adjusted event rates for each year were then obtained by multiplying the O:E ratio and the overall event rate.

Next the O:E ratios were used to calculate a rate ratio (RR) for year of admission for ANGIO and non-ANGIO centers, with year considered as a linear, continuous variable, via a Poisson regression analysis. A rate ratio of 0.8 would mean that there was an average of a 20% reduction in the rate for each year of the study period. Interaction between year and ANGIO centers was ascertained for all estimates.

To investigate the role late splenectomy had on mortality, we utilized a Cox-proportional hazard model with late splenectomy as a time-varying covariate. Patients who had undergone early splenectomy or who died within 6 hours of admission (prior to the time they would be eligible for splenectomy) were excluded from this analysis. This analysis was adjusted for the same patient and facility level covariates described above.

All analyses were performed with SAS version 9.4 (Cary, NC), and all figures were created using R version 3.3.2. This study was exempt from Institutional Review Board approval at Indiana University.

RESULTS:

In total, 53,689 patients with Grade III or higher BSI were included for analysis with nearly even distribution across each year. Considering the entire cohort, 16,375 patients (30.5%) had a Grade III BSI, 28,079 patients (52.3%) had a Grade IV BSI, and 9,235 patients (17.2%) had a Grade V BSI. Patients treated at ANGIO centers had higher ISS, more commonly had Grade IV BSI, and had lower admission GCS motor scores (Table 1). ANGIO centers were more commonly Level I centers, were more commonly university affiliated, and tended to be larger (Table 1). All patient and facility level information shown in Table 1 were included in our adjusted models.

Angiography Rate:

In centers that utilized ANGIO, the rate of ANGIO steadily and significantly increased from 2008 to 2014 across all severities (Figure 1). For all high-grade BSI, the adjusted rate of ANGIO increased by 16% per year (RR, 1.16 [95% confidence interval (CI): 1.15-1.18]). ANGIO utilization also increased in grade III BSI (RR, 1.14 [95% CI: 1.10-1.18]), grade IV BSI (RR, 1.17 [95% CI: 1.15-1.20]), and grade V BSI (RR, 1.14 [95% CI: 1.10-1.18]) when considered separately. If using 2008 as a reference group, the rate of ANGIO utilization increased from 5.7% in 2008 to 14.1% in 2014 (difference, 8.4% [95% CI: 7.2% to 9.7%]).

Overall Splenectomy Rate:

The overall splenectomy rate has been stable over time across all splenic injury severities at ANGIO centers (Figure 2). In ANGIO centers, there was no change in the overall splenectomy

rate amongst patients with grade III-V BSI considered jointly (RR, 1.00 [95% CI: 0.99-1.00]) or grade III (RR, 0.99 [95% CI: 0.96-1.01]), grade IV (RR, 1.00 [95% CI: 0.98-1.01]), or grade V (RR, 1.00 [95% CI: 0.99-1.01]) considered separately. In contrast, the rate of overall splenectomy decreased in patients treated at non-ANGIO centers with grade III-V BSI considered jointly (RR, 0.96 [95% CI: 0.93-0.99]) and with grade III (RR, 0.84 [95% CI: 0.76-0.92]) and grade IV BSI (RR, 0.95 [95% CI: 0.90-0.99]) considered separately. The rate of overall splenectomy did not significantly change in patients treated at non-ANGIO centers with grade V BSI (RR, 1.01 [95% CI: 0.96-1.06]). There was significant interaction between ANGIO center and year in all high-grade BSI (p-value=0.02), grade III BSI (p-value<0.01), and grade IV BSI (p-value=0.04) but not in grade V BSI (p-value=0.72). This indicates that the overall splenectomy rate decreased substantially more in non-ANGIO centers compared to ANGIO centers for all severities but grade V BSI, where there was no significant difference. In all high-grade BSI using 2008 as a reference, patients treated at an ANGIO center had a rate of overall splenectomy of 24.1% in 2008 and 23.5% in 2014 (difference, -0.7% [95% CI: -1.9% to 0.6%]) versus patients treated at a non-ANGIO center who had a rate of 27.0% in 2008 and 20.7% in 2014 (difference, -6.3% [95% CI: -9.9% to -2.0%]).

