

Clinical Research

Effectiveness of Preoperative Antibiotics in Preventing Surgical Site Infection After Common Soft Tissue Procedures of the Hand

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Abstract

Background Antibiotic prophylaxis is a common but controversial practice for clean soft tissue procedures of the hand, such as carpal tunnel release or trigger finger release. Previous studies report no substantial reduction in the risk of surgical site infection (SSI) after antibiotic prophylaxis, yet are limited in power by low sample sizes and low overall rates of postoperative infection.

Questions/Purposes Is there evidence that antibiotic prophylaxis decreases the risk of SSI after soft tissue hand surgery when using propensity score matching to control for potential confounding variables such as demographics, procedure type, medication use, existing comorbidities, and postoperative events?

Methods This retrospective analysis used the Truven Health MarketScan® databases, large, multistate

commercial insurance claims databases corresponding to inpatient and outpatient services and outpatient drug claims made between January 2007 and December 2014. The database includes records for patients enrolled in health insurance plans from self-insured employers and other private payers. Current Procedural Terminology codes were used to identify patients who underwent carpal tunnel release, trigger finger release, ganglion and retinacular cyst excision, de Quervain's release, or soft tissue mass excision, and to assign patients to one of two cohorts based on whether they had received preoperative antibiotic prophylaxis. We identified 943,741 patients, of whom 426,755 (45%) were excluded after meeting one or more exclusion criteria: 357,500 (38%) did not have 12 months of consecutive insurance enrollment before surgery or 1 month of enrollment after surgery; 60,693 (6%) had concomitant bony, implant, or incision and drainage or débridement procedures; and 94,141 (10%) did not have complete data. In all, our initial cohort consisted of 516,986 patients, among whom 58,201 (11%) received antibiotic prophylaxis. Propensity scores were calculated and used to create cohorts matched on potential risk factors for SSI, including age, procedure type, recent use of steroids and immunosuppressive agents, diabetes, HIV/AIDs, tobacco use, obesity, rheumatoid arthritis, alcohol abuse, malnutrition, history of prior SSI, and local procedure volume. Multivariable logistic regression before and after propensity score matching was used to test whether antibiotic prophylaxis was associated with a decrease in the risk of SSI within 30 days after surgery.

Results After controlling for patient demographics, hand procedure type, medication use, existing comorbidities (eg, diabetes, HIV/AIDs, tobacco use, obesity), and postoperative events through propensity score matching, we

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found that the risk of postoperative SSI was no different between patients who had received antibiotic prophylaxis and those who had not (odds ratio, 1.03; 95% CI, 0.93–1.13; $p = 0.585$).

Conclusions Antibiotic prophylaxis for common soft tissue procedures of the hand is not associated with reduction in postoperative infection risk. While our analysis cannot account for factors that are not captured in the billing process, this study nevertheless provides strong evidence against unnecessary use of antibiotics before these procedures, especially given the difficulty of conducting a randomized prospective study with a sample size large enough to detect the effect of prophylaxis on the low baseline risk of infection.

Level of evidence: Level III, therapeutic study

Introduction

Clinical practice guidelines in orthopaedic surgery recommend the use of antibiotic prophylaxis before some procedures, including total joint replacement, closed hip fracture surgery, spine surgery, open fracture treatment, and internal fixation [5, 6, 24, 28]. However, antibiotic use in clean, soft tissue hand surgery does not have the same level of support. Prior studies have found no relationship between risk of surgical site infection (SSI) and antibiotic prophylaxis for procedures such as carpal tunnel release, trigger finger release, ganglion cyst excision, surgery for de Quervain's tenosynovitis, and mass excision [7, 16, 17, 27, 32]. Routine use of antibiotics therefore may not decrease the risk of infection, but nevertheless can contribute to antibiotic resistance and other unexpected consequences, such as *Clostridium difficile*-related colitis.

Previous studies regarding antibiotic prophylaxis in hand surgery have several limitations, however. First, the low risk of infection—previously reported to be as low as 0.5%—and potentially small treatment effect require very large sample sizes for adequate statistical power [17, 32]. Moreover, multicenter reviews may not fully capture infections that were treated outside the institutions included in the study, or may not produce results generalizable to institutions outside the study area. Finally, subjects in previous studies were not randomized to treatment groups, and instead received antibiotic prophylaxis based on surgeon discretion [27, 32]. If not corrected for during analysis, this nonrandom treatment assignment can lead to selection bias when estimating treatment effect [12].

