SURVEILLANCE OF HEMODIALYSIS RELATED INFECTIONS: A PROSPECTIVE MULTICENTER STUDY, FIRST REPORT FROM TURKEY

ABSTRACT

Background: There is neither a surveillance system nor a study to reveal the HD related infection rates in Turkey. We aimed to investigate the infection rate among HD outpatients and implement CDC's surveillance system.

Methods: A multicenter prospective surveillance study is performed to investigate the infection rate among HD patients. CDC National Healthcare Safety Network dialysis event (DE) protocol is adopted for definitions and reporting.

Results: During April 2016–April 2018, 9 centers reported data. A total of 199 DEs reported in 10035 patient-months, and the overall DE rate was 1.98 per 100 patient-months. Risk of blood culture positivity is found to be 17.6 times higher when hemodialysis was through a tunneled catheter than through an arteriovenous fistula. DE rate was significantly lower in patients educated about the care of their vascular access site. Mean body mass index was significantly higher in patients with any DE. *Staphylococcus aureus* was the most causative microorganism among mortal patients. Outcomes of DEs were hospitalization (73%), loss of vascular access (18.2%), and death (7.7%).

Conclusions: This first surveillance study in Turkey gave insight into current DE status and will guide to generate a national surveillance system for maintaining much lower DE rates.

What is already known about this topic? Infections are among the most common causes of death in hemodialysis patients. Surveillance of infections in dialysis patients constitutes an important part of prevention. There is neither a surveillance system nor a study to reveal the HD related infection rates in Turkey.

What does this article add? This is the first hemodialysis infections surveillance study in Turkey and revealed that NHSN DE surveillance system can be easily implemented even in a high workload dialysis unit and be adopted as a nationwide DE surveillance program. Results have highlighted the importance of optimizing vascular access, appropriate care of catheters and the patient education for vascular access site care.

INTRODUCTION

With the prolongation of the average life span, the frequency of chronic diseases in our country and all over the world is increasing. According to the National Nephrology, Dialysis and Transplantation Registry Report of Turkey 2018, it is noteworthy that both the incidence and the prevalence of end-stage renal disease (ESRD) that require renal replacement therapy (RRT) increased. In Turkey, while the point prevalence of end-stage renal disease requiring RRT was 314 per million population in 2001, this number tripled and reached 988.4 per million population by the end of 2018. After cardiovascular/cerebrovascular diseases and malignancies, infections are the fourth most common cause of death in HD patients in Turkey.[1]

Monitoring of HD related infections in dialysis patients constitutes an important part of prevention. American Center for Disease Prevention and Control (CDC) implemented a surveillance program reporting dialysis events regarding infection related adverse events of HD in 1999. The surveillance program initially gathered data from voluntarily participating HD centers. Afterwards, the program progressed into a mandatory system all HD units registered. However, there is neither a surveillance system nor a study to reveal the HD related infection rates in Turkey. In this study, we aimed to implement the CDC's surveillance system, investigate the infection rate among HD outpatients, and reveal the characteristics and risk factors of the patients.

MATERIALS AND METHOD

A multicenter prospective surveillance program was performed to investigate the infection rates among HD patients. We implemented a central database for data collection with a web interface compatible with mobile devices called TR-HIES (www.tr-hies.org). CDC National Healthcare Safety Network (NHSN) Dialysis Event (DE) protocol was adopted for definitions

and reporting. [2] All patients, including transient patients taking dialysis in the HD unit were included in the study. After the patient information form in the system was filled, patients were followed for DE. The network's computer algorithm determined if case definitions for infection were met.

Dialysis event: Three DEs are defined:

1- Use of intravenous antibiotic: Antibiotics and antifungals initiated in the patient are reported independently of the cause and duration of treatment. Patient should be entered as intravenous antibiotic use in dialysis related events even if he or she has taken treatment for 1 day. Antivirals and oral antibiotics are not included.

2- Positive blood culture: All positive blood cultures of outpatients and all positive blood cultures that have been taken 1 day after the admission to the hospital of inpatients are recorded.

3- Local vascular access site infection: All patients who have one or more symptoms of pus, redness or swelling at vascular access site are reported regardless of whether the patient received treatment for infection or not.

According to the CDC DE protocol, 21-day rule was applied to prevent two events that may be related to each other from being reported as different events. There must be at least 21 days between the starting days of the two same type DE.

Data analysis

To calculate DE rate, the number of DE developed within that month and the total number of patients received HD during the first 2 working days of the same month are recorded. DE rates are calculated for each vascular access type and given as per 100 patient months. If the

patient had more than one vascular access, only their vascular access type with the highest risk of infection was reported.