Early Splenectomy:

The rate of early splenectomy was stable over time across all splenic injury severities in ANGIO and non-ANGIO centers, with the exception of grade III BSI treated at non-ANGIO centers (Figure 3). In ANGIO centers, there was no significant change in all high-grade BSI (RR, 1.01 [95% CI: 1.00-1.02]), grade III BSI (RR, 1.00 [95% CI: 0.97-1.03]), grade IV BSI (RR, 1.01 [95% CI: 0.99-1.02]), or grade V BSI (RR, 1.01 [95% CI: 0.99-1.03]). In non-ANGIO

centers, there was significantly reduced early splenectomy rates in grade III BSI (RR, 0.83 [95% CI: 0.74-0.94]) but no significant differences in all high-grade BSI (RR, 0.98 [95% CI: 0.94-1.01]), grade IV BSI (RR, 0.96 [95% CI: 0.91-1.01]), or grade V BSI (RR, 1.03 [95% CI: 0.98-1.09]). There was significant interaction between year and ANGIO center status for only grade III BSI (p-value<0.01). This indicates a significant reduction in the early splenectomy in patients with grade III BSI treated at non-ANGIO centers compared with ANGIO centers, but no significant differences in the rate of early splenectomy between ANGIO and non-ANGIO centers.

Late Splenectomy:

The rate of late splenectomy was significantly reduced over time in ANGIO and non-ANGIO centers (Figure 4). In ANGIO centers, late splenectomy significantly decreased over time in all high-grade BSI (RR, 0.95 [95% CI: 0.93-0.97]), grade III BSI (RR, 0.94 [95% CI: 0.89-0.99]), grade IV BSI (RR, 0.97 [95% CI: 0.94-1.00]), and grade V BSI (RR, 0.95 [95% CI: 0.91-0.98]). In non-ANGIO centers, late splenectomy significantly decreased in high-grade BSI (RR, 0.89 [95% CI: 0.83-0.95]), grade III BSI (RR, 0.84 [95% CI: 0.71-1.00]), and grade V BSI (RR, 0.88 [95% CI: 0.77-1.00]). In patients with grade IV BSI treated at non-ANGIO centers, the late splenectomy did not significantly decrease (RR, 0.91 [95% CI: 0.82-1.00], p-value=0.06) despite a larger effect size than ANGIO centers. Interaction amongst ANGIO centers, non-ANGIO centers, and year was nearly significant when all high-grade BSI was considered jointly (p-value=0.057), but was not significant in grade III BSI (p-value=0.23), grade IV BSI (p-value=0.21), or grade V BSI (p-value=0.26). This indicates a trend towards a faster decline in the rate of late splenectomy in non-ANGIO centers compared to ANGIO centers in all high-grade

BSI. Using 2008 as a reference year, the late splenectomy rate in high-grade BSI in patients treated at ANGIO centers decreased from 5.4% in 2008 to 4.1% in 2014 (difference, -1.4% [95% CI: -1.8% to -0.8%]) and in patients treated at non-ANGIO centers decreased from 6.0% in 2008 to 3.3% in 2014 (difference, -3.5% [95% CI: -4.6% to -1.7%]).

Mortality:

There were no significant changes in the rate of mortality over time for patients with high-grade BSI in ANGIO or non-ANGIO centers. In patients treated at ANGIO centers, there was no difference in mortality in high-grade BSI (RR, 1.01 [95% CI: 0.99-1.02]), grade III BSI (RR, 1.01 [95% CI: 0.98-1.05]), grade IV BSI (RR, 1.00 [95% CI: 0.98-1.03]), or grade V BSI (RR, 1.01 [95% CI: 0.99-1.03]). In patients treated at non-ANGIO centers, there was no difference in mortality in high-grade BSI (RR, 0.96 [95% CI: 0.91-1.01]), grade III BSI (RR, 0.96 [0.84-1.08]), grade IV BSI (RR, 0.92 [95% CI: 0.85-1.00]), or grade V BSI (RR, 0.99 [95% CI: 0.80-1.04]). There was a trend towards interaction between ANGIO center and mortality in high-grade BSI (p-value=0.054) and grade IV BSI (p-value=0.054) but not in grade III BSI (p-value=0.39) or grade V BSI (p-value=0.58). Using 2008 as a reference year, the mortality in patients with high-grade BSI treated at ANGIO centers increased from 9.8% in 2008 to 10.3% in 2014 (difference, 0.4% [95% CI: -0.4% to 1.3%]) and at non-ANGIO centers decreased from 11.5% in 2008 to 6.6% in 2014 (difference, -2.6% [95% CI: -4.9% to 0.4%]).