Therefore, we asked: is there evidence that antibiotic prophylaxis decreases the risk of SSI after soft tissue hand surgery when using propensity score matching to control for potential confounding variables such as demographics, procedure type, medication use, existing comorbidities, and postoperative events?

Patients and Methods

Data and Study Cohort

We conducted a retrospective analysis using administrative insurance claims data from the Truven Health Market-Scan[®] Commercial and Medicare Supplemental Databases (Truven Health Analytics, an IBM Company, Ann Arbor, MI, USA). The database includes records for more than 50 million individuals across the United States who received private health insurance from self-insured employers and other private health plans between January 2007 and December 2014. Claims reflect services provided to enrollees, their spouses, and their dependents in inpatient and outpatient settings, and include outpatient pharmacy claims. Procedures and diagnoses were identified in the data using Current Procedural Terminology (CPT) codes and ICD-9-Clinical Modification (ICD-9-CM) codes, respectively.

Patients treated with any of the following soft tissue hand procedures were assessed for inclusion: carpal tunnel release; trigger finger release; ganglion or retinacular cyst excision; de Quervain's release; or soft tissue mass excision. The earliest instance of a procedure was considered for patients who may have had multiple operations. Patients were excluded if they did not have at least 1 month of insurance enrollment after surgery or 12 months of consecutive insurance enrollment before surgery. Moreover, we excluded patients who underwent concomitant bony, implant, or incision and drainage or débridement procedures on the day of treatment to limit analysis to clean soft tissue procedures. Only patients with complete data were considered.

A two-tailed, z-test power analysis for logistic regression was conducted using G*Power software (Version 3.1.9.3; University of Dusseldorf, Dusseldorf, Germany) [14] to determine the minimum sample size needed to detect a very small effect size similar to that reported by Tosti et al. [32]. Based on their study, we assumed that the probabilities of SSI were 0.8% and 0.5% without and with antibiotics, respectively. A minimum total sample size of 79,910 patients is needed to detect the corresponding effect size with 90% power at a significance level of 0.05, given a low correlation with other covariates and a prophylaxis rate of 15%, which falls in the range of previously reported values [7, 32].

The Research and Compliance Office of Stanford University deemed the study exempt from human studies review.

Cohort Characteristics

We identified 943,741 patients who underwent one of the selected soft tissue hand procedures. Of these 943,741 individuals, 426,755 (45%) were deemed ineligible

owing to exclusion criteria: 357,500 (38%) did not meet continuous enrollment criteria; 60,693 (6%) had concomitant bony, implant, or incision and drainage or débridement procedures; and 94,141 (10%) did not have complete data. Overall, 516,986 patients were included in the initial study cohort before propensity score matching (Fig. 1). Carpal tunnel release was the most represented of all procedures in the initial study cohort at 48% (250,613 of 516,986).

Of all 516,986 patients included in the initial study cohort, 58,201 (11%) received intravenous antibiotic prophylaxis on the day of the procedure (Table 1). The overall 30-day SSI rate was 1.5% (6933 of 458,785) for patients who did not receive prophylaxis and 1.4% (832 of 58,201) for patients who did. Across the entire initial cohort, the 30-day SSI rate was highest in patients with soft tissue mass excision at 9% (3325 of 35,100) and lowest in those with de Quervain's release at 1% (151 of 25,972) (Table 2).

Explanatory Variables

We examined whether the risk of SSI within 30 days after soft tissue hand surgery was decreased after antibiotic prophylaxis. Prophylaxis was identified by claims made for intravenous antibiotics on the day of surgery. Patients were further characterized by demographics (age, sex, insurance plan type), geographic region (Northeast, North Central, South, West), year of treatment, and procedure type.

Additionally, specific covariates were captured to control for potential effects on treatment assignment or outcome. Covariates representing diagnoses and procedures in the year before surgery included history of diabetes, HIV/AIDs, tobacco use, obesity, rheumatoid arthritis, alcohol abuse, malnutrition, and prior hand SSIs. A patient's relative comorbidity burden in the year before surgery was further assessed using the van Walraven formulation of the Elixhauser index, which represents 30 comorbidities as a single numeric score that describes overall association with mortality [34]. Use of prescription steroids or immunosuppressive agents within 30 days before the procedure was captured to identify patients who potentially were in an immunosuppressed state. To account for postoperative factors that could affect SSI risk, we also assessed use of oral antibiotics on and within 30 days after the procedure, and the occurrence of unrelated procedures or infection events during the 30-day postoperative observation period. Finally, potential geographic differences in antibiotic prophylaxis tendencies were assessed as state- and year-specific prophylaxis frequency and overall soft tissue hand procedure volume.