Additional data

Other characteristics of the patients like demographic features, immunization status, comorbid diseases, serostatus for hepatitis B, hepatitis C, and HIV; MRSA colonization etc. were also recorded.

This study was approved by the Ethical Committee of Yildirim Beyazit University.

Statistical analysis

Results were analyzed with SAS JMP® 11 statistical software package. Bivariate correlations among all variables were calculated in the multivariate analysis. Comparisons between groups for continuous variables were performed with Student's t-test if they were distributed normally and with Kruskal–Wallis test if they were not distributed normally. Nominal variables were compared with Pearson χ^2 and Fisher's Exact test. A p value below 0.05 was considered statistically significant.

RESULTS

During April 2016 – April 2018, 9 centers from 7 different provinces reported at least 1 month of dialysis event data to the system. Characteristics of the patients are given in Table 1. Among all the patients, 741(78.1%) had at least one co-morbidity. Serologic test results of the patients are given in Table 2.

A total of 199 DEs reported in 10035 patient-months, and the overall DE rate was 1.98 per 100 patient-months during the surveillance period. Data for each event type and vascular access type are given in Figure 1. Eighty-one percent of the patients had received training for

vascular access care. DE rate was significantly lower in patients educated about the care of their vascular access site ($p<0.0001$). Mean body mass index (BMI) was significantly higher in patients with any DE (p:0.009).

DEs were significantly more common in patients with catheters (tunneled or non-tunneled) compared to patients with AV fistulas ($p<0.0001$). The risk of blood culture positivity is found to be 17.6 times higher (%95 CI 7.21-43.08) when hemodialysis was through a tunneled catheter than through an arteriovenous fistula.

62.8% of the catheters were inserted in a teaching and research hospital. We found no relationship between DE and the type of hospital where CVC was inserted.

Among all DEs, 1.66% of the patients had cellulitis, 10.4% had urinary tract infection, and 16.5% had pneumonia. Fever and hypotension were observed in 56.3% and 13.2% of all DEs, respectively. Outcomes of DEs were hospitalization (73%), loss of vascular access (18.2%), and death (7.7%).

Isolated microorganisms from blood cultures are given in Table 3. Fifty-four percent of the microorganisms were Gram positive. Methicilin resistance was 1% in staphylococcus. Third generation cephalosporin resistance was 50% among *Enterobacteriacea*. *Staphylococcus aureus* was the most causative microorganism among mortal patients.

DISCUSSION

To the best of our knowledge, this is the first study regarding surveillance of HD related infections in Turkey. Despite the advances in dialysis technology, infections that develop in hemodialysis patients remain important, and prevention of these infections is mainly based on surveillance. Data from the National Nephrology, Dialysis and Transplantation Registry Report of Turkey showed that with a rate of 9.98%, infections are one of the most common death causes in HD patients. Type of vascular access is important for the risk of infection.

Now, it is a well-known fact that, AV fistula has the lowest risk of infection. Therefore, it has been a core aim to increase its usage as a prevention measure for dialysis events. “Fistula First” initiative of the Centers for Medicare and Medicaid Services campaigned for use of AV fistula and set objectives to increase AV fistula usage above 66% meanwhile decreasing CVC below 10% among prevalent hemodialysis patients. Although nationwide data in Turkey show that the >66% goal has been achieved with a rate of 77.41%, the facilities included in this surveillance program had lower rates. In our study, rate of the patients receiving HD via CVC was 42.2% and for these patients, the risk of bacteremia was 17.6 times higher than the patients with AV fistula. NHSN Dialysis Safety Network reported that the bloodstream infection (BSI) rate ratio between CVC and AV fistula BSI rates was 8.2. In our study population, proportion of patients receiving HD via catheter was higher than the rate reported in the national registry report. Since centers involved in the study are all tertiary hospitals’ HD units, patients’ characteristics can be different from the general population.

In 1999, the Centers for Disease Control and Prevention (CDC) developed the Dialysis Surveillance Network for monitoring hemodialysis related infections. Definitions updated over the years and a few reports regarding the data have been published. In the recent years, several countries started to implement this surveillance system. Surveillance plays critical role for improving health care quality and safety of HD patients and can guide infection control programs, find the gaps where improvements might be needed. Moreover, this approach can raise the awareness of the healthcare workers regarding infection prevention. Gork et al reported a significant decrease in dialysis related infections in a 9-year lasting study period .[3(p)] Their study consisted of both surveillance and intervention which includes checklists, ready kit for the care of vascular access, education, and an infection prevention team. They achieved a significant trend of decrease in access-related infection rates. Integration a HD specific surveillance system in HD units can cause considerable decrease in

HD related infections as well as antimicrobial consumption. [4] NHSN reported a significant decrease in BSI and access related infection rates in 2014. [5] However, rates of intravenous antimicrobial start were similar with previous reports. This result highlights the need for different efforts for achieving similar lower rates for antimicrobial consumption and lowering rates of colonization and infection of HD patients with multidrug resistant organisms. Tracking antimicrobial use and antimicrobial resistance of organisms in HD patients is essential for programs to prevent antimicrobial resistance.

