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Original Article

Outcomes in necrotizing soft tissue infections are worse in rural versus urban Montana: a 10-year single center retrospective review

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Abstract: Time to definitive surgical debridement has been recognized as a predictor for morbidity and mortality in necrotizing soft-tissue infections (NSTI). Rural patients are at particular risk due to limited local resources, decreased access to care, and prolonged transport times. The aim of the current study was to examine the outcomes of NSTI requiring surgical treatment in a previously non-described setting. This retrospective study (2010-2020) from a single tertiary care center in Montana reviewed patients ≥18 years old with a NSTI via ICD9/10 codes. Rural-Urban Continuum Codes (RUCC; characterizing counties by population size) were used to distinguish urban versus rural counties. Race (White and American Indian/Alaskan Native (AI/AN)) was self-described. Qualitative and quantitative comparisons between groups were determined using the appropriate two-tailed statistical tests. An aggregate of 177 patients was identified. Mean age in AI/AN was significantly lower (P<0.0001) compared to White patients with no preexisting condition delineation. NSTI demonstrated an elevated incidence in both rural areas and AI/AN patients. Diabetes was also significantly higher (P=0.0073) in rural versus urban patients. Both rural and AI/AN patients faced extended travel distance for treatment. AI/AN patients had a significantly different infection location than White. Furthermore, polymicrobial species were significantly more prevalent in AI/AN patients. Morbidities (defined as septic shock and/or amputation) were significantly higher in AI/AN patients and rural environments (P<0.01). There was no significant difference in all-cause mortality between respective groups. The state of Montana presents unique challenges to optimizing NSTI treatment due to excessive distances to regional tertiary care facilities. This delay in treatment can lead to increased morbidity.

Keywords: Necrotizing soft tissue infections, rural, trauma, emergent care

Introduction

Necrotizing soft tissue infection (NSTI) is a rare but potentially fatal disease that has been extensively reviewed in the literature [1-4]. NSTIs generally involve the muscle, fascia, or subcutaneous tissue, and are usually caused by bacterial toxins [1]. They are characterized clinically by a precipitous disease progression with significant local tissue damage [2]. Following symptom onset, disease progression is typically measured in hours [3] and a recent meta-analysis demonstrated that surgical debridement within 12 hours of presentation reduced patient mortality compared to surgery after 12 hours [5].

Thus, the gold standard [6] for treating NSTI is expeditious diagnosis, early surgical debridement of necrotic tissue, and antimicrobial treatment. To expedite diagnosis, a novel diagnostic scoring system, the Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) score [7] was developed. The score is based on total white cell counts, C-reactive protein (CRP), hemoglobin, sodium, creatinine, and glucose values, and is aimed to distinguish necrotizing fasciitis from other soft tissue infections. However, as has been noted in the literature [8], CRP value is not commonly collected in an emergency department (ED) limiting the effective utilization of the LRINEC score.

In the United States, with a current population density of approximately 88.2/mi^2 nationally, 85.3% patients live within 60 minutes of a Level I or II trauma center [9]. However, distance from a trauma center and time to treatment are well documented sources of disparity in rural care. Previous studies have demonstrated that states with poor trauma center access and increased time to treatment have a relatively higher burden of mortality [10]. However, limited literature exists describing the experience of NSTI in a rural setting to assist physician and surgeon decision-making processes [11].

The goal of this study was to evaluate NSTIs within the sparsely populated, racially, and geographically diverse rural state of Montana.

Methods

After approval from the Institutional Review Board, this study was conducted at a single rural 305-bed American College of Surgeons (ACS) verified Level II Trauma center that serves as a four-state referral center in the upper mountain west region.

NSTI criteria and data abstraction

Non-randomized data was abstracted from the hospital registry between 2010 to 2020. Inclusion criteria included all patients ≥18 years old with a NSTI via International Classification of Disease (ICD) version 9/10 code: necrotizing fasciitis (728.86/M72.6), gas gangrene (040.0/A48.0), other specified necrotizing vasculopathies (447.5/M31.8), necrotizing vasculopathy, unspecified (447.5/M31.9), necrotizing enterocolitis, unspecified (557.0/K55.30), subacute necrotizing myelitis of central nervous system (323.9/G37.4) and other acute necrotizing hemorrhagic encephalopathy (323.61/G04.39). A diagnosis of NSTI was established through a chart review identifying patients with NSTI as the primary diagnosis or additional diagnosis, surgical reports that clearly indicated the presence of necrosis in the fascia and subcutaneous tissue, or microbiological laboratory report.