Outcome Variables

The primary outcome assessed was SSI occurring within 30 days after surgery. An SSI was defined as a record of either an infection-related procedure or a diagnosis of infection during the 30-day postoperative observation

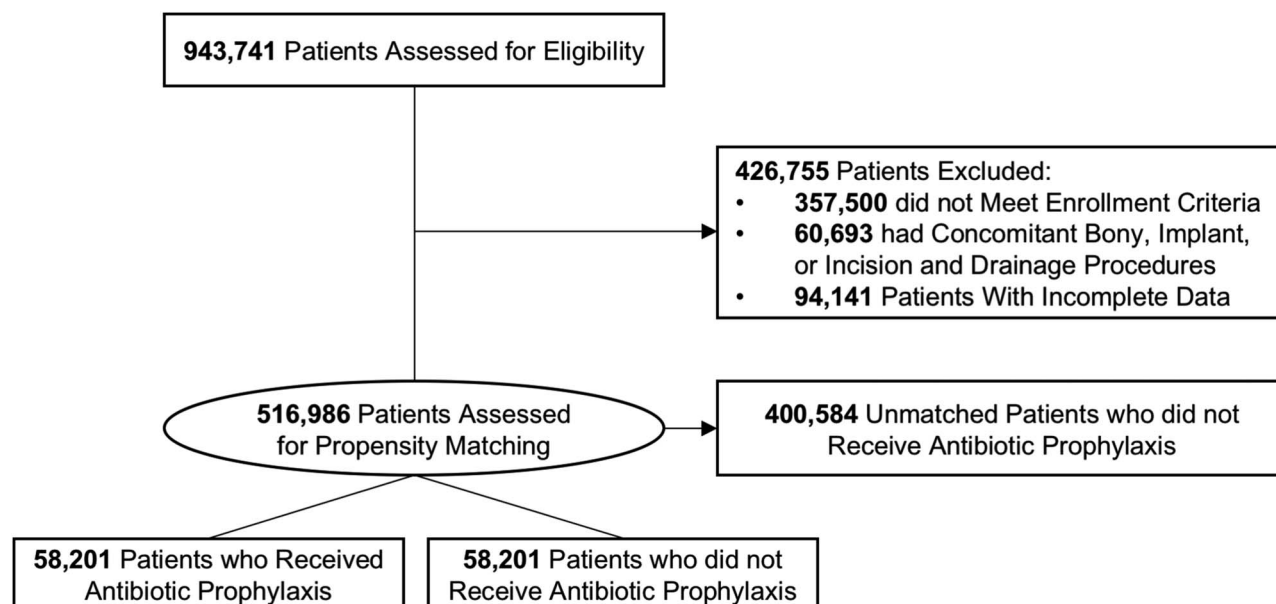


Fig. 1 The initial study cohort included 516,986 patients before propensity score matching. Treatment and control cohorts matched using propensity scores consisted of 58,201 individuals each. Patients

may be excluded on the basis of multiple criteria. All included patients were assessed in univariable and multivariable logistic regression.

