Prospective Cohort Study of Incidence and Risk Factors for Catheter-Associated Urinary Tract Infections in 212 Intensive Care Units of 9 Middle Eastern Countries: INICC Findings

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Abstract

Objectives: Identify urinary catheter (UC)-associated urinary tract infections (CAUTI) incidence and risk factors (RF) in 9 Middle Eastern Countries.

Methods: We conducted a prospective cohort study, between 01/01/2014 and 02/12/2022, in 212 ICUs of 67 hospitals in 38 cities in 9 Middle Eastern countries (Bahrain, Egypt, Jordan, Kuwait, Lebanon, Morocco, Saudi Arabia, Turkey, United Arab Emirates). To estimate CAUTI incidence, we used number of UC-days as denominator, and number of CAUTIs as numerator. To estimate CAUTI RFs, we analyzed the following 10 variables using multiple logistic regression: Gender, age, length of stay (LOS) before CAUTI acquisition, UC-days before CAUTI acquisition, UC-device utilization (DU) ratio, hospitalization-type, ICU type, facility-ownership, country income level classified by World Bank, and time period.

Results: 50,637 patients, hospitalized 434,523 patient-days, acquired 580 CAUTIs. The pooled CAUTI rate per 1,000 UC-days was 1.84. The following variables were independently associated with CAUTI: Age, rising risk 1% yearly (adjusted odds ratios [aOR]=1.01;95%CI=1.01-1.02; p<0.0001); female gender (aOR=1.31;95%CI=1.09-1.56;p<0.0001); LOS before CAUTI acquisition, rising risk 6% daily (aOR=1.06;95%CI=1.05-1.06;p<0.0001); UC/DU ratio (aOR=1.11;95%CI=1.06-1.14;p<0.0001). Lower-middle income countries (aOR=4.11;95%CI=2.49-6.76;p<0.0001) had a similar risk to upper-middle countries (aOR=3.75;95%CI=1.83-7.68;p<0.0001), but both were higher risk factors compared to high-income countries. The ICU with the highest risk for CAUTI was Neurologic ICU (aOR=27.35;95%CI=23.03-33.12;p<0.0001), followed by Medical ICU (aOR=6.18;95%CI=2.07-18.53;p<0.0001) when compared to cardiothoracic ICU. The time period 2014–2016 (aOR=7.36;95%CI=5.48-23.96; p<0.0001) and the time period 2017–2019 (aOR=1.15;95%CI=3.46-15.61; p<0.0001) had a similar risk to each other, but a higher risk when compared to the time period 2020-2022.

Conclusion: The following CAUTI RFs are unlikely to change: age, gender, ICU type, and country income level. Based on these findings it is suggested to focus on reducing LOS, UC/DU ratio, and implementing evidence-based CAUTI prevention recommendations.

Keywords: Catheter-Associated Urinary Tract Infections; Risk Factors; Intensive Care Units; INICC; Incidence; Rates.

Introduction

Low- and middle-income countries (LMICs) have been found to have higher rates of catheter-associated urinary tract infections (CAUTIs) than high-income nations[1,2]. According to a publication from the International Nosocomial Infection Control Consortium (INICC), there were 3.16 CAUTIs for every 1,000 UC-days in LMICs[2]. A report from the CDC National Healthcare Safety Network (NHSN) reported 1.3 CAUTIs per 1,000 urinary catheter (UC)-days[3].

CAUTI are an independent, significant risk factor for mortality in ICU, according to recent studies[4-6]. According to an investigation, mortality rates for ICU patients without any healthcare-associated infections (HAI) are 17.1%, CAUTI mortality rates are 30.15%, and CAUTI combined with central line-associated bloodstream infections and ventilator-associated pneumonia results in a mortality rate of 63.4%[2]. Twenty-eight community hospitals in the Southeast of the United States were found to have a median yearly cost of HAIs per facility of $594,683, with CAUTIs accounting for a mean of $758 per infection[7].

Other studies identified the following variables as CAUTI risk factors (RFs): female gender[8]; age > 60[9]; length of catheterization[10,11]; and poor hygiene[12]. During a cross-sectional study at Bugando Medical Centre, Ndomba, A. L. M., et al. (2022) conducted a study that showed outpatient settings as a higher risk factor for CAUTI than inpatient settings. Individual risk factors for those outpatients included older age, level of education, and duration of the catheter[13], Sulaiman K.A., et al. (2022) found type-O blood type to be a protective factor for CAUTI and non-O blood type as a risk factor[14].