As in surveillance of hospital-acquired infections, standard definitions and calculations are important in terms of monitoring and comparing units' own rates. NHSN did not report DE rates since 2014. Our DE rates for all types are lower than the rates reported by the NHSN in 2014 and 2011.[5,6] There are several reasons for lower DE rates. First, all centers participating in the study are at a tertiary care university hospital with high workload and they are all strictly controlled by the government. Benchmarking of data from a dialysis unit at a tertiary care university hospital with data from US outpatient dialysis units is not optimal, since there can be many differences in patient population, staff education and facility of the unit. On the other hand, NHSN reports significant differences in DE rates among facilities in US. Second, since this is the first study for surveillance of DE infections in our country, healthcare personnel are not familiar with this type of a data gathering system and this might have caused some underreporting. Even NHSN which implemented the system many years ago, discuss the quality of the data and problems understanding the system. However, in our opinion implementation of an official nationwide surveillance system would have a significantly positive effect on data quality. Third, in NHSN report 2014, 6005 outpatient HD facilities reported data. Both the number of the patients and the centers are very high from our study’s numbers. Therefore, it is not appropriate to compare these DE rates. There have been many differences among DE rates reported from different countries. Quebec Public Health

Expertise and Reference Centre reported that their vascular access related BSI rate was 0.22 cases per 100 patient-periods. [7] They report that in 2016–2017, incidence rates for tunneled and non-tunneled catheters have significantly decreased compared to rates for 2012-2016 while rates for AV fistulas and grafts have remained stable. In a surveillance study from Kuwait reported rates of hospitalization, IV antimicrobial start, and positive blood culture were 4.3, 9.0 and 1.1 per 100 patient-months respectively. [8] In an Irish study from two HD units for a period of 6 weeks, rate of hospitalizations, IV antimicrobial starts, and positive blood cultures were 13, 8.52 and 3.14 per 100 patient months, respectively. [9] China reported 33 outpatient HD centers' surveillance of dialysis events data in 2017. [10] Overall DE rate was 1.47 per 100 patients-months.

In our study outcomes of DEs were hospitalization (73%), loss of vascular access (18.2%), and death (7.7%). In NHSN report 2014, hospitalization rate and death for all types of DE are reported as 21.9% and 0.8%, respectively. [5] In Chinese report, hospitalization and death were observed 63.34% and 1.79%, respectively. [10]

Serostatus of the patients for hepatitis B and hepatitis C were similar with the National Registry Report.[1] However, anti-HIV positivity rate was higher in our study (0.08% vs 0.4%). This may be a result of centers' characteristics. In contrast to published surveillance studies, we also searched vaccination rates for seasonal influenza and pneumococcal vaccine which are recommended for HD patients. Unfortunately, 32.2% for seasonal influenza vaccination and 5.8% for pneumococcal vaccination rates are both very low. Bond et al reported that vaccination against influenza and pneumococcal disease is associated with improved survival in dialysis patients. [11] Infection prevention strategies must include topics regarding raising vaccination rates for HD patients.

Most reported microorganisms responsible for BSI were coagulase-negative Staphylococcus and *S. aureus*. This data is similar with NHSN's and other studies' data. [5,7,8,10] Rate of

methicillin resistance among *S. aureus* was 46% in NHSN's 2014 report and 1% in our report. In Qebec report *S. aureus* accounts most of the cases resulting in death (44%), however oxacillin resistance was 10.7% among *S. aureus*. [7] China reported 17.86% methicillin resistance among *S. aureus* isolates. [10] In this study, screening for MRSA carriage was performed in 13.3% of the patients. Among these, 0.8% were positive. A study from Turkey reported rate of *S. aureus* and MRSA carriage in HD patients as 28.3% and 4.9%, respectively. They found a statistically significant difference between HD patients and healthy controls in terms of *S. aureus* colonization. [12] Another study from Turkey reported MRSA nasal carriage rate as 11% and found that history of catheter infection in the last one year is an independent risk factor for nasal carriage of MRSA. [13] Considering both the low prevalence of BSI due to MRSA found among HD patients in this study and low MRSA carriage, active MRSA screening for HD patients doesn't seem to be a viable measure in Turkey. However, further studies are needed to make a recommendation.