We next evaluated mortality among patients with late splenectomy. Late splenectomy was associated with a significantly increased rate of mortality in grade III BSI (hazard ratio (HR), 1.98 [95% CI: 1.32-2.96]) and grade IV BSI (HR, 1.69 [95% CI: 1.35-2.10]). For Grades

V BSI, there was no significant difference in mortality in patients who underwent late splenectomy (HR, 1.01 [95% CI: 0.79, 1.29]).

DISCUSSION:

Utilizing the NTDB, we studied 53,689 patients who sustained high-grade BSI. Several retrospective studies indicate an association between ANGIO and decreased rates of failure of NOM^{2,3,5-15,27-30}. Further, several centers now advocate ANGIO for all Grade III to V or IV to V BSI⁹⁻¹⁵. Thus, the 8.4% increase rate of ANGIO from 2008 to 2014 is not surprising. It is also not surprising that the greatest change occurred amongst patients with Grade IV BSI, where the rate of ANGIO increased by 10.8%. In this analysis, we found no change in the utilization of early splenectomy over time at ANGIO and non-ANGIO centers. This finding was contrary to our initial hypothesis and suggests that selection bias may not be a factor in the relationship between ANGIO and splenic salvage. However, we did find interesting results when considering overall and late splenectomy rates at ANGIO and non-ANGIO centers.

If increased ANGIO use on a nationwide basis resulted in improved splenic salvage, we would expect centers that utilized ANGIO frequently would have decreased overall and late splenectomy rates compared with centers that did not utilize ANGIO. However, our study shows that the overall splenectomy rate in centers that utilized ANGIO remained stable despite increasing ANGIO utilization rates. In contrast, non-ANGIO centers experienced significant decreases in the rate of overall splenectomy. Both ANGIO and non-ANGIO centers experienced decreased rates of late splenectomy across all severities. However, the rate of decrease tended to be steeper in non-ANGIO centers than in ANGIO centers. Regardless, this means that ANGIO centers and non-ANGIO centers experienced a similar change in late splenectomy over time.

Thus, increased ANGIO utilization was not the only factor that drove decreased utilization of late splenectomy over time.

The reason for the decreased overall splenectomies in non-ANGIO centers and decreased late splenectomy in ANGIO and non-ANGIO centers is not entirely clear. In a large multi-institutional study by Peitzman et al, only one-third of centers had a protocol for management of BSI, and studies have shown that implementation of a protocol (regardless of ANGIO utilization), results in improved late splenectomy rates ^{1,9,11,31-33}. It is possible that non-ANGIO centers and ANGIO centers both developed protocols that improved splenic salvage during the study period. Massive transfusion protocols were also developing and expanding during the study period ^{34,35}. It is possible that these protocols, or other unmeasured temporal trends, were associated with improvements in splenic salvage. Further, non-ANGIO centers were predominantly Level II, non-university affiliated, and small (<400 beds) centers that treated on average 12.5 patients with high-grade BSI per center per year compared with 19.2 patients per center per year in ANGIO centers. It is possible that these centers were slower to adopt protocols for BSI, and after adoption, had heightened rate of splenic salvage compared with ANGIO centers. Regardless of the mechanism, our study provides evidence that increased ANGIO utilization is not the only driver of decreased late splenectomy rates over time in patients with high-grade BSI.

With increasing rates of ANGIO use, it is important to consider the complications associated with ANGIO. In a study of 88 patients who underwent ANGIO, ANGIO was associated with a 14% risk of major complications including splenic abscesses, infarction, cysts, and contrast-induced renal-insufficiency ³⁶. In another study, the morbidity of patients undergoing NOM with ANGIO was equivalent to the morbidity of patients undergoing