Nevertheless, no study has simultaneously looked at many Middle Eastern nations to find CAUTI RFs in ICUs. In addition, no prospective study has been done over 8 years. Additionally, no study has examined simultaneously the relationships between the ten variables listed below and their association with CAUTI: (1) age, (2) gender, (3) length of stay (LOS) prior to CAUTI acquisition, (4) UC-days prior to CAUTI acquisition, (5) UC-device utilization (DU) ratio as a marker of patient illness severity, (6) hospitalization type, (7) ICU type, (8) facility ownership, (9) income level of the country according to world bank and (10) time period. The objectives of this study are to provide CAUTI rates stratified by various variables, and determine whether the aforementioned ten variables are CAUTI RFs.

Methods

Between January 1, 2014, and February 12, 2022, patients admitted to 212 ICUs at 67 hospitals spread across 38 cities in 9 Middle Eastern nations (Bahrain, Egypt, Jordan, Kuwait, Lebanon, Morocco, Saudi Arabia, Turkey, United Arab Emirates) participated in this multinational, multi-center, cohort, prospective study.

The INICC Surveillance Online System (ISOS), an online platform that incorporates CDC/NHSN standards and procedures, is used for INICC CAUTI surveillance[3]. Additionally, ISOS gathers patient-specific data on all patients, with and without CAUTI[15]. Data from all patients admitted to the ICU allow matching by multiple variables to determine CAUTI RFs.

Data for each patient were gathered at the time of ICU admission. From the moment of admission till discharge, infection prevention professionals (IPP) visited at each patient's bedside every day. Data on all prospectively included patients who were admitted to an ICU were collected using the ISOS. IPPs bring a tablet to the ICU bedside of every hospitalized patient, login in to ISOS, and upload the patient's data[15].

In addition to patient information, such as gender, age, hospitalization type, and the use of invasive devices, the information provided at the time of patient admission also includes location-specific information, including the setting, country, city, admission date, and ICU type. IPPs upload data about the patient's invasive devices and positive cultures up until the patient is discharged. A specialist in infectious diseases approaches the patient to determine if there is a HAI if the patient exhibits all required criteria. The ISOS instantly shows an alert and refers the IPP to an online module where they may check all the CDC NHSN criteria to validate the existence and type of HAI when IPPs upload the results of the culture to the system[15]. The participating hospitals' IRBs authorized this study with their approval. The patients' and hospital's names are kept anonymous.

Healthcare-associated infection: The CDC's definitions of HAI in 1991 and all their subsequent updates through 2022 were utilized during surveillance[3]. The current and updated CDC definition of HAIs has been used by all IPPs of all participant hospitals over the 8 years of this study. That is, our IPPs started using the newly revised definitions whenever the CDC updated them[3].

Catheter-associated urinary tract infections: A urinary tract infection (UTI) where an indwelling urinary catheter was in place for more than two consecutive days in an inpatient location on the **date of event**, with day of device placement being Day 1, ***AND*** an indwelling urinary catheter was in place on the date of event or the day before. If an indwelling urinary catheter was in place for more than two consecutive days in an inpatient location and then removed, the date of event for the UTI must be the day of device discontinuation or the next day for the UTI to be catheter-associated[3].

Indwelling Urinary Catheter (IUC): A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags). These devices are also often called Foley catheters. Indwelling urinary catheters (IUC) that are used for intermittent or continuous irrigation are also included in CAUTI surveillance[3].

Urinary catheter / device utilization Ratio: UC/DU was calculated as a ratio of UC-days to patient-days for each location type. As such, the UC/DU of a location measures the use of invasive devices and constitutes an extrinsic CAUTI RF. UC/DU ratio also serve as a marker for the severity of illness of patients which is an intrinsic RF for HAI[3].