Table 1. Cohort characteristics

Variable	Initial cohort			Matched cohort			Unmatched
	Received antibiotic prophylaxis		SMD	Received antibiotic prophylaxis		SMD	Received antibiotic prophylaxis
	No	Yes		No	Yes		No
Number of patients	458,785	58,201		58,201	58,201		400,584
Age (mean, SD)	54 (15)	53 (15)	0.09	53 (15)	53 (15)	0.02	55 (15)
Male (%)	164,704 (36)	21,605 (37)	0.03	21,677 (37)	21,605 (37)	0.003	143,027 (36)
Type of insurance (%)							
Comprehensive	48,674 (11)	5484 (9)	0.12	5390 (9)	5484 (9)	0.03	43,284 (11)
EPO	6260 (1)	1167 (2)		1167 (2)	1167 (2)		5093 (1)
HMO	56,983 (12)	5887 (10)		5599 (10)	5887 (10)		51,384 (13)
POS	35,259 (8)	3876 (7)		3547 (6)	3876 (7)		31,712 (8)
PPO	281,871 (61)	38,213 (66)		38,938 (67)	38,213 (66)		242,933 (61)
POS w/ capitation	2463 (1)	401 (1)		399 (1)	401 (1)		2064 (1)
CDHP	17,661 (4)	1819 (3)		1799 (3)	1819 (3)		15,862 (4)
HDHP	9614 (2)	1354 (2)		1362 (2)	1354 (2)		8252 (2)
Region (%)							
Northeast	70,067 (15)	9983 (17)	0.12	9998 (17)	9983 (17)	0.02	60,069 (15)
North Central	131,542 (29)	17,148 (30)		17,711 (30)	17,148 (30)		113,831 (28)
South	171,337 (37)	21,987 (38)		21,617 (37)	21,987 (38)		149,720 (37)
West	73,640 (16)	8295 (14)		8152 (14)	8295 (14)		65,488 (16)
Unknown	12,199 (3)	788 (1)		723 (1)	788 (1)		11,476 (3)
Year (%)							
2008	57,419 (13)	4166 (7)	0.29	3935 (7)	4166 (7)	0.02	53,484 (13)
2009	72,652 (16)	6901 (12)		6847 (12)	6901 (12)		65,805 (16)
2010	65,113 (14)	6738 (12)		6744 (12)	6738 (12)		58,369 (15)
2011	70,265 (15)	8706 (15)		8826 (15)	8706 (15)		61,439 (15)
2012	76,233 (17)	11,173 (19)		11,270 (19)	11,173 (19)		64,963 (16)
2013	64,006 (14)	10,277 (18)		10,441 (18)	10,277 (18)		53,565 (13)
2014	53,097 (12)	10,240 (18)		10,138 (17)	10,240 (18)		42,959 (11)
Procedure (%)							
Carpal tunnel release	219,930 (48)	30,683 (53)	0.15	31,032 (53)	30,683 (53)	0.02	188,898 (47)
De Quervain's release	23,131 (5)	2841 (5)		2836 (5)	2841 (5)		20,295 (5)
Ganglion cyst excision	41,087 (9)	6402 (11)		6494 (11)	6402 (11)		34,593 (9)
Retinacular cyst excision	34,842 (8)	3580 (6)		3373 (6)	3580 (6)		31,469 (8)
Soft tissue mass excision	31,999 (7)	3101 (5)		3044 (5)	3101 (5)		28,955 (7)
Trigger finger release	107,796 (24)	11,594 (20)		11,422 (20)	11,594 (20)		96,374 (24)

Table 1. continued

Variable	Initial cohort			Matched cohort			Unmatched
	Received antibiotic prophylaxis			Received antibiotic prophylaxis			Received antibiotic prophylaxis
	No	Yes	SMD	No	Yes	SMD	No
Medication use							
Immunosuppressants, within 30 days before surgery (%)	1838 (0.4)	222 (0.4)	0.003	218 (0.4)	222 (0.4)	0.001	1620 (0.4)
Steroids, within 30 days before surgery (%)	14,419 (3)	1554 (3)	0.03	1489 (3)	1554 (3)	0.01	12,930 (3)
Oral antibiotics, same day as surgery (%)	22,175 (5)	3525 (6)	0.05	3470 (6)	3525 (6)	0.004	18,705 (5)
Oral antibiotics, within 30 days after surgery (%)	35,071 (8)	4583 (8)	0.01	4382 (8)	4583 (8)	0.01	30,689 (8)
Comorbidities							
Diabetes (%)	86,992 (19)	12,041 (21)	0.04	11,718 (20)	12,041 (21)	0.01	75,274 (19)
HIV/AIDS (%)	569 (0.1)	68 (0.1)	0.002	73 (0.1)	68 (0.1)	0.002	496 (0.1)
Tobacco use (%)	29,045 (6)	6918 (12)	0.19	6721 (12)	6918 (12)	0.01	22,324 (6)
Obesity (%)	36,895 (8)	7157 (12)	0.14	6998 (12)	7157 (12)	0.01	29,897 (8)
Rheumatoid arthritis (%)	12,630 (3)	1690 (3)	0.01	1608 (3)	1690 (3)	0.01	11,022 (3)
Alcohol abuse (%)	1694 (0.4)	247 (0.4)	0.01	245 (0.4)	247 (0.4)	0.001	1449 (0.4)
Malnutrition (%)	797 (0.2)	122 (0.2)	0.01	121 (0.2)	122 (0.2)	<0.001	676 (0.2)
History of hand SSI before surgery (%)	20,745 (5)	2587 (4)	0.004	2428 (4)	2587 (4)	0.01	18,317 (5)
van Walraven index (mean, SD)	1.4 (4.5)	1.5 (4.8)	0.01	1.4 (4.8)	1.5 (4.8)	0.01	1.4 (4.4)
State procedure volume (mean, SD)	4944 (3195)	4805 (3194)	0.04	4854 (3197)	4805 (3194)	0.02	4958 (3194)
State antibiotic frequency (mean, SD)	0.12 (0.06)	0.15 (0.07)	0.54	0.15 (0.07)	0.15 (0.07)	0.003	0.11 (0.06)
Postoperative events							
Other surgeries within 30 days after surgery (%)	80,887 (18)	12,856 (22)	0.11	12,566 (22)	12,856 (22)	0.01	68,321 (17)
Other infections within 30 days after surgery (%)	18,690 (4)	2586 (4)	0.02	2445 (4)	2586 (4)	0.01	16,245 (4)
Outcomes							
SSI within 30 days after surgery (%)	6933 (1.5)	832 (1.4)	0.01	810 (1.4)	832 (1.4)	0.003	6123 (1.5)