immediate splenectomy¹⁸. Frandon et al. reported a 4% major complication rate amongst patients with BSI undergoing ANGIO with a 56% minor complication rate³⁷. In a multi-institution study by Haan et al, the rate of major complication was 20% and minor complication was 23%³⁸. The rapid increase in ANGIO usage has significant cost implications. The procedure related charges for splenic embolization is estimated to be \$19,062 per embolization with similar per patient total hospital cost and total hospital charges³⁹. Based on an estimate of 39,000 patients experiencing a BSI every year, the increase in ANGIO utilization we saw in our study resulted in an additional \$194 million dollars of healthcare costs from 2008 to 2014^{1,28,40}. If we assume 20% of patients with BSI have grade IV or V injuries and a nationwide policy was instituted adopting ANGIO for all grade IV and V BSI, this would result in \$149 million dollars per year of healthcare costs, potentially unnecessary as demonstrated by splenic salvage rates at non-ANGIO centers^{12,21}. Lastly, The results of this study also provide a cautionary tale for overaggressive use of NOM in BS since we observed a significant increase in mortality for patients with Grade III and Grade IV BSI who undergo splenectomy greater than 6 hours from admission.

This study does have important limitations. Residual confounding may have occurred based on year-by-year confounders that were not measured or for which an inappropriate adjustment was made. For example, institution of massive transfusion protocols, increased utilization of written protocols for the management of BSI, changes in trends in patient medication, such as increased use of direct thrombin inhibitors, or specific imaging characteristics such as arterial blush are not included in the NTDB and may confound our results. By comparing year-to-year trends and center level information, rather than patient level information, many of these possible unmeasured confounders are likely to be experienced

similarly across institutions, which would minimize confounding in the relationship between ANGIO and non-ANGIO centers. Information bias is also of concern. If over time recording patterns at facilities changed systematically, these changes could significantly influence our results. The steady rate of splenectomy in ANGIO centers and the progressive and near linear increase in angiography makes it less likely that information bias was impacting our results. Further, facilities have a vested interest to accurately report angiography and splenectomy given the reimbursement associated with these codes.

Another potential bias is misclassification of splenic injury severity based on AIS, since radiologic information is not available from the NTDB. It is likely that over-time, individual facilities would report a similar AIS for the same pattern of BSI, so the year-by-year comparison is unlikely to be influenced by this effect. Another limitation was that the most frequent source of missing data was in the time to splenectomy (5.5% missing). This time was imputed and patients were grouped as having early or late splenectomies based on an *a priori* defined cutoff of 6 hours. It is possible that imputation influenced the rate of early or late splenectomy. Imputation would not change the rate of overall splenectomy. Further, a sensitivity analysis performed with and without the imputed data revealed similar trends in the rate of early and late splenectomy.

In light of these limitations, our study demonstrates that despite the rapidly expanding use of ANGIO, the overall splenectomy rate remained stable for high-grade BSI in centers that utilized ANGIO but decreased in centers that did not utilize ANGIO. Late splenectomy rates decreased at similar rates in ANGIO and non-ANGIO centers and, may be decreasing more rapidly in non-ANGIO centers. At an institutional level, increased ANGIO utilization does not appear to impact the rates of overall splenectomy or late splenectomy. The role of ANGIO in

BSI needs to be better clarified by a large, multi-institutional randomized control trial in order to provide the information needed to make informed decisions about ANGIO in the setting of BSI¹⁷. Until such a trial is undertaken, on a population basis, expanding the use of ANGIO does not appear to impact the overall rate of splenic salvage.

TABLES AND FIGURES:

Table 1: Patient and hospital characteristics in ANGIO and non-ANGIO centers. *SBP=systolic blood pressure, GCS=Glasgow coma score, ACS=American College of Surgeons, ANGIO=Splenic angiography or embolization

Year	ANGIO Center	Non-ANGIO Center	p-value
Patient Level Information:			
Number of Patients:	49,401	4,288	
Year, %			
2008	13.8	13.3	0.37
2009	12.9	13.3	
2010	13.3	14.4	
2011	14.2	13.8	
2012	16.0	15.3	
2013	14.9	14.8	
2014	15.0	15.1	
Age ≥55 y, %	20.6	20.3	0.56
Male, %	67.9	67.3	0.42
Non-white, %	24.9	24.4	0.47
Admission SBP<90 mmHg, %	13.4	13.6	0.73
Injury Severity Score, %			
0-10	10.1	14.7	<0.01
10-24	43.8	43.3	
≥25	46.1	42.1	
Splenic Injury Severity, %			
3	30.3	32.8	<0.01
4	52.6	48.8	
5	17.1	18.4	
GCS Motor Score, %			
6	74.1	76.1	<0.01
2-5	8.3	9.7	
1	17.6	14.2	
Facility Level Information:			
Number of Facilities:	367	49	
ACS Certified, %	59.1	66.2	0.26
Level I Center, %	49.9	17.8	<0.01
Region, %			
Northeast	27.1	35.6	0.25
Midwest	20.3	12.3	
South	31.2	27.4	
West	21.4	24.7	
Bed size, %			
≤200	5.2	12.2	<0.01
201-400	31.1	50.0	
401-600	33.2	25.7	
>600	30.5	12.2	
University Affiliated, %	43.1	21.6	<0.01