Publicly owned facilities (owned or controlled by a public corporation or a governmental body, where control is the capacity to decide on the corporate strategy); ***not-for-profit privately owned facilities*** (legal or social organizations established for the exclusive goal of creating goods and services, whose legal position prohibits them from serving as a source of revenue, profit, or other financial gains for the unit(s) that established, controlled, or financed them); and, ***for-profit privately owned facilities*** (legal organizations created to produce goods and services with the potential to bring in a profit or other financial gains for their owners)[16].

To estimate rates of CAUTI per 1,000 UC-days, we divided the number of CAUTIs by the number of UC-days, and multiplied the result by 1,000.

To estimate CAUTI RFs, using multiple logistic regression, patients with and without CAUTI were compared. We analyzed the following ten variables and its association with the outcome (CAUTI): age; gender; LOS before CAUTI acquisition; UC-days before CAUTI acquisition; UC/DU ratio as a marker of severity of illness of patient; hospitalization type (medical, surgical); ICU type (cardio-thoracic, neurologic, neuro-surgical, adult-oncology, medical, medical-surgical, pediatric, respiratory, surgical, trauma, coronary, pediatric-oncology); facility ownership (publicly owned, not-for-profit privately owned, for-profit privately owned, teaching hospitals)[16]; and time period (period 1: 1998 to 2001, period 2: 2002 to 2005, period 3: 2006 to 2009, period 4: 2010 to 2013, period 5: 2014 to 2017, and period 6: 2018 to 2022). We didn't analyze the impact of UC type because the use of suprapubic catheters was less than 1%, showing a lack of balance with indwelling catheters. The evaluated outcome was the acquisition of CAUTI according to CDC/NHSN definitions[3].

Statistically significant variables were independently associated with an increased risk for CAUTI. The Wald test was employed as the test statistic, and a two-sided .05 Type I error rate was chosen as the level of statistical significance. The adjusted odds ratios (aORs) and associated 95% confidence intervals (CIs) for statistically significant factors were calculated from the results of multiple logistic regression. All statistical analyses were performed using R software, version 4.1.3.

Results

An international, multicenter, cohort, prospective surveillance study of CAUTIs was carried out in 212 ICUs of 67 hospitals in 38 cities, across 9 Middle Eastern nations participating in INICC from January 1, 2014, to February 12, 2022: Bahrain, Egypt, Jordan, Kuwait, Lebanon, Morocco, Saudi Arabia, Turkey, United Arab Emirates.

In this cohort research, 50,637 patients had 580 CAUTIs across 434,523 patient days. Data on the setting and the patient are presented in Table 1. Table 2 displays the stratified CAUTI rate by ICU type, facility ownership type, country economic level as determined by the World Bank, and UC type.

Table 1: Setting and patient characteristics.

Data collected from January 1st 2014 to February 12th 2022

Patient characteristics	
Total patients, n	50,637
Total patients-days, n	434,523
Average LOS, mean, SD	*M*= 8.58, *SD*= 11.47
Gender, n (%)	
Male	41,261 (81.48%)
Female	9,376 (18.52%)
Age, mean, SD	*M*= 43.37, *SD*= 27.51
Survival status, n (%)	
Alive	41,261 (81.48%)
Death	9,376 (18.52%)
Number of patients per Hospitalization type	
Medical hospitalization, n (%)	37,889 (74.82%)
Surgical hospitalization, n (%)	12,748 (25.18%)
CAUTI, n	580
Invasive device utilization	
UC-utilization ratio, mean, SD	*M*= 0.65, SD= 0.79
Total UC-days, n, mean, SD	293,970, *M*= 5.92, SD= 9.86
Number of UC-days per type of UC	
Indwelling catheter, n (%)	292,915 (99.64%)
Suprapubic catheter, n (%)	1,055 (0.36%)
Setting characteristics	
ICUs, n	212
Number of patients admitted per type of ICU, n (%)	
Medical-Surgical ICU	29,807 (58.86%)
Pediatric ICU	4,508 (8.90%)
Cardio-thoracic ICU	2,371 (4.68%)
Coronary ICU	3,741 (7.39%)
Medical ICU	3,593 (7.10%)
Neuro-Surgical ICU	86 (0.17%)
Neurologic ICU	185 (0.37%)
Adult-Oncology ICU	3,131 (6.18%)
Pediatric-Oncology ICU	1,463 (2.89%)
Respiratory ICU	44 (0.087%)
Surgical ICU	1,665 (3.29%)
Trauma ICU	43 (0.085%)
Hospitals, n	67
Cities, n	38
Countries, n	9
Number of countries, stratified per income level according to World Bank	
Lower middle income country	2 (22.22%)
Upper middle income country	3 (33.33%)
High income country	4 (44.44%)
Number of patients admitted per facility ownership, n (%)	
Publicly owned facilities	30,250 (59.74%)
For-profit privately owned facilities	8,193 (16.18%)
Teaching hospitals	12,194 (24.08%)