SMD = standardized mean difference; EPO = exclusive provider organization; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization; CDHP = consumer-driven health plan; HDHP = high-deductible health plan; SSI = surgical site infection.

Table 2. Volume and 30-day infection rates by procedure

Procedure	Patients experiencing 30-day SSI/all patients undergoing procedure (%)
Carpal tunnel release	1874/250,613 (1%)
De Quervain’s release	151/25,972 (1%)
Ganglion cyst excision	345/47,489 (1%)
Retinacular cyst excision	912/38,422 (2%)
Soft tissue mass excision	3325/35,100 (9%)
Trigger finger release	1158/119,390 (1%)
Total	7765/516,986 (2%)

SSI = surgical site infection.

period. We assumed that claims were submitted for all instances of SSIs, and that absence of a claim during the observation period reflected an absence of infection.

Statistical Methods

Summary statistics were represented as frequencies for categorical variables and means and standard deviations for continuous variables. Differences in covariate distributions between treatment and control cohorts were quantified using a chi-square test for categorical variables and a t-test for continuous variables. The effect of antibiotic prophylaxis on the risk of postoperative SSI was tested using multivariable logistic regression before and after propensity score matching of treatment and control cohorts, and was represented as an odds ratio (OR) with 95% CIs and a significance level of 0.05. Data extraction and manipulation were performed using SAS (Version 9.4; SAS Institute, Cary, NC, USA), and further statistical analysis was performed using R (Version 3.4.2; R Foundation for Statistical Computing, Vienna, Austria). We used the MatchIt R package for propensity score analysis [18].

Propensity Score Matching

The large and diverse sample afforded by this dataset allows for generalizable results and adequate statistical power to detect a small effect size. To limit potential selection bias, we used propensity score matching to create a treatment and a control cohort that were balanced with respect to variables that could influence the risk for SSIs and the likelihood (or “propensity”) of receiving antibiotic prophylaxis, an approach often used in studies with non-random treatment assignment [12]. A propensity score is a single number that reflects a patient’s probability of receiving antibiotic prophylaxis based on the value of

measured covariates that could influence SSI risk or treatment assignment, and is generated using multivariable logistic regression [4, 11, 30]. Matching generated a treatment cohort of patients who had received prophylaxis and a control cohort of patients who had not received prophylaxis, and was conducted using the nearest-neighbor method in which each patient in the treatment cohort was matched one-to-one with the patient in the control cohort with the closest propensity score. Treated patients were matched to a corresponding control patient in order of descending propensity score. Patients in the control cohort who were not matched were not included in analyses conducted after matching.