FIGURE LEGENDS

Figure 1: Adjusted rates of angiography over time. The line for angiography centers and non-angiography centers represents a fitted line obtained from a Poisson regression. Rates were adjusted for patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status).

Figure 2: Adjusted rates of overall splenectomy over time. The line for angiography centers and non-angiography centers represents a fitted line obtained from a Poisson regression. Rates were adjusted for patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status).

Figure 3: Adjusted rates of early splenectomy over time. The line for angiography centers and non-angiography centers represents a fitted line obtained from a Poisson regression. Rates were adjusted for patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status).

Figure 4: Adjusted rates of late splenectomy over time. The line for angiography centers and non-angiography centers represents a fitted line obtained from a Poisson regression. Rates were adjusted for patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status).

Figure 5: Adjusted rates of mortality over time. The line for angiography centers and non-angiography centers represents a fitted line obtained from a Poisson regression. Rates were adjusted for patient level (age, gender, race, admission SBP, ISS, splenic injury severity, GCS motor score) and facility level information (ACS verification, trauma level, region, number of beds, and university hospital status).

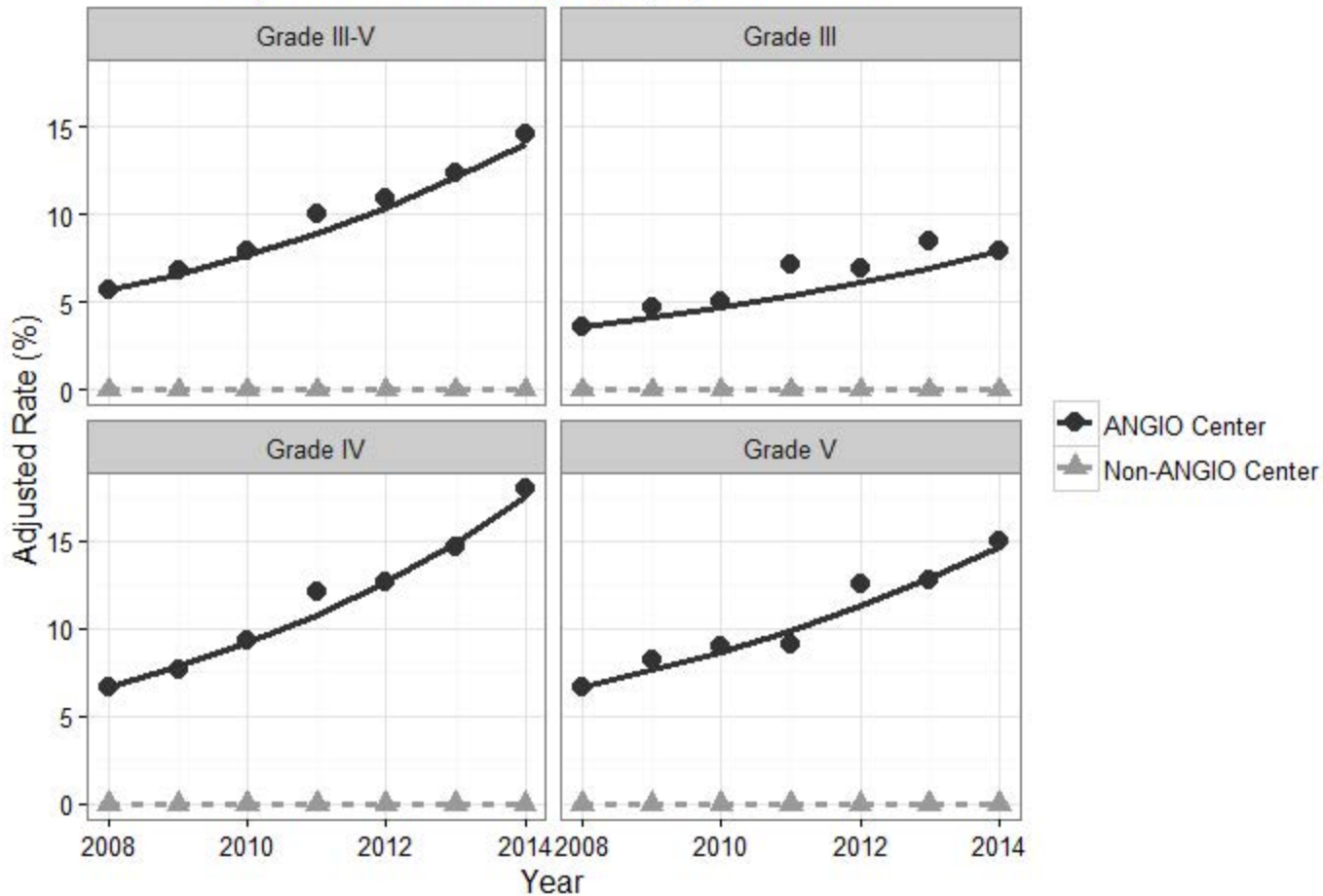
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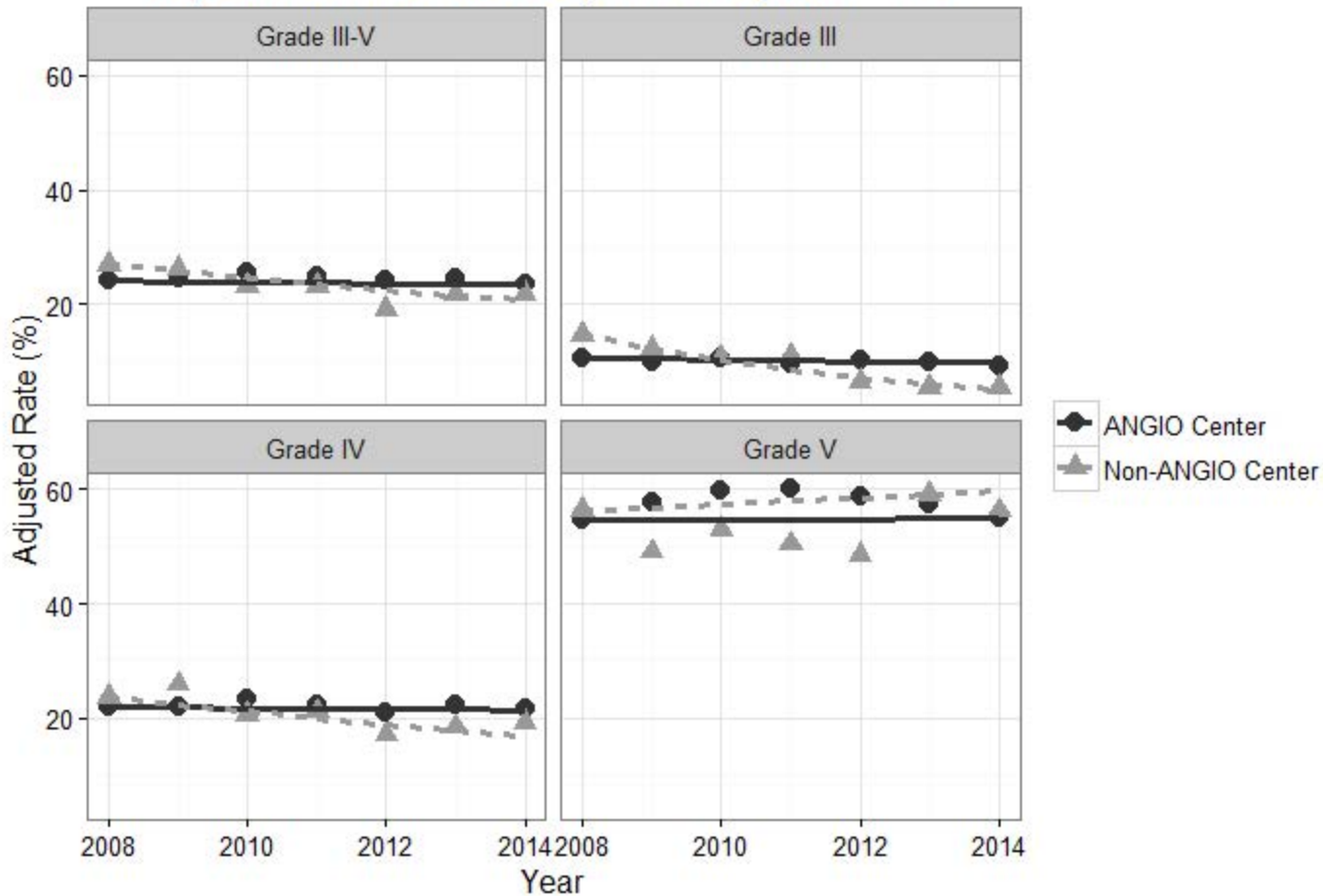
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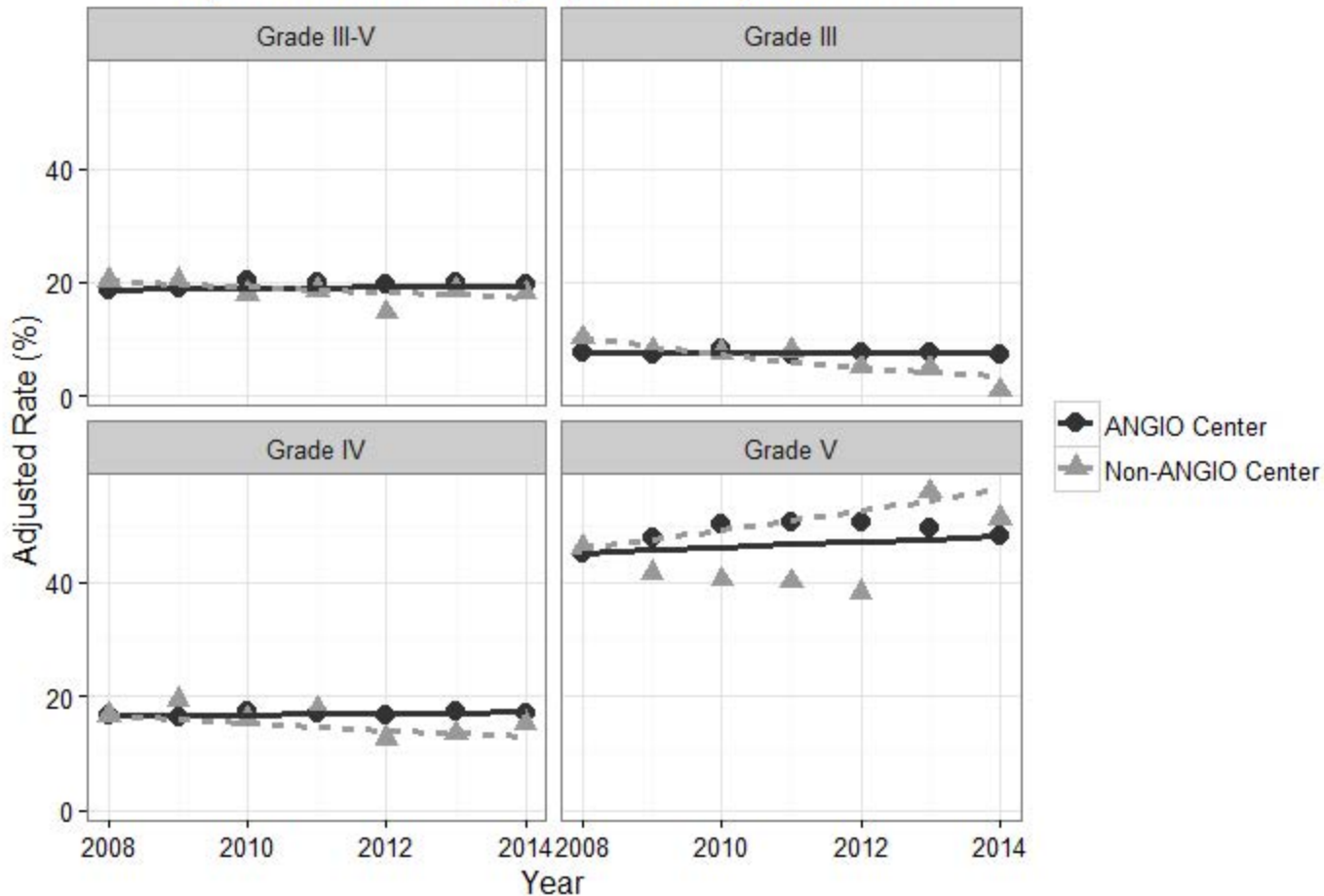
Adjusted Rate of Angiography Over Time