Exclusion criteria for NSTI cases include those patients <18 years old or with cellulitis as the primary or additional diagnosis via ICD-9/10 (682.9/L03.90), or those not treated ultimately at the facility.

Demographic and other pertinent variables were recorded from the eligible patients. Patient morbidities were abstracted from the hospital registry, specifically amputation from the surgical report and septic shock via ICD-9/10 (785.52/R65.21).

Rural-urban continuum codes

Rural-Urban Continuum Codes (RUCC) characterizing counties by population size were used to distinguish urban (≤3) to rural (≥4) counties. Groups were also distinguished by race, with all cases self-described Caucasian/White being one, all cases within American Indian/Alaskan Native being another.

Normal lab values

As defined by [12], the following values were used as normal for a mixed adult population laboratory values: Total white blood count, 4.5-11 mm^3; hemoglobin, 13-17 g/dL; serum sodium, 136-145 mmol/L; serum creatinine, 52.5-100 μmol/L; 2 hr postpandrial glucose, <7.8 mmol/L.

Laboratory risk indicator for necrotizing fasciitis (LRINEC) score

As defined in [7], the following criteria are required for the model: C-reactive Protein (mg/L) ≥150 scores 4 points (not standardly taken at the study facility Emergency Department); total white cell count (per mm^3) between 15-25 scores 1 point, and >25 scores 2 points; hemoglobin (g/dL) between 11-13.5 scores 1 point, and <11 scores 2 points; serum sodium (mmol/L) <135 scores 2 points; creatinine (μmol/L) >141 scores 2 points; and glucose (mmol/L) >10 scores 1 point. The points are summed to a maximum of 13, a score ≥6 raises suspicion of necrotizing fasciitis (NF), and a score ≥8 is strongly predictive of NF [7].

Standardized incidence ratios

The NSTI Standardized Incidence Ratios (SIR) were also derived and compared using total adult population (≥18 years old) for each county based on 2010 Census (US Census Bureau). Standardized Incidence Ratios (SIR) [13] are generally used when disease incidences in a study cohort are being compared to the disease incidences in the reference population. The SIR, a statistic, is the ratio of the observed

number of cases in the study cohort to the expected number of cases in the general population, such as the general population of a geographic region from which the study cohort was selected. An SIR greater than 1 indicates disease incidences in the cohort under study exceeds what is expected in the general population. Generally, a 95% Confidence Interval for SIR is constructed to determine if incidence rates in the cohort are significantly greater than expected incidence rates. An interval with lower end greater than 1 indicates significantly higher SIR in the cohort compared to the reference population.

Statistics

All analyses were performed using statistical computing software R (R Foundation for Statistical Computing, Vienna, Austria). Variables were summarized using descriptive statistics. Counts and percentages were used for categorical variables. Means and standard deviations were used to summarize continuous variables. Demographic and other outcome variables were compared between urban and rural, and between White and AI/AN. Statistical inference was made by constructing 95% confidence and/or testing hypothesis at 5% significance level. Quantitative variables were compared using two-sample t-test. The two-sample t-test determines if the (unknown) population means of two groups being compared are equal. Welch's test, a corrected version of two sample t-test, is used to evaluate the equality of the means when the assumption of homogeneity is violated. Percentages were compared using two-sample z-test. Independency of the groups was tested using Pearson's chi-square test or Fisher exact test when observed counts were less than five. The significance of the SIRs was compared among groups with 95% confidence interval. All *p*-values less than 5% were considered statistically significant.

Results

Demographics

Across the 10 years of this retrospective study, a total of 177 eligible patients were identified. Partitioning the patients by their home county, 45.2% (*n*=80) were urban (RUCC ≤3) and 54.8% (*n*=97) rural (RUCC ≥4). Applying self-descriptive race, the groups consisted of 65.5% (*n*=116) White and 28.3% (*n*=50) American Indian/Alaskan Native (AI/AN); of the remaining 6.2% patients, seven were undeclared/unknown race, three Black/African American and one Asian patient.