We evaluated the quality of matching by assessing whether the treatment and control cohorts became more similar (“balanced”) across the set of measured covariates after matching. Balance for each covariate was quantified as a standardized mean difference (SMD), which assesses the distance between the means of the covariate in each of the two groups, normalized by sample variance for continuous variables or by the prevalence of each variable level for noncontinuous variables [2]. Cohorts were considered balanced across a given covariate if the SMD was less than 0.1, a common benchmark in propensity score matching studies [25]. Matching was repeated using stricter calipers, which limit the permissible difference in propensity scores between matched patients to improve the closeness of match.

Before matching, the patients who were treated and untreated were unbalanced across numerous covariates, including plan type, geographic region, treatment year, procedure type, tobacco use, obesity, state-specific annual prophylaxis frequency, and the occurrence of other, unrelated procedures during the 30 days after hand surgery. Propensity score matching yielded 58,201 patients in each of the treated and untreated cohorts, for a total sample size of 116,402.

Prophylaxis rates ranged from 3% (1751 of 51,699) to 26% (13,260 of 51,699) in patients with first-decile and tenth-decile propensity scores, respectively. Compared with lower propensity score deciles, higher deciles—corresponding to an increased likelihood of receiving antibiotic prophylaxis—were characterized by the following: younger age; different distributions of patients across insurance plan type and geographic region; later year of treatment; a higher proportion of patients who underwent carpal tunnel release; increasing use of same-day oral antibiotics; history of diabetes, tobacco use, and obesity; different annual state procedure volume and prophylaxis frequency; and a higher proportion of patients who underwent other, unrelated procedures during the 30 days after hand surgery. Matching improved balance across most covariates and reduced the SMD across all covariates to less than 0.1 (Fig. 2).

