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Statistical Methods and Management of Indeterminacy in Medical Sciences. Surgical Site Infection Study after Vascular Surgery Procedures

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Abstract. Surgical site infections (SSIs) are one of the main infection control problems in modern hospitals, significantly prolonging the stay at the hospital and increasing the cost of treating patients with infections. They are the leading cause of failure for both patients and staff, including the need for repeated surgeries. The objective of this study is the epidemiological and microbiological analysis, through neutrosophic statistical tools, of surgical site infections after vascular surgery in a highly specialized vascular surgery center in the city of Guayaquil, in which 327 vascular operations were performed, during the year 2019 and the follow-up of patients was taken into account as required, until 2020. The neutrosophic hypothesis tests applied allowed us to identify possible problems in the vascular surgery room from their comparison with multicenter studies described in the literature, specifically, from the National and State HAI Progress Report of the USA, as well as to rule out the classification of the state of the patient as a possible predictor of SSI diagnoses at this hospital.

Keywords: neutrosophic statistics, neutrosophic hypothesis test, surgical site infection, vascular surgery.

1 Introduction

Nosocomial infections (from the Latin nosocomium «hospital») are infections acquired during a hospital stay that were not present or during the incubation period nor at the time of patient admission [1]. Today, this concept extends to the hospital and the entire non-strictly hospital healthcare environment (day hospital, ambulatory surgery centers, ambulatory hemodialysis centers, chronic disease centers, etc.), so the term extends to healthcare-related infections [2]. They constitute a problem with repercussions on mortality and hospital stay, assuming a high cost due to the use of antimicrobials, the need for isolation, and the performance of diagnostic and therapeutic tests [6].

According to the World Health Organization (WHO), more than 1.4 million people worldwide contract infections in hospitals. Between 5 and 10% of patients admitted to hospitals in the developed world will contract one or more infections, with the risk of infection in developing countries being 2 to 20 times higher than in developed countries. In the United States, one in every 136 hospital patients becomes seriously ill from an infection acquired in a hospital, equivalent to 2 million cases and approximately 80,000 deaths per year, at the cost of about $ 4.5 trillion US [2].

Of the types of nosocomial infection due to medical care, surgical site infection (SSI) is one of the most common and affects tissues manipulated or adjacent to the surgical site. Surgical site infections (SSI) are a type of infection that occurs after a surgical intervention, in an area of the body where the operation was carried out, involving the skin, tissues, and organs or implanted material, revealing itself as a combination of signs and symptoms that show infection [3].

At present, all health centers have a mandatory goal for the safety of their patients to reduce nosocomial infections. A patient with a surgical site infection has a five times higher risk of dying than a patient with the same uninfected condition [9]. At the same time, each infection at the surgical site causes the patient to spend in the hospital one more week than expected, which leads to additional expenses and, in addition, the loss of health expectations placed on the surgical procedure itself [10].

Different studies have identified risk factors that can influence the appearance of SSI. Among others, the following are worth noting as intrinsic factors: malnutrition and protein depletion, advanced age, diabetes, cancer, chronic vascular disease and obesity, alteration of immune function due to disease or therapeutic regimens, smoking, chronic organ failure, recurrent infection in a remote location and decreased tissue perfusion. Extrinsic factors include hand-washing for surgery, prolonged preoperative (more than 24 hours), prolonged hospitalization, re-operation, shaving, surgical clothing, duration of surgery, air conditioning, instruments, surgical technique, antisepsis of skin, prophylactic antibiotics, sterilization [3].

Despite the improvement in surgical techniques, the better knowledge of the pathomechanisms of the infection, and the greater knowledge of their control, the problems associated with SSI continue to be the most common and serious complications after surgery, also in the field of vascular surgery, where the incidence ranges between 2.1% and 4.1%. (1, 2, 3) and a mortality of 10 to 48% [4].

The objective of this study is the epidemiological and microbiological analysis of surgical site infections after vascular surgery in a highly specialized vascular surgery center in the city of Guayaquil, using neutrosophic statistics tools.

2 Materials and methods

The study was carried out in a specialized vascular surgery hospital room in the city of Guayaquil, in which 327 vascular surgical procedures were performed, during 2019. Among the main procedures performed are those involving the incision of vessels: arteries of the lower extremities, abdominal aortic aneurysm, aortic-iliac prosthesis, intra-abdominal vascular anastomoses, femoral implants, and the placement of aortic-duodenal prostheses.