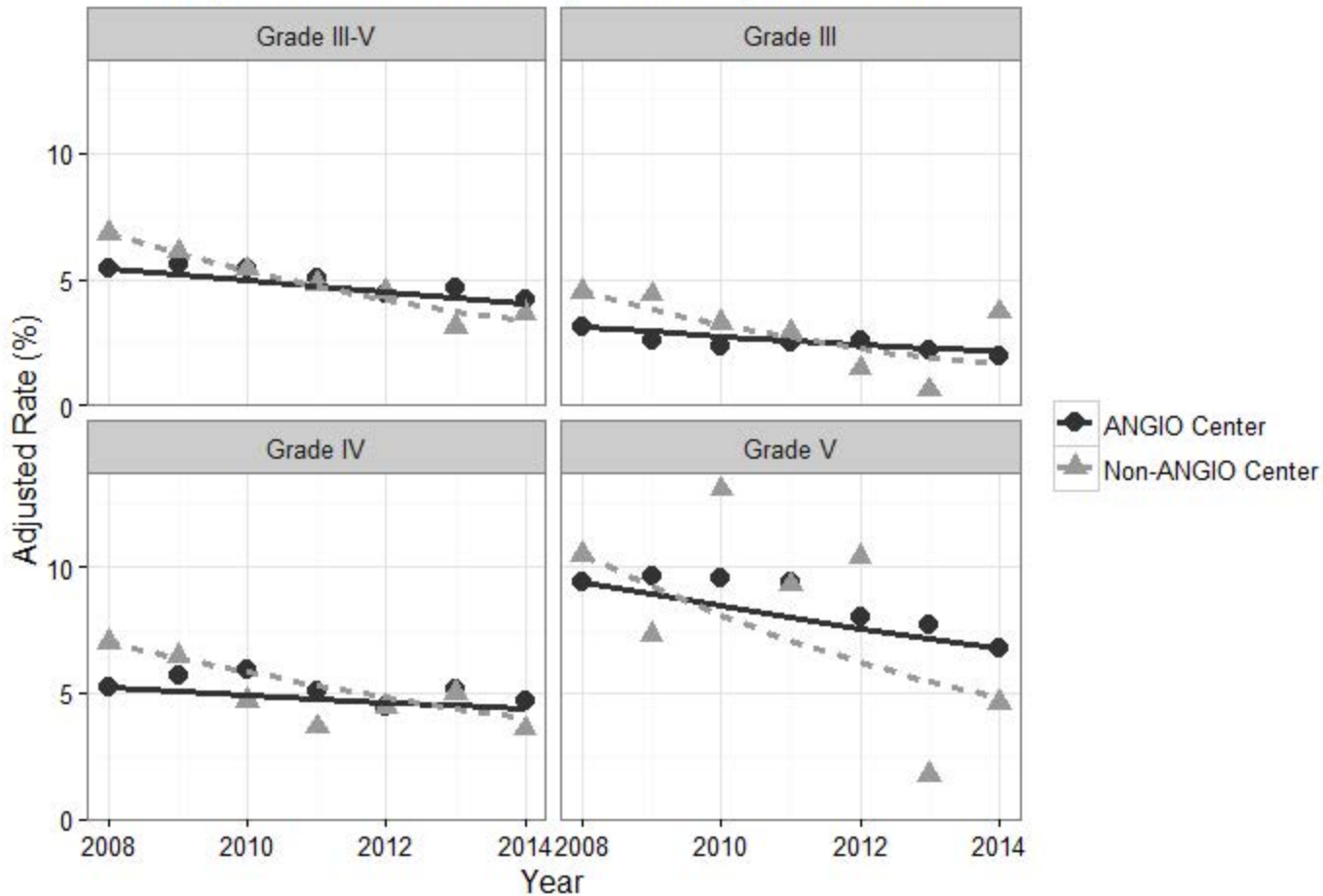
Adjusted Rate of Overall Splenectomy Over Time



Adjusted Rate of Early Splenectomy Over Time



Adjusted Rate of Late Splenectomy Over Time



Adjusted Rate of Mortality Over Time