The CDC published key interventions for prevention of BSI in HD patients. According to these recommendations, education for vascular access site care for all HD patients is essential. One of the most striking result of this study is the low infection rate among patients who received education about the care of their vascular access site. This result revealed the importance of engaging patients for prevention strategies. Data on the HD patients' perspective on infection prevention is limited in the literature. In a survey study, CDC staff evaluated the HD patients' view and role on infection prevention strategies. [14] Participating patients concluded that patients should take the responsibility for their vascular access site care and should be observant for infection prevention steps. HD patients spend much of their time in healthcare facilities, and they can have a positive effect for both their and other patients' safety regarding infections. [15]. In our study population, 80% of the patients were

educated. Next step for lowering the BSI rates among HD patients must be to increase this rate to 100 %.

Some parameters identified as risk factors can be improved. Our study revealed that obesity is one of the important risk factors for DEs. This may be related to the co-morbidities of obesity. It has been shown in the literature that obesity is not only a risk factor for BSI, but also increases mortality due to BSI. [16] Therefore, it is also important to make recommendations to patients for weight control.

Making Dialysis Safer for Patients Coalition was founded by CDC and CDC Foundation in 2016. [17] The coalition consists of a wide range of healthcare organizations and stakeholders and aims to prevent bloodstream infections in HD patients and raise awareness on recommended infection prevention practices. “Core Interventions for Bloodstream Infection Prevention” compiled by the coalition includes evidence-based practices for CVC care as well as benchmarking data collected through NHSN related with infection rate measures, education of staff and patients, audit and competency assessments. Several centers reported significant, rapid and sustained reductions in DE rates after participating the Collaborative. [18–20] After the early success of the Collaborative was shown, CDC compiled checklists regarding the Core interventions used by Collaborative participants. [21] These checklists focused on hand hygiene and glove use, catheter exit site care, catheter connection and disconnection, arteriovenous fistula and graft cannulation and decannulation, and routine dialysis station disinfection. The most important outcome of our study was preparation of similar checklists for the Dialysis Services Unit of the Ministry of Health. After evaluating our project, Ministry of Health General Directorate of Health Services officially distributed these checklists to all dialysis centers in Turkey. Moreover, they made it mandatory to complete checklists for each HD patient. This was an unexpected result of utmost impact that we neither have intended nor foreseen while beginning the study.

This study has some limitations. First, like NHSN, we included data from all participating HD units regardless of the number of months reported. This can certainly lower the quality of the data. Second, all centers participating in the study are at a tertiary hospital. Therefore, rates may not reflect the national data. Third, we conducted the study with one infectious diseases specialist and one nephrologist from each center. High workload at these centers cause underreporting.

In conclusion, hemodialysis units are not covered in the National Nosocomial Infection Network run by the Turkish Ministry of Health General Directorate of Public Health. This first surveillance study revealed that NHSN DE surveillance system can be easily implemented even in a high workload dialysis unit and be adopted as a nationwide DE surveillance program. Results have highlighted the importance of optimizing vascular access, appropriate care of catheters and the patient education for vascular access site care. Awareness of healthcare workers regarding infections in HD patients is one of the most important points of preventing, and this study provided a great contribution for raising awareness of healthcare workers in dialysis units. Revealing that DE rates are lower in patients who are educated about the care of their vascular access site will hopefully make healthcare workers more attentive. While there are caveats with international comparisons as discussed above, we have established a baseline that will facilitate us to demonstrate the effect of future infection prevention and control and antimicrobial stewardship strategies.

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Potential conflicts of interest

All authors report no conflicts of interest relevant to this article.

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Table 1. Characteristics of the patients (n=949)