The registration of SSI cases was carried out in collaboration with the center's Department of Microbiology. For each patient submitted to the analyzed procedures, general demographic data (age, sex, reason for hospital admission, date of admission, discharge or death), risk factors, diagnostic and therapeutic procedures, and information on the patient's condition described using the scale of the American Society of Anesthesiology (ASA) [5] were collected and are shown in table 1.

ASA Class	Definition	Definition
I	Normally healthy patient	Healthy, nonsmoking, no or minimal alcohol use
II	Patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 <BMI <40), well-controlled DM / HTN, mild lung disease
III	Patient with severe systemic disease	Substantive functional limitations; 1 or more moderate-to-severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥ 40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA <60 weeks, history (> 3 months) of MI, CVA, TIA, or CAD/stents
IV	Patient with an incapacitating systemic disease that is a constant threat to life	Old traumatic wounds with retained devitalized tissue and those wounds including (but not limited to): recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD, or ESRD not undergoing regularly scheduled dialysis involve existing clinical infection or perforated viscera. This definition suggests that organisms causing a postoperative infection are present in the operative field before the operation
V	Moribund patient who is not expected to survive for 24 h with or without operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology, or multiple organs/system dysfunction

Table 1. ASA Physical Status Classification (PSC)

The criteria for the diagnosis of infections were based on the recommendations of the National Health Care Network (2021) [7] regarding:

1) Division into clinical forms of infection: superficial, deep, organ-related

2) Qualification standards for superficial infections of the MCA up to 30 days after surgery, and in the case of surgery with the use of an implant (deep and organ infections), up to 1 year.

The local infection control team performed scoring of infections in the room during hospitalization. If the infection developed after hospital discharge, the review and grading were carried out in collaboration with the hospital's outpatient staff. The basis for the post-discharge registry was a screening form, filled out in the outpatient clinic and delivered to the team.

Based on the results of the microbiological examination and the medical record, the team decided on the qualification of the case. The microbiological tests of the materials of the patients with symptoms of infection were carried out in the microbiological diagnostic laboratories of the hospital itself. In nine cases, mixed flora was grown. The species affiliation of the grown strains was determined using routine diagnostic methods, and their susceptibility to drugs was tested using the disk diffusion method.

The analysis used the standardized SSI risk index analysis method. The Surgical Site Infection Risk Index is a tool to study morbidity in patient populations (small and well described), based on an integrated analysis of three categories of variables (which are real indicators of STM risk). According to [7], the Standardized Infection Ratio (SIR) is the primary summary measure used by the National Healthcare Safety Network (NHSN) to track healthcare-associated infections (HAI).

In this study, the same risk factors were adopted for their use in the analysis, of the degree of microbial contamination of the surgical area. Wounds that occur during surgery in the dirty or contaminated field were classified as an increased risk of HAIs. The classification was carried out by the surgeon during or immediately after the procedure. Procedures performed in the presence of trophic-inflammatory changes were classified as contaminated.

To carry out the statistical comparison between the SIR values standardized by the NHSN, with the proportions observed in the hospital studied, a neutrosophic hypothesis test of comparison of proportions was used since these allow applying levels of significance with a certain level of indeterminacy.

According to [1], "The neutrosophic statistics (NS) is the alternative of classic statistics to be applied under the uncertain environment. NS is based on neutrosophic numbers. NS logic is the extension of the fuzzy logic and deals with the measure of indeterminacy" (p. 1).

Smarandache [8] defines the neutrosophic hypothesis as a statement about the neutrosophic values of one or more population characteristics. Therefore, we start from the Z statistic of the classical statistic comparison test of proportions [11]:

$$\text{Statistic } Z = \frac{\widehat{P_1} - \widehat{P_2}}{\sqrt{pq\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}} \quad (1)$$

And a neutrosophic critical region is applied for $z > min[z_{\alpha 1}, z_{\alpha 2}]$

To determine the relationship between the patient's status (as a measure of risk factors), regarding the suffering of SSI, a neutrosophic Chi-square test was performed, due to the vagueness regarding the information collected on 18 of the patients, which prevented assigning a unique ASA Physical Status Classification. This test was performed to determine the feasibility of using the patient's status category as a predictor of SSI.