Comparison of demographic variables, hospital and ICU stay, distance to regional trauma center, Charlson Score, and SIR are presented in **Table 1**. Patient ages were similar between urban and rural environments; however, AI/AN patients (51.5, 95% CI [47.3, 55.7]) were significantly younger ($P<0.001$) than White patients (63.1, 95% CI [60.0, 66.3]). Rural patients in this study travelled over five times greater distances than their urban counterparts, and AI/AN patients had to travel 57% farther than White patients for tertiary treatment. This indicates an extended distance travelled for treatment by those living in rural areas and AI/AN patients across the 10 years of the study. The incidence of NSTI was significantly elevated in rural areas and in AI/AN patients ($P<0.0001$).

Tertiary facility laboratory values upon arrival

Across all groups displayed in **Table 2**, the mean total white blood cell (WBC) counts, and serum creatinine were elevated, compared to both normal adult reference and the LRINEC scoring system normal values, with no significant variations between the groups. Although compared to normal reference ranges glucose was elevated for all groups, only the rural patient group was elevated in the context of the LRINEC scoring system.

Across the study groups, serum sodium was below normal adult reference values and the LRINEC scoring system normal values with similarity across all groups.

The mean hemoglobin values were low in the urban, rural, and especially in AI/AN patients. Of note, is the significant difference between white and AI/AN patients ($P=0.0048$).

Preexisting conditions

There were no significant differences between urban and rural patients, or White and AI/AN patients with respect to preexisting conditions such as hypertension, anemia, thyroid disease, renal disease, or obesity. Although there was no difference between races for diabetes,

Table 1. Demographics

	Total Montana Patients			Race		
	Urban (RUCC ≤3; n=80)	Rural (RUCC ≥4; n=97)	*p* Value	White (n=116)	American Indian/Alaskan Native (n=50)	*p* Value
Mean Age [95% CI]	57.9 [53.9, 61.8]	60.5 [57.2, 63.9]	0.3118	63.1 [60.0, 66.3]	51.5 [47.3, 55.7]	**<0.0001**
Sex, Female n (%)	41 (51.3%)	41 (42.3%)	0.2330	55 (47.4%)	20 (40.0%)	0.3686
Mean hospital LOS, days [95% CI]	8.6 [6.0, 11.2]	11.7 [8.9, 14.5]	0.1075	9.4 [7.2, 11.7]	13.9 [9.7, 18.1]	0.0651
Mean ICU LOS, days (n) [95% CI]	4.4 (16) [0.65, 8.12]	6.7 (19) [3.7, 9.8]	0.3117	5.0 (23) [2.1, 7.9]	6.9 (12) [2.8, 11.0]	0.4266
Mean Charlson Score (n) [95% CI]	2.0 (55) [1.5, 2.4]	2.1 (52) [1.6, 2.6]	0.6782	2.1 (72) [1.7, 2.5]	2.0 (30) [1.3, 2.6]	0.6983
Mean Distance to State Regional Trauma Center in Miles [95% CI]	43.2 [24.8, 61.7]	244.3 [222.1, 266.6]	**<0.0001**	126.3 [102.0, 150.6]	198.4 [158.0, 239.2]	**0.0032**
NSTI Incidence/100,000 Pt/years (Standardized Incidence Ratio, 95% CI)	2.5	5.3 SIR=1.72, 95% CI [1.4, 2.1]	**<0.0001**	3.1	21.1 SIR=28.3, 95% CI [21.0, 37.3]	**<0.0001**

Rural-Urban Continuum Codes (RUCC; characterizing counties by population size). Bolded text *p* values <0.05 were considered significant.