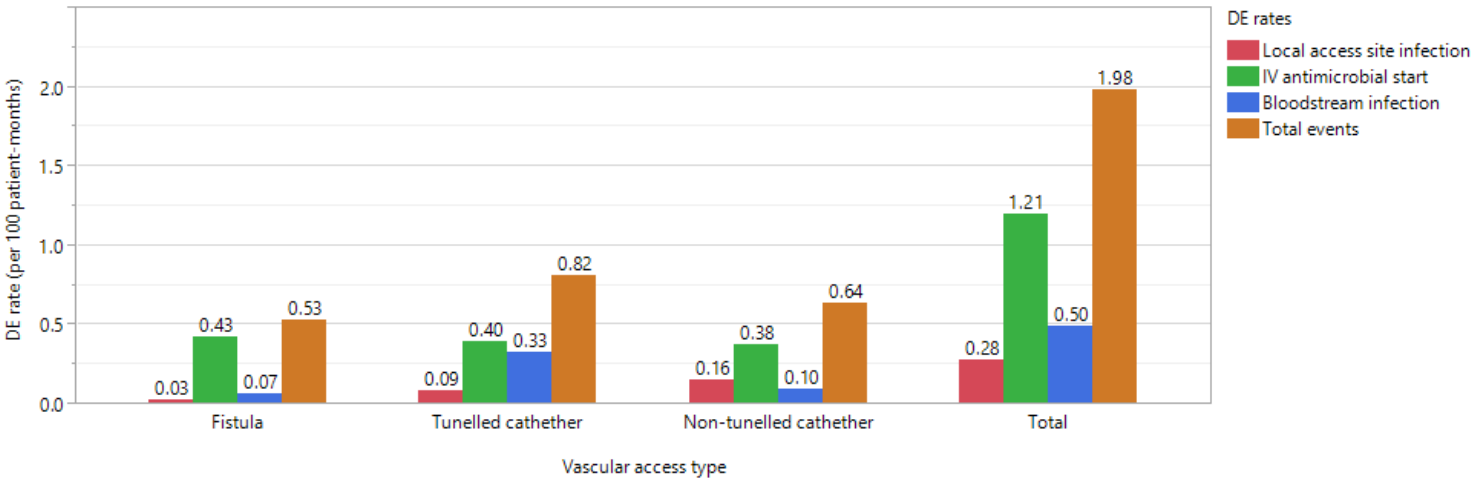
Demographics	
Age (years), mean (range)	59 (9-89)
Male, n (%)	536(56.4)
Years of HD, mean (range)	6.7 (0-32)
Addiction, n (%)	
Cigarette	129(13.59)
Alcohol	15(1.58)
Drug	2 (0.21)
Comorbidity, n (%)	
Hypertension	556(58.6)
Diabetes mellitus	290(30.6)
Coronary arterial disease	148(15.6)
Asthma / Chronic obstructive pulmonary disease	60(6.3)
Cerebrovascular disease	22(2.3)
At least one co-morbidity	741(78.1)
Immunization status, n (%)	
Influenza vaccine	306(32.2)
Pneumococcal vaccine	55(5.8)
Received training for vascular access care, n (%)	
Yes	764(80.5)
No	185(19.5)
MRSA colonization, n (%)	
Yes	1 (0.8)
No	126(99.2)
Unknown	822
Type of vascular access, n (%)	
Tunneled catheter	192(19.01)
Non-tunneled catheter	234(23.17)
AV fistula	577(57.13)
AV graft	7(0.69)
Type of hospital where the catheter inserted, n (%)	
Teaching and Research Hospital	634 (62.8)
University Hospital	160 (15.8)
State Hospital	117(11.6)
Private Hospital	99(9.8)

Table 2. Serologic test results of the patients

	Positive, n (%)	**Negative, n (%)**	**Not reported, n (%)**
HBsAg	32 (3.4)	881(92.8)	36(3.8)
Anti-HBs	473(49.8)	397(41.8)	79(8.4)
Anti-HCV	22(2.3)	887(93.5)	40(4.2)
Anti-HIV	4 (0.4)	856(90.2)	87 (9.4)

Table 3. Isolated microorganisms from blood cultures

Microorganism	**Fistula**	**Catheter**	**Total, n (%)**
Staphylococcus coagulase-negative	3	7	10 (27)
Staphylococcus aureus	2	5	7 (18.9)
Escherichia coli	1	5	6 (16.2)
Klebsiella pneumonia	1	3	4 (10.8)
Enterobacter cloaca	1	2	3 (8.1)
Pseudomonas aeruginosa	0	3	3 (8.1)
Enterococcus faecalis	0	2	2 (5.4)
Candida spp	0	1	1 (2.7)
Enterococcus faecium	1	0	1 (2.7)
Total	**9**	**28**	**37 (100)**


DE rates
Local access site infection
IV antimicrobial start
Bloodstream infection
Total events
DE rate (per 100 patient-months)
0.0
0.5
1.0
1.5
2.0
0.03
0.43
0.07
0.53
0.09
0.40
0.33
0.82
0.16
0.38
0.10
0.64
0.28
1.21
0.50
1.98
Fistula
Tunelled cathether
Non-tunelled cathether
Total
Vascular access type