4 Results

In the studied center, 16 cases of surgical site infections were diagnosed. The mean/average age of the sample was 58.8 years, and the mean age of the patients diagnosed with SSI was slightly higher (59.3). The influence of the duration of the surgery on the onset of the infection was analyzed and a statistically significant difference was observed: patients who underwent a longer surgery were more likely to develop an infection (T = 2.0087, p = 0, 0485) for a 95% confidence level.

The microbiological cleaning of the field did not affect morbidity, nor did it affect the patient's condition during qualification for surgery expressed by the ASA score and age.

Furthermore, hospitalization in this hospital before the procedure lasted longer, especially in the population diagnosed with PD, although the mean length of stay is, in general, shorter (Table 1).

Variable	Total	SSI
Number of treatments	327	16
Procedures in the clean field/clean-contaminated field [%]	98.0	100.0
Status of the patients according to the ASA scale: 3/4/5 [%].	76.8	82.5
Hospitalization before procedure [days]	4	3
Average length of stay in total [days].	16	2. 3

Mean age of patients [years].	67	66
Proportion of women among operated patients [%].	19.8	25.0
Average duration of the procedure [min]	116	
Duration of the procedure above the norm [min]	145	

Table 2. Patient characteristics and procedures performed

Hospital specialists applied an effective method of post-discharge surveillance, grading SSI cases both during the ward stay and in cooperation with the hospital outpatient clinic (Table 3). The mean time to onset of the first symptoms of infection was 34 days. Among all diagnosed cases, more than half of the infections are in the "deep" category, so almost half of the patients required treatment.

Observed Variables	Diagnosed cases	
MND Standard	**Frequency**	**[%]**
Superficial	5	33.33%
Deep	8	53.33%
Organ related	2	13.33%
SSI cases - time of detection	**Frequency**	**[%]**
Before discharge	2	13.33%
After discharge	9	60.00%
Rehospitalization	4	26.67%
Time since operation	**Frequency**	**[%]**
<21 days	7	46.67%
21-50 days	5	33.33%
> 51 days	3	20.00%

Table 3. Characteristics of diagnosed cases

In the hospital setting (re-hospitalization), all cases of SSI occurred in the form of superficial infections. Analysis of the risk index was only possible in approximately 95% of the data, the remaining part of the records contained deficiencies, mainly in terms of the description of the patients' conditions (ASA scale).

More than half of the operated patients were diagnosed with one of the risk factors analyzed; the rest of the patients had no risk (22%) or had a higher risk (2 or 3 risk factors). As a result, morbidity reached values of 5.6%.

To compare the incidence of SSI in patients with a different load of selected risk factors, with the US NHSN infection control program [10], the neutrosophic hypothesis test of comparison of proportions for a neutrosophic alpha $\alpha = [0.01,0.05]$ was proposed.

H0: p1 = p2.

H1: p1> p2.

$\alpha = [0.01,0.05]$

Neutrosophic critical region: $z > min[1.645, 2,32]$

The frequency and proportion data for both the NHSN data and the selected sample are shown in Table 4.

Source	Total interventions	SSI Cases	Proportion
NHSN	31,339	128	0.004
Show	327	15	0.047

Table 4. Proportion of SSI cases

Applying (1) we obtain:

$$\text{Statistic } Z = \frac{0.047-0.004}{\sqrt{0.0045*0.9955(\frac{1}{317}+1/31339)}} = 11.359$$

The equality hypothesis is rejected since the value of the Z statistic belongs to the neutrosophic rejection region, so it can be stated that the proportion of SSI cases observed in the sample studied is higher than the results published by the NHSN.

ASA classification of each patient is shown in table 5, in which P represents the patient; SSI, whether he suffered an infection or not, and PSC stands for Physical State Classification. Please note that the interval was

[3,4] for seven patients, while for eleven patients, it was [4,5].