ICU = intensive care unit; UC = urinary catheter; DU= device utilization; LOS = length of stay; CAUTI = Catheter associated urinary tract infections; SD = standard deviation

Table 2: Catheter associated urinary tract infections rates stratified per ICU type, per facility ownership type, and per urinary catheter type.

	Patients, *n*	**Patient days, *n***	**UC-days, *n***	**CAUTIs, *n***	**CAUTI rate [a]**	**95% CI**
ICU type [b]						
Neuro-surgical	86	1,487	937	6	6.41	6.24-6.57
Neurologic	185	2,111	1,980	11	5.55	5.45-5.66

Respiratory	44	573	366	2	5.46	5.22-5.71
Coronary	3,741	22,355	5,438	23	4.22	4.17-4.28
Medical	3,593	32,515	21,909	79	3.61	3.58-3.63
Trauma	43	593	327	1	3.05	2.87-3.25
Surgical	1,665	15,819	10,165	31	3.04	3.01-3.08
Pediatric	4,508	39,418	12,278	32	2.61	2.57-2.64
Adult-oncology	3,131	15,290	13,652	34	2.49	2.46-2.52
Medical-surgical	29,807	276,599	220,718	354	1.61	1.59-1.62
Cardio-thoracic	2,371	19,079	7,761	6	0.77	0.75-0.79
Pediatric-oncology	1,463	8,684	4,277	1	0.23	0.21-0.25
Lower-middle income						
Pooled	4,941	44,030	19,263	53	2.75	2.72-2.77
Publicly owned facilities	190	1,387	983	0	0	NA
For-profit privately owned facilities	1,065	6,471	4,300	39	9.06	8.98-9.16
Teaching hospitals	3,686	36,172	13,980	14	1.01	0.98-1.02
Upper-middle income						
Pooled	13,164	98,630	78,046	193	2.47	2.46-2.48
Publicly owned facilities	25	463	188	2	10.64	10.17-11.12
For-profit privately owned facilities	4,631	25,166	18,002	35	1.94	1.92-1.97
Teaching hospitals	8,508	73,001	59,856	156	2.61	2.59-2.62
High income						
Pooled	32,532	291,863	202,499	334	1.64	1.64-1.67
Publicly owned facilities	30,035	269,958	188,224	324	1.72	1.71-1.73
For-profit privately owned facilities	2,497	21,905	14,275	10	0.71	0.68-0.72
Urinary catheter type (pooled)	36,021	345,316	293,970	543	1.84	1.83-1.85
Indwelling catheter	35,903	344,086	292,915	541	1.85	1.84-1.86
Suprapubic catheter	118	1230	1055	2	1.89	1.81-1.98

ICU = intensive care unit; CI = confidence interval UC = urinary catheter; CAUTI = Catheter associated urinary tract infection; CI = confidence interval.

a- Rate of catheter associated urinary tract infection per 1,000 urinary catheter-days

b- ICUs are listed in order of the highest to lowest ***c****atheter associated urinary tract infections* ***rate***

Using multiple logistic regression, the following variables were identified as significantly associated with CAUTI **(Table 3)**: Age, rising risk 1% yearly (adjusted odds ratios [aOR]=1.01;95%CI=1.01-1.02; p<0.0001); female gender (aOR=1.31;95%CI=1.09-1.56;p<0.0001); LOS before CAUTI acquisition, rising risk 6% daily (aOR=1.06;95%CI=1.05-1.06;p<0.0001); UC/DU ratio (aOR=1.11;95%CI=1.06-1.14;p<0.0001). Lower-middle income countries (aOR=4.11;95%CI=2.49-6.76;p<0.0001) had a similar risk to upper-middle countries (aOR=3.75;95%CI=1.83-7.68;p<0.0001), but both were higher risk factors compared to high-income countries. The ICU with the highest risk for CAUTI was Neurologic ICU (aOR=27.35;95%CI=23.03-33.12;p<0.0001), followed by Medical ICU (aOR=6.18;95%CI=2.07-18.53;p<0.0001) when compared to cardiothoracic ICU. The period 2014–2016 (aOR=7.36;95%CI=5.48-23.96; p<0.0001) and the period 2017–2019 (aOR=1.15;95%CI=3.46-15.61; p<0.0001) had a similar risk to each other, but a higher risk when compared to the time period 2020-2022.