Table 2. Laboratory values from the tertiary facility

	Total Montana Patients			Race		
	Urban (RUCC ≤3; n=80)	Rural (RUCC ≥4; n=97)	*p* Value	White (n=116)	American Indian/Alaskan Native (n=50)	*p* Value
Mean total white cell count, mm^3 [95% CI]	15.6 [13.7, 17.5]	16.9 [13.6, 20.2]	0.5980	16.9 [14.0, 19.8]	15.8 [13.4, 18.2]	0.6765
Mean Hemoglobin, g/dL [95% CI]	11.8 [11.2, 12.4]	11.3 [10.7, 11.8]	0.3254	12.1 [11.6, 12.6]	10.6 [9.9, 11.4]	**0.0048**
Mean Sodium, mmol/L [95% CI]	133.3 [132.1, 134.5]	133.3 [132.2, 132.5]	0.9663	133.1 [132.1, 134.1]	133.4 [131.8, 134.9]	0.8315
Mean Creatinine, µmol/L [95% CI]	134.3 [104.1, 164.4]	173.9 [132.6, 215.2]	0.2418	134.8 [111.8, 157.8]	197.8 [128.9, 266.7]	0.0719
Mean Glucose, mmol/L [95% CI]	8.4 [7.4, 9.4]	10.7 [9.2, 12.2]	0.0510	9.9 [8.6, 11.1]	9.5 [8.0, 11.1]	0.7835

Rural-Urban Continuum Codes (RUCC; characterizing counties by population size). Bolded text *p* values <0.05 were considered significant. To convert glucose values to mg/dL, multiply by 18.015. To convert creatinine values to mg/dL, multiply by 0.01131 [7].

Table 3. Foremost patient preexisting conditions

	Total Montana Patients			Race		
	Urban (RUCC ≤3; n=80)	Rural (RUCC ≥4; n=97)	*p* Value	White (n=116)	American Indian/Alaskan Native (n=50)	*p* Value
Preexisting Conditions						
[Δ]All Diabetes, n (%)	26 (32.5%)	51 (52.6%)	**0.0073**	48 (41.4%)	28 (56.0%)	0.0828
Hypertension, n (%)	40 (50.0%)	48 (49.5%)	0.9456	64 (55.2%)	22 (44.0%)	0.1863
Anemia, n (%)	11 (13.8%)	21 (21.7%)	0.1741	18 (15.5%)	12 (24.0%)	0.1925
Thyroid, n (%)	12 (15.0%)	19 (19.6%)	0.4242	21 (18.1%)	9 (18.0%)	0.9873
[‡]All Kidney, n (%)	15 (18.8%)	22 (22.7%)	0.5222	22 (19.0%)	15 (30.0%)	0.1171
Obesity, n (%)	13 (16.3%)	23 (23.7%)	0.2197	26 (22.4%)	9 (18.0%)	0.5224

[Δ]All Diabetes includes Diabetes, Type I, Type II, and Diabetes Mellitus. [‡]All Kidney includes chronic kidney disease, acute kidney injury, acute kidney failure, chronic kidney failure. Rural-Urban Continuum Codes (RUCC; characterizing counties by population size). Bolded text *p* values <0.05 were considered significant.

Table 4. Infection locations and predominant microbial genera

	Total Montana Patients			Race		
	Urban (RUCC ≤3)	Rural (RUCC ≥4)	*p* Value	White	American Indian/ Alaskan Native	*p* Value
Body Location	n=53	n=74		n=78	n=46	
Head/Neck, n (%)	2 (3.8%)	3 (4.1%)	0.9523	3 (3.8%)	2 (4.3%)	0.8909
Trunk/Torso, n (%)	30 (56.7%)	30 (40.6%)	0.1079	43 (55.1%)	14 (30.4%)	**0.0132**
Upper Extremities, n (%)	14 (26.4%)	10 (13.5%)	0.1093	14 (18.0%)	9 (19.6%)	0.9832
Lower Extremities, n (%)	21 (39.6%)	43 (58.1%)	0.0608	32 (41.0%)	31 (67.4%)	**0.0080**
Predominant Reported Microbial Genera	n=80	n=97		n=116	n=50	
Streptococcus, n (%)	23 (28.8%)	29 (29.9%)	0.9993	29 (37.2%)	23 (50.0%)	**0.0126**
Staphylococcus, n (%)	23 (28.8%)	29 (29.9%)	0.9993	32 (41.0%)	17 (37.0%)	0.5185
Prevotella, n (%)	11 (12.5%)	10 (11.3%)	0.9968	12 (15.4%)	9 (19.6%)	0.2684
Enterococcus, n (%)	4 (5.0%)	11 (11.3%)	0.2164	6 (7.7%)	8 (17.4%)	**0.0456**
Pseudomonas, n (%)	5 (6.3%)	4 (4.1%)	0.7664	6 (7.7%)	3 (6.5%)	0.9985
Polymicrobial Infections, n (%)	22 (27.5%)	29 (29.9%)	0.8543	26 (33.3%)	23 (50.0%)	**0.0041**

Rural-Urban Continuum Codes (RUCC; characterizing counties by population size). Bolded text *p* values <0.05 were considered significant.

patients living in rural areas had significantly greater rates of diabetes than those living in urban areas (51 vs 26%, *P*=0.0073; **Table 3**).