P	SSI	PSC	P	SSI	PSC	P	SSI	PSC	P	SSI	PSC	P	SSI	PSC	P	SSI	PSC	P	SSI	PSC
1	NO	2	51	NO	3	101	NO	2	151	NO	1	201	NO	2	251	NO	2	301	NO	1
2	NO	5	52	NO	2	102	NO	2	152	NO	2	202	NO	2	252	NO	2	302	NO	2
3	YES	4	53	NO	3	103	NO	2	153	NO	4	203	NO	1	253	NO	1	303	NO	3
4	NO	[3,4]	54	YES	3	104	NO	5	154	NO	2	204	NO	1	254	NO	2	304	NO	3
5	NO	2	55	NO	[4,5]	105	NO	[3,4]	155	NO	4	205	NO	4	255	NO	1	305	NO	4
6	NO	1	56	NO	3	106	NO	1	156	NO	2	206	NO	3	256	NO	4	306	NO	1
7	NO	2	57	NO	3	107	NO	1	157	NO	4	207	NO	3	257	NO	1	307	NO	3
8	NO	3	58	NO	2	108	YES	1	158	NO	1	208	NO	5	258	NO	[4,5]	308	NO	1
9	NO	2	59	NO	1	109	NO	4	159	NO	4	209	NO	3	259	NO	1	309	NO	2
10	NO	3	60	NO	3	110	NO	[3,4]	160	NO	3	210	NO	2	260	NO	3	310	NO	3
11	NO	2	61	NO	3	111	NO	5	161	NO	1	211	NO	3	261	NO	3	311	NO	2
12	YES	4	62	NO	3	112	NO	1	162	NO	2	212	NO	1	262	NO	1	312	NO	5
13	NO	3	63	NO	3	113	YES	3	163	NO	3	213	NO	1	263	NO	2	313	NO	1
14	NO	4	64	NO	1	114	NO	5	164	NO	4	214	NO	[4,5]	264	NO	2	314	NO	3
15	NO	4	65	NO	1	115	NO	1	165	NO	4	215	NO	3	265	NO	3	315	NO	[4,5]
16	NO	[3,4]	66	NO	1	116	NO	2	166	NO	2	216	NO	5	266	NO	1	316	NO	2
17	YES	1	67	NO	3	117	NO	2	167	NO	4	217	NO	3	267	NO	3	317	NO	5
18	NO	4	68	NO	2	118	NO	3	168	NO	5	218	NO	[4,5]	268	NO	1	318	NO	1
19	NO	1	69	NO	5	119	NO	4	169	NO	1	219	NO	1	269	NO	2	319	NO	3
20	NO	2	70	NO	4	120	NO	4	170	NO	[4,5]	220	NO	2	270	NO	1	320	NO	3
21	NO	2	71	NO	5	121	NO	3	171	YES	5	221	NO	2	271	NO	1	321	NO	3
22	NO	3	72	NO	4	122	NO	1	172	NO	1	222	NO	4	272	NO	2	322	NO	3
23	NO	1	73	NO	1	123	YES	3	173	NO	2	223	NO	3	273	NO	3	323	NO	2
24	NO	2	74	NO	2	124	NO	2	174	YES	3	224	NO	2	274	NO	1	324	NO	2
25	NO	5	75	YES	2	125	NO	1	175	NO	1	225	NO	1	275	NO	1	325	NO	5
26	NO	5	76	NO	2	126	NO	1	176	NO	3	226	NO	3	276	NO	[4,5]	326	NO	1
27	NO	2	77	NO	5	127	NO	2	177	NO	3	227	NO	1	277	NO	3	327	NO	3
28	NO	4	78	NO	1	128	NO	3	178	NO	2	228	YES	2	278	NO	5			
29	NO	3	79	NO	3	129	NO	2	179	NO	1	229	NO	5	279	NO	1			
30	NO	3	80	NO	1	130	NO	1	180	NO	3	230	NO	1	280	NO	1			
31	NO	2	81	NO	3	131	NO	3	181	NO	3	231	NO	[3,4]	281	NO	[4,5]			
32	NO	2	82	NO	1	132	NO	1	182	NO	2	232	NO	2	282	NO	1			
33	NO	5	83	NO	3	133	YES	4	183	NO	1	233	NO	2	283	NO	2			
34	NO	3	84	NO	3	134	NO	4	184	NO	3	234	NO	4	284	NO	2			
35	NO	5	85	NO	2	135	NO	4	185	NO	3	235	NO	1	285	NO	3			
36	NO	[4,5]	86	YES	4	136	NO	4	186	NO	2	236	NO	3	286	NO	3			
37	YES	1	87	NO	2	137	NO	1	187	NO	3	237	NO	1	287	NO	2			
38	NO	1	88	NO	[3,4]	138	NO	2	188	NO	5	238	NO	3	288	NO	2			
39	NO	3	89	NO	3	139	NO	4	189	NO	2	239	NO	2	289	NO	3			
40	NO	2	90	NO	2	140	NO	3	190	NO	1	240	NO	1	290	NO	1			
41	NO	3	91	NO	4	141	NO	2	191	NO	2	241	NO	4	291	NO	3			
42	NO	5	92	NO	4	142	NO	[4,5]	192	NO	1	242	NO	[3,4]	292	NO	3			
43	NO	3	93	NO	2	143	NO	1	193	NO	4	243	NO	2	293	NO	2			
44	NO	1	94	NO	1	144	YES	4	194	NO	3	244	NO	3	294	NO	2			
45	NO	1	95	NO	1	145	NO	2	195	NO	1	245	NO	1	295	NO	2			
46	NO	1	96	NO	3	146	NO	3	196	NO	3	246	NO	2	296	NO	1			
47	YES	5	97	NO	1	147	NO	3	197	NO	3	247	NO	1	297	NO	2			
48	NO	3	98	NO	3	148	NO	3	198	NO	2	248	NO	1	298	NO	2			
49	NO	1	99	NO	2	149	NO	4	199	NO	3	249	NO	4	299	NO	1			
50	NO	2	100	NO	3	150	NO	3	200	NO	[4,5]	250	NO	3	300	NO	2			