Table 3: Multiple logistic regression analysis of risk factors for catheter associated urinary tract infections.

	aOR	**95% CI**	**P value**
Age	1.01	1.01-1.02	<0.0001
Gender, female	1.31	1.09-1.56	<0.0001
Length of stay	1.06	1.05-1.06	<0.0001
UC-days	0.97	0.97-0.99	<0.0001
UC/DU ratio	1.11	1.06-1.14	<0.0001
Surgical Hospitalization	1.04	0.83-1.32	0.73
Reference: Lack of use of UC			
Indwelling catheter	7.23	4.81-10.87	<0.0001
Suprapubic catheter	5.45	0.98-30.27	0.06
Reference: For-profit privately owned facilities			
Publicly owned facilities	1.48	0.97-2.27	0.07
Teaching hospitals	0.56	0.29-1.07	0.08
Reference: Cardiothoracic			
Neurologic ICU	27.35	23.03-33.12	<0.0001
Medical ICU	6.18	2.07-18.53	<0.0001
Pediatric ICU	5.83	1.83-18.53	<0.0001

Coronary ICU	5.44	1.64-18.03	<0.0001
Surgical ICU	4.83	1.58-14.79	<0.0001
Medical-Surgical ICU	4.02	1.34-12.07	<0.0001
Adult-Oncology ICU	3.42	0.74-15.78	0.12
Pediatric-Oncology ICU	0.36	0.03-4.25	0.41
Reference: High income country			
Lower-middle income country	4.11	2.49-6.76	<0.0001
Upper-middle income country	3.75	1.83-7.68	<0.0001
Reference: Time period 3 (2020-2022)			
Time Period 1 (2014-2016)	7.36	5.48-23.96	<0.0001
Time Period 2 (2017-2019)	1.15	3.46-15.61	<0.0001

ICU = intensive care unit; UC = urinary catheter; LOS = length of stay; CAUTI = catheter associated urinary tract infection; aOR = adjusted odds ratio; CI = confidence interval.

The pooled CAUTI rate per 1,000 UC-days was 1.84. Age, gender, LOS, UC/DU ratio, lower-middle and upper-middle income countries, neurologic ICU, and time periods 1 and 2 were associated with the highest risks for CAUTI. After adjusting by all confounders, in this study, surgical hospitalization and facility ownership were not associated with CAUTI risk.

Discussion

Pooled rates of CAUTI in our study conducted in ICUs are lower to those pooled CAUTI rates in ICUs reported by INICC[2]. CAUTI rate in ICUs of LMICs is 3.16 CAUTIs per 1,000 UC-days per the last INICC report[2]. However, pooled rates of CAUTI in our present study are higher than those of ICUs of the CDC/NHSN report, 1.3 CAUTI per 1,000 UC-days[3]. According to this study, the CAUTI rate at ICUs in lower middle-income countries is 2.75 per 1,000 UC-days; the CAUTI rate at ICUs in upper middle-income countries is 2.47 per 1,000 UC-days; and the CAUTI rate at ICUs in high-income countries is 1.64 per 1,000 UC-days. The highest CAUTI rate is in lower middle-income countries, and the lowest is in high-income countries. This is consistent with previous studies comparing CAUTI rates in ICUs of LMICs with CAUTI rates in ICUs of high-income countries, showing higher CAUTI rates in LMICs compared with high-income countries [17].

Female gender is a significant risk factor for CAUTI. As shown in an urban academic health system of over 2500 beds, encompassing two large academic medical centers, two community hospitals and a pediatric hospital, Letica-Kriegel, A. S., et al. also found that being female was found to statistically increase chances of acquiring CAUTI[18].