Location of infection and microbial genus

Of the 177 patients within the study, 127 patients had defined body areas listed within the electronic health record for NSTI. Disease presentation was similar for head/neck, trunk/torso, and upper extremities between urban and rural patients. However, rural patients had a much greater rate of lower extremity NSTI compared to urban patients (43 vs 21%, *P*= 0.06) (**Table 4**). White patients had a significantly greater number of infections in the trunk/torso, compared to AI/AN patients, whereas AI/AN patients had significantly more NSTIs in the lower extremities (*P*<0.05).

Across the patients included within this study, samples taken for microbiological laboratory analysis included numerous microbial genera, and thus, only the major genera are listed. Between urban and rural patients, there were no differences in the reported microbial genera. However, AI/AN patients showed significantly more streptococcus and enterococcus infections. Furthermore, AI/AN patients had significantly greater percentage of polymicrobial infections than their White counterparts (*P*=0.004).

Morbidity and mortality

As shown in **Table 5**, extremity amputation occurred significantly more often in rural and AI/AN patients (*P*=0.0193). In addition, septic shock was shown to occur over four times more

Table 5. Morbidity and mortality

	Total Montana Patients			Race		
	Urban (RUCC ≤3; n=80)	Rural (RUCC ≥4; n=97)	*p* Value	White (n=116)	American Indian/ Alaskan Native (n=50)	*p* Value
Amputations, n (%)	8 (10.0%)	24 (24.7%)	**0.0193**	14 (12.1%)	17 (34.0%)	**0.0019**
Septic Shock, n (%)	2 (2.5%)	11 (11.3%)	**0.0394**	4 (3.5%)	9 (18.0%)	**0.0028**
Morbidity defined as Amputation and/or Septic Shock, n (%)	10 (12.5%)	31 (32.0%)	**0.0040**	18 (15.5%)	22 (44.0%)	**0.0002**
Preexisting Conditions and Morbidity (Amputation and/or Septic Shock)	n=10	n=31		n=18	n=22	
[Δ]All Diabetes, n (%)	8 (80.0%)	25 (80.7%)	1.0000	13 (72.2%)	19 (86.4%)	0.4295
Hypertension, n (%)	9 (90.0%)	21 (67.7%)	0.2385	13 (72.2%)	16 (72.7%)	1.0000
Anemia, n (%)	3 (30.0%)	9 (29.0%)	1.0000	5 (27.8%)	6 (27.3%)	1.0000
Thyroid, n (%)	2 (20.0%)	10 (32.3%)	0.6937	4 (12.9%)	7 (31.8%)	0.7235
[‡]All Kidney, n (%)	4 (40.0%)	12 (38.7%)	1.0000	5 (27.8%)	11 (50.0%)	0.2026
Obesity, n (%)	3 (30.0%)	7 (22.6%)	0.6834	6 (33.3%)	4 (18.2%)	0.3003
All-cause Mortality, n (%)	19 (23.8%)	26 (26.8%)	0.7711	29 (25.0%)	14 (28.0%)	0.8324

[Δ]All Diabetes includes Diabetes, Type I, Type II, and Diabetes Mellitus. [‡]All Kidney includes chronic kidney disease, acute kidney injury, acute kidney failure, chronic kidney failure. Rural-Urban Continuum Codes (RUCC; characterizing counties by population size). Bolded text *p* values <0.05 were considered significant.

in rural vs urban patients and occurred five times more in AI/AN patients vs White ($P<0.05$).

Morbidities (defined as amputation and/or septic shock) were significantly increased in rural environments and AI/AN patients. While many patients with morbidity had pre-existing conditions that predisposed them to the NSTI, there was no difference in their incidence when comparing urban vs rural, or White vs AI/AN ($P>0.05$).

Forty-five patients died, with an overall mortality of 25.4%, of which 37 patients had at least one preexisting condition (82.2%). There was no significant difference in all-cause mortality when comparing rural vs urban, or White vs AI/AN ($P>0.7$).