Table 5 SSI-PSC ratio per patient

A deneutrosophication process, using the midpoint of the intervals [3,4] and [4,5] (3.5 and 4.5 mean points respectively), allows generating two new intermediate categories to be able to apply the classic statistics Chi-square test for contingency tables. From which we obtained table 6, after processing the data with IBM SPSS software.

			PSC							
			1,00	2,00	3,00	3,50	4,00	4,50	5,00	Total
SSI	YES	Score	3	2	4	0	5	0	2	16
		% in PSC	3,7%	2,4%	4,6%	0,0%	13,9%	0,0%	8,7%	4,9%
	NO	Score	78	80	83	6	31	11	21	311
		% in PSC	96,3%	97,6%	95,4%	100,0%	86,1%	100,0%	91,3%	95,1%
Total		Score	81	82	87	6	36	11	23	327
		% in PSC	100,0%	100,0%	100,0%	100,0%	100,0%	100,0%	100,0%	100,0%

Table 6. Contingency table SSI-PSC

Table 6 shows the new categories obtained through the de-neutrosophication process, which have zero frequency in the first row. This means that no patient with a certain level of indeterminacy in his information about his risk factors was diagnosed with SSI. In general, the diagnosed cases represent 4.9% of the total of surgeries performed. It indicates that morbidity is not related to risk factors of patients regarding ASA classification.

The statistical analysis confirms the differences in morbidity between the population from the United States and the sample of the studied hospital, which indicates the need for a permanent and detailed review of the epidemiological risk factors and the practice and the prevention measures to improve the current situation. On the other hand, a statistically significant relationship between the physical state (risk factors) of the patients and their SSI diagnosis could not be established.

Conclusions

At the analyzed institution, the follow-up of the hospital infections is being carried out for several years now, using active infection monitoring tools and databases. From the very first years of the current century, specific monitoring of certain surgical procedures was introduced. One of the most important elements was the attempt to implement the supervision of infections that appeared after the patients were discharged.

This study confirms the need and feasibility of the follow-up after the patient is discharged, especially in a unit that uses implants, where exceptional reliability in monitoring infections one year after the surgery is required. The data registered by the Ecuadorian health centers, on many occasions, do not register information after the patient is discharged, so its sensibility was lesser.

The neutrosophic hypothesis tests applied, allowed identifying possible problems of the vascular surgery room of an Ecuadorian hospital based on its comparison with multicenter studies described in the literature, specifically, of the National and State HAI Progress Report from the USA, developed by specialist of the CDC, along with the National Healthcare Safety Network (NHSN); as well as ruling out the classification of the patient's state as a possible predictor of SSI diagnosis in this hospital.

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