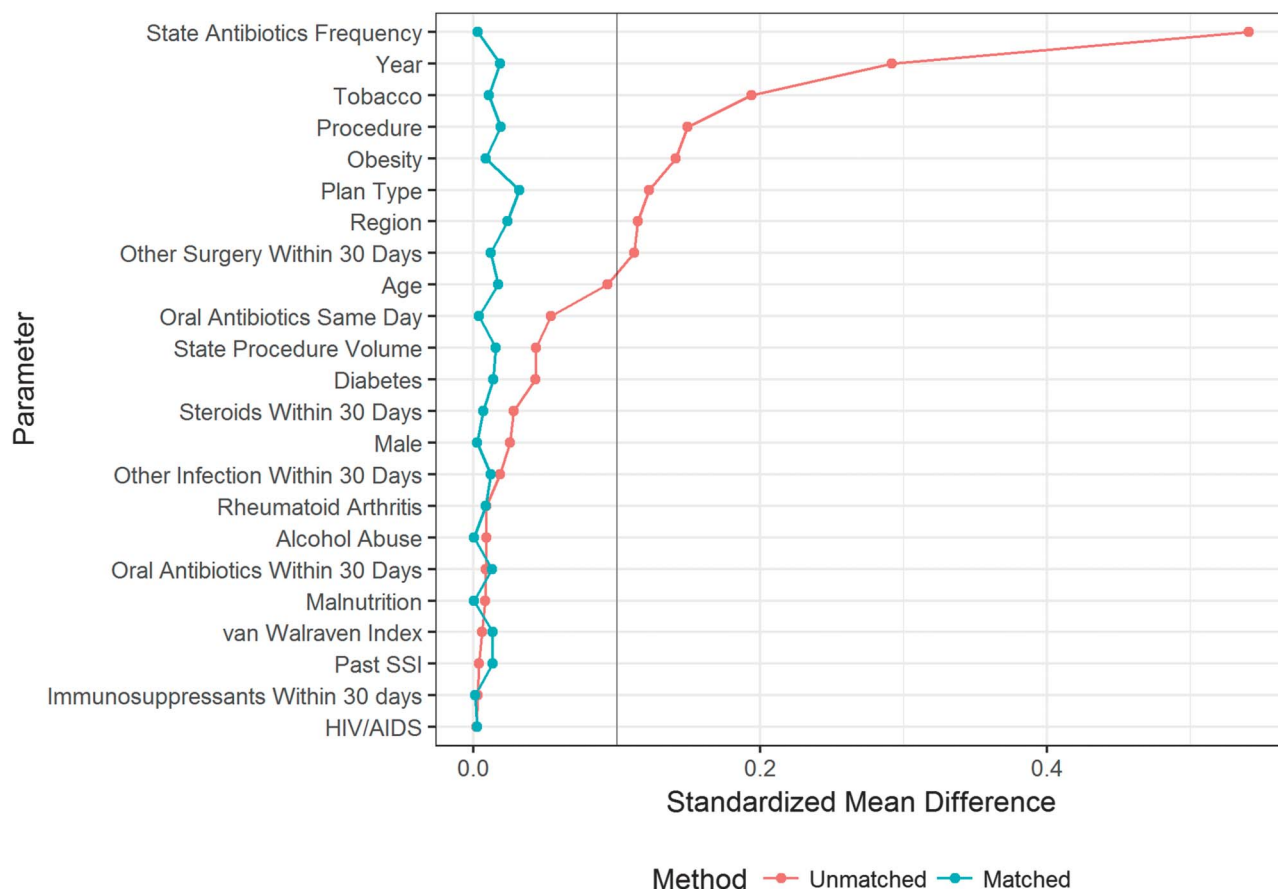


Fig. 2 To assess the improvement in covariate balance owing to propensity score matching, the standardized mean difference between cohorts across covariates was calculated before and after matching. Cohorts were considered balanced with respect to

a given covariate if the standardized mean difference was less than 0.1 (demarcated in the image with a vertical line), a common benchmark in propensity score matching studies. SSI = surgical site infection.

Results

After controlling for relevant confounding variables such as demographics, hand procedure type, medication usage, existing comorbidities (eg, diabetes, HIV/AIDS status, tobacco use, obesity), and unrelated postoperative events through propensity score matching, we found that the risk of postoperative SSI was no different between patients who had received antibiotic prophylaxis and those who had not (OR, 1.03; 95% CI, 0.93-1.13; $p = 0.585$), a result that was maintained after applying various caliper requirements to the matching algorithm (Fig. 3).

Discussion

Previous studies have cast doubt on the effectiveness of antibiotic prophylaxis in soft tissue hand surgery, showing no differences in the risk of postoperative SSI with its use

[7, 17, 26, 32]. Given low overall SSI rates, however, these studies may not be adequately powered to detect a small treatment effect from prophylaxis. We therefore aimed to revisit the hypothesis that antibiotic prophylaxis does not decrease SSI risk, using an administrative claims database to maximize sample size and propensity score matching to reduce selection bias that could otherwise result from nonrandom treatment assignment. Our analysis confirmed our hypothesis and therefore supports previously reported findings that prophylaxis does not reduce the risk of postoperative SSI.

Antibiotic prophylaxis will likely remain an important component of surgical workup in certain situations, such as in open trauma with wound contamination and in bony injury [10, 19]. The validity of this indication may be inferred from our data, which showed that the 30-day SSI rate after soft tissue mass excision procedures exceeded those of the other procedures studied; billing codes corresponding to these mass excision procedures encompass excision of tumor or vascular malformations, but