Discussion

The current study evaluated the outcomes of NSTI requiring surgical treatment in the context of diverse urban-rural settings. Although population-based studies have been reported on NSTIs [14], the present study is, to our knowledge, the first description of rural NSTI trends within a sporadically populated region in the United States (US). For example, studies covering the US from 1998-2010 show an overall NSTI incidence rate of 1.5 cases/100,000 patients/year [15], with more current literature putting this closer to 9.5 cases/100,000 patients/year [16]. The overall NSTI incidence rate for all patients within this study was 3.3 cases/100,000 patients/year and was markedly increased to 5.3 cases for rural populations.

Deaths from NSTI have been shown to be disproportionally greater in minority populations such as Black, Hispanic, and American Indian individuals compared to White [17]. In the current study, AI/AN patients have seven times the NSTI incidence of White patients and are over a decade younger at the time of diagnosis. Additionally, the significantly lower age for AI/AN patients compared to Whites is similar to the age range seen in both AI/AN in Arizona [18] and remote First Nations communities in Canada [19].

As mentioned in the literature [8], CRP is not a standard protocol in the ED nor the facility where this study was conducted, thus 85.9% of the study population had no CRP value to follow the LRINEC scoring system. Yet, in utilizing the LRINEC score without a CRP value for all study participants: 4 patients would be considered a high risk (LRINEC score ≥8), 22 a moderate risk (LRINEC score 6-7) and the remaining patients a low risk (LRINEC score ≤5).

In this study, tissue cultures for AI/AN patients were much more frequently streptococcus and enterococcus in origin, compared to White patients. Furthermore, the AI/AN patients had a greater percentage of polymicrobial infections. Group A streptococci (GAS) have been shown to cause severe invasive diseases including NSTI, and the risk for invasive GAS infection is 10 times higher among First Nations communities in Canada than among the general population [19]. An important characteristic of the genus Enterococcus is the high level of intrinsic antibiotic resistance [20]. In the last two decades, particularly virulent strains of Enterococcus that are resistant to vancomycin (vancomycin-resistant Enterococcus (VRE)) have emerged in nosocomial infections of hospitalized patients [21].

Prompt surgical debridement within 6 hours lowers mortality of NSTI by 50% [5] and delays in surgical debridement due to interhospital transfers increase risk of in-hospital mortality [22]. As a tertiary care facility in a sparsely populated rural state, approximately 50% of the trauma patient population at this facility are interhospital transfers. As shown, the rural patient group travels almost 200 miles farther than the urban group, and the AI/AN patient group travels almost 75 miles farther than White patient group to the tertiary facility. Further, although across the groups the majority of the laboratory values shown are outside of normal values, they are similar between the groups. However, assessing the mean laboratory values with the LRINEC scoring system, those patient groups who travel further have a higher LRINEC score (rural and NA/AI; 7), than those significantly closer (urban and white patients; 4). While rural and AI/AN groups did not have an increased mortality from NSTI, there were significantly greater incidences of amputations and septic shock suggesting that transport distances were also potential contributing factors.

Once diagnosed, the mainstay treatment of NSTI is appropriate resuscitation and antibiot-

ics, along with prompt and aggressive surgical debridement [4]. However, many primary/initial healthcare facilities in rural Montana have minimal surgical support. In a study across 1981-2005, the overall supply of general surgeons per 100,000 population declined in those two decades, and small and isolated rural areas of the United States continue to have significantly fewer general surgeons per 100,000 population than urban areas [23]. As a result, rural patients who require emergent surgical procedures, such as NSTI debridement, in Montana are at a disadvantage and face serious risk of increased morbidity and mortality.

Conclusion

Lack of surgical providers in rural healthcare facilities, excessive distances to regional tertiary care facilities, and racial disparities within rural areas present unique challenges to optimizing NSTI treatment and outcomes in the state of Montana.

Limitations

This was a non-randomized, retrospective, observational, single-center study which may be subject to selection and/or surveillance bias. As a retrospective analysis, the project could be subject to some intrinsic limitations including inconsistency in the definition of an NSTI, the potential for missed enrollment due to possible errors in documentation and varying adherence to the institutional practice recommendations which could have resulted in selection bias.

Disclosure of conflict of interest

None.

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