The LOS prior to acquisition of CAUTI was associated to a 6% daily increase in risk of CAUTI. A study conducted in cardiac surgical patients by Gillen, J. R., et al. similarly showed the role of LOS prior to CAUTI acquisition as a significant risk factor for CAUTI through both univariate and multivariate analyses[19].

The UC/DU ratio was associated with risk for CAUTI. Likewise stated by Meddings, J., et al., utilization of urinary catheters, such as unnecessary placement and prolonged usage, are large risk factors for acquiring a CAUTI. Their results showed that using a reminder or a stop order was able to reduce CAUTI rate by 52%[20].

Analyzing the time period, we discovered that the risk for CAUTI was decreasing over time, which is consistent with more recent improvements in infection prevention techniques than those from earlier in the past. Infection prevention and control practices may have changed over time. In order to avoid this particular bias and also to adjust to changes in infection prevention and control practices, we adjusted our analysis to the time period.

We identified a similar CAUTI rate in those patients using an indwelling catheter compared with those using a suprapubic catheter. This is consistent with the study of Baan et al., which found a similar CAUTI rate comparing both catheter types[21]. We identified a higher risk for CAUTI in those patients using an indwelling catheter compared with those using a suprapubic catheter. This is inconsistent with the study of Han et al., because they found that indwelling catheterization is not associated with an increased urinary tract infection risk compared to suprapubic tubes and intermittent catheterization if the catheterization duration is 5 days or less. However, a suprapubic tube or intermittent catheterization is associated with a lower rate of urinary tract infection if longer-term catheterization is expected in the postoperative period[22].

Some of the CAUTI RFs identified in our study are unlikely to change, such as age, gender, ICU type, and country income level. However, some of the RFs for CAUTI we identified can be modified; for example, LOS prior to acquisition of a CAUTI, UC/DU ratio, and neurologic ICUs. Based on our findings, it is suggested that we focus on strategies to reduce UC/DU ratio, reduce LOS, and implement an evidence-based set of CAUTI prevention recommendations, such as those published by HICPAC[23]. Also, the high rate of CAUTI prevalent in the Middle East[1,2,24,25] can be reduced by utilizing a strategy of monitoring compliance with recommendations and providing performance feedback to healthcare personnel, as demonstrated in several LMICs[24-29].

Our research has some limitations. Firstly, because this study is a part of a surveillance system in which hospitals voluntarily engage at no cost, it is not representative of all hospitals in the Middle East. Secondly, the CAUTI rates in our research are probably lower than the CAUTI rates found in other hospitals that are not participating in our study because the hospitals that take part in our surveillance system are most likely those that have a higher-quality CAUTI surveillance and prevention program, because they join our study in a volunteer way and at no cost. Third, the proportion of suprapubic catheters is significantly lower than that of indwelling catheters and for that reason we didn't analyze impact of this variable. Lastly, we used the UC/DU ratio as a marker for the severity of patients' illnesses rather than severity illness scores that were gathered by the IPPs of the collaborating hospitals.

Conclusion

In conclusion, our study identified several independent risk factors for CAUTI in ICUs, including age, female gender, LOS, UC/DU ratio, lower- and upper- middle-income countries, and neurologic ICUs. Some of these risk factors have been identified in previous studies as well, further validating our results. Our findings have important implications for the prevention of CAUTI, including reducing LOS and UC/DU ratio, and implementing evidence-based prevention recommendations.

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Author Contributions

Rosenthal, V.D. was responsible for conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing original draft; review & editing; design; software development; technical support; drafting tutorials for surveillance process; training of data collectors; provision of study patients; data validation; data assembly; data interpretation; epidemiological analysis; drafting of the manuscript; search, and insertion of scientific references.

Zhilin Jin and Ruijie Yin contributed equally to data curation; formal analysis; methodology; validation; writing original draft; review & editing; building machine learning models; conducting statistical analysis; critical revision for important intellectual content; and final approval of the manuscript.

Eric Brown and Bhavarth Shukla provided substantial contributions to the interpretation of data for the work, reviewing it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Brandon Hochahn Lee contributed with edition of the manuscript, search, and insertion of scientific references.

Remaining authors were involved in the provision of study patients.

All authors were involved in critical revision of the manuscript for important intellectual content, and final approval of the manuscript.

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