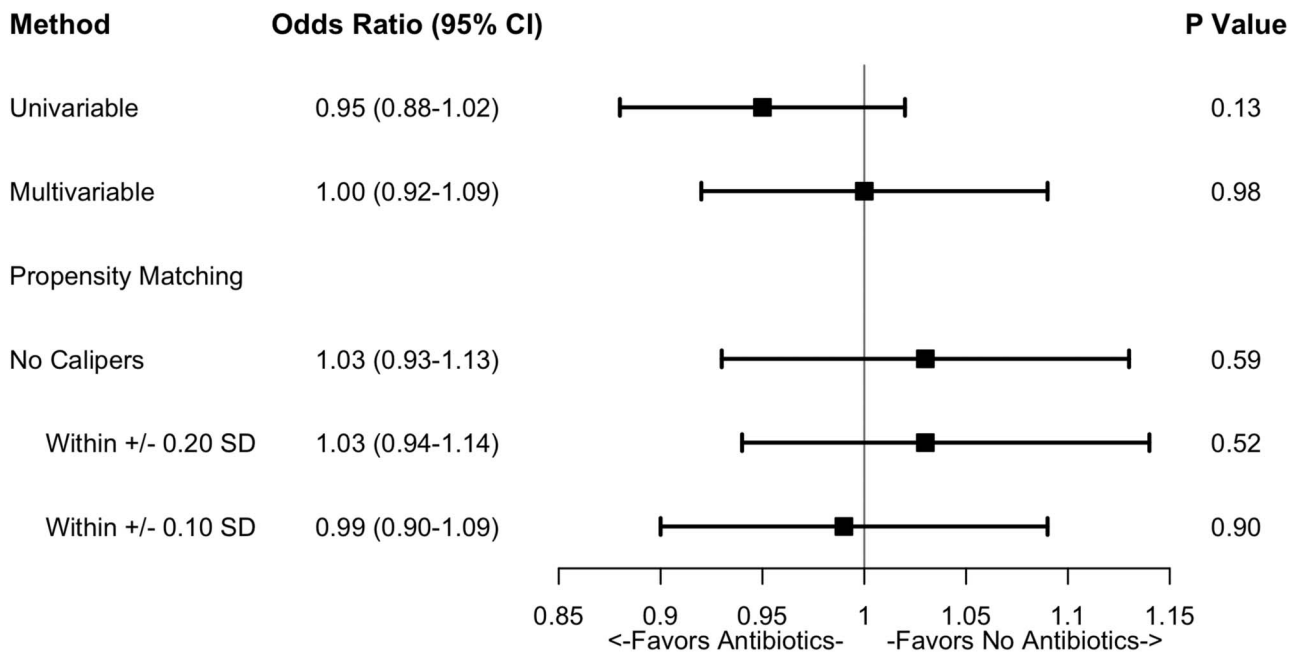


Fig. 3 The effect of antibiotic prophylaxis on the risk of surgical site infection within 30 days after surgery was assessed using unadjusted univariable logistic regression and multivariable regression before and after propensity score matching. Propensity score matching was

repeated using several caliper requirements, which limit the permissible difference in propensity scores between matched patients to improve the closeness of match. Statistical significance was assessed at a significance level of $p = 0.05$.

sometimes may be used in the excision of pyogenic granulomas, which can be associated with superficial skin infections. Even with the inclusion of patients undergoing this procedure, however, antibiotic prophylaxis was not found to have an effect in reducing the risk of postoperative SSI. Despite this result, we found that antibiotic prophylaxis was still being used in more than 10% of our study cohort, in line with the range of 10% to 48% reported by Tosti et al. [32].

This study has several limitations. As with any claims data analysis, diagnoses or interventions that may act as confounders but were not captured in billing codes could not be accounted for in multivariable and propensity score analysis. Our matching algorithm incorporated a broad range of putative risk factors for SSIs in orthopaedic surgery, spanning from existing comorbidities, to geographic variation in prophylaxis use, to treatment and patient characteristics [7, 13, 15, 21, 22]. It nevertheless is reasonable to suspect that the cohort treated with antibiotic prophylaxis represents patients at higher risk for SSI even after matching—for example, if treatment was provided preferentially to patients with an unmeasured risk factor—which could bias results toward the alternative hypothesis that there is a difference in SSI risk between the treated and untreated cohorts. However, other unobservable factors such as length of surgery, suture material, surgical technique, or timing of antibiotic administration,

may be present in both cohorts equally and bias results toward the null hypothesis [9, 20]. Inaccuracies in medical claims coding that lead to misclassification of treatment or outcome also could bias results toward the null hypothesis [33]. While such factors could be mitigated in a randomized, prospective study, we believe that the sample size necessary to detect a very small treatment effect would be difficult to attain in this setting, and that a retrospective analysis that controls for a wide range of potential confounding variables therefore is appropriate. Another limitation of our study is that we did not explore the harms or costs of not using antibiotics; SSIs can negatively affect revision rates, cost, and quality of life, and can lead to reimbursement penalties for providers [3, 23, 35]. Nevertheless, such implications must be weighed against the well-documented adverse effects of routine antibiotic administration, such as pseudomembranous colitis and the increased emergence of community-acquired methicillin-resistant *Staphylococcus aureus* strains [1, 8, 29, 31] and of antimicrobial resistance more generally [1, 29, 32]. Finally, the external validity of our study is limited by the generalizability of commercial administrative claims data, which may not be representative of other populations, such as individuals who are on Medicare or Medicaid, are uninsured, or are self-pay.

Based on the results from our analysis and on the implications of antibiotics overuse, we conclude that

antibiotic prophylaxis for common soft tissue hand procedures is not associated with a reduction in postoperative infection risk. Therefore, health systems may benefit from implementing care pathways that avoid unwarranted or routine use of antibiotics prior to common soft tissue hand surgery.

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