Original Investigation / *Özgün Araştırma*

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Pseudo-Outbreaks of *Stenotrophomonas maltophilia* on a Pediatric Intensive Care Unit in Türkiye

Türkiye'de Bir Çocuk Yoğun Bakım Ünitesinde *Stenotrophomonas maltophilia*'ya Bağlı Yalancı Salgın

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Abstract

Objective: Healthcare associated infections are an important health problem that can occur as a complication of modern medical practices and pose a threat to public health. We report an outbreak of pseudo-heparin injectors infected with *S. maltophilia*.

Material and Methods: This retrospective study was conducted at a PICU between November 2021 and February 2022.

Results: Two hundred and twenty-five patients were followed up in our pediatric intensive care unit during the study period, and *S. maltophilia* growth was detected in the control catheter cultures taken immediately after catheterization in 12 (5.33%) of them. Of these patients, 121 jugular and three femoral catheters were inserted. It was determined that the catheter cultures were taken with the same brand (E brand) heparin injectors. Mean age of the 12 patients included in the study was 70.58 ± 81.02 months, seven (58.3%) were male. Of the patients, six were hospitalized due to pneumonia, three postoperatively, two due to non-vehicle traffic accident (NVTA) and one due to chronic renal failure. Six patients had comorbid conditions, of whom five had syndromic conditions and one had chronic renal failure. Mean hospital stay of the patients in the intensive care unit was 27.17 ± 34.41 days. Eleven (91.67%) of the patients were discharged with good recovery. One patient (NVTA) died due to non-sepsis causes. A statistically significant decrease was found in the white blood cell values from the seventh day after the catheterization of the patients (p= 0.014). In addition, mean platelet values

Öz

Giriş: Sağlık bakımı ilişkili enfeksiyon, modern tıbbi uygulamaların bir komplikasyonu olarak meydana gelebilen ve halk sağlığı için tehdit oluşturabilen önemli bir sağlık sorunudur. Biz *S. maltophilia* ile enfekte olmuş heparinli enjektörlere bağlı bir yalancı salgını rapor ediyoruz.

Gereç ve Yöntemler: Bu retrospektif çalışma, Kasım 2021 ile Şubat 2022 tarihleri arasında çocuk yoğun bakım ünitesinde yürütülmüştür.

Bulgular: Çalışma sürecinde çocuk yoğun bakım ünitesine (ÇYBÜ) 225 hasta yatışı olmuş ve 124 hastaya kateter takılmıştır. Bu 124 hastanın 12 (%5.33)'sinde kateter takıldıktan sonra kateterden alınan kan kültürlerinde *S. maltophilia* üremesi saptandı. Bu hastaların 121'ine juguler ve üçüne femoral kateter takıldı. Kataterden alınan kan kültürleri, aynı marka (E marka) heparin enjektörleri ile alındı. Çalışmaya alınan 12 hastanın yaş ortalaması 70.58 ± 81.02 aydı, yedisi (%58.3) erkek idi. Hastaların altısı pnömoni, üçü postoperatif, ikisi araç dışı trafik kazası (ADTK) ve biri kronik böbrek yetmezliği tanısı ile yatırıldı. Altı hastada komorbid durum mevcut olup bunların beşinde sendromik durumlar ve bir hastada kronik böbrek yetmezliği olduğu saptandı. Hastaların yoğun bakım ortalama yatış süresi 27.17 ± 34.41 gün olarak saptandı. Hastaların 11'i şifa ile taburcu edildi. Bir hasta (ADTK) sepsis-dışı nedenlerden dolayı kaybedildi. Hastaların kateter takılmasından yedinci güne kadar geçen süre içerisinde beyaz küre değerlerinde istatistiksel olarak anlamlı bir azalma saptanmıştır (p= 0.014). Ayrıca ortalama trombosit değerleri kateter takıldıktan sonra yükselme göstermemiş, aksine sürekli azalma eğilimi

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did not increase after insertion of the catheter, on the contrary, they showed a constant tendency to decrease (p= 0.272). Procalcitonin values did not increase in the period after the insertion of the catheter, on the contrary, they showed a continuous decrease (p= 0.309). CRP values were shown to decrease statistically significantly in the days after the catheter was inserted (p= 0.027).

Conclusion: Considering antibiotic resistance and mortality, it is vital to pay attention to sterilization rules and to control the effectiveness of sterilization in terms of gram-negative bacteria that are resistant even to disinfectants.

Keywords: *Stenotrophomonas maltophilia*, sterilization, pediatric intensive care unit, epidemic management

göstermiştir (p= 0.272). Prokalsitonin değerleri de kateter takıldıktan sonraki süreçte artış göstermemiş, aksine sürekli azalma eğilimi göstermiştir (p= 0.309). CRP değerleri, kateter takıldıktan sonraki günlerde istatistiksel olarak anlamlı düzeyde düştüğü gösterildi (p= 0.027).

Sonuç: Antibiyotik dirençleri ve mortalite göz önüne alındığında, dezenfektanlara bile dirençli olan gram-negatif bakteriler açısından sterilizasyon kurallarına dikkat etmek ve sterilizasyonun etkinliğini kontrol etmek hayati önem taşımaktadır.

Anahtar Kelimeler: *Stenotrophomonas maltophilia*, sterilizasyon, çocuk yoğun bakım ünitesi, salgın yönetimi

Introduction

Healthcare-associated infections are an important health problem that can occur as a complication of modern medical practices and pose a threat to public health (1). Disinfection and sterilization applied to eliminate microorganisms in instruments and materials used in invasive interventions and operations applied to patients for diagnosis and treatment are of vital importance in the control of infections (2). Physical, chemical and biological tests should be used and documented as evidence of an effective sterilization process (3,4).

Sources of *Stenotrophomonas maltophilia* in hospitals include faucets, water systems, sinks, irrigation solutions, disposable nebulizers, central venous catheters, ventilators, endoscopes, hemodialysis fluids, contaminated disinfectants, hand soaps, patient files, and inadequate disinfection practices (5-10). In our study, we report an outbreak of pseudo-*S. maltophilia*.

Materials and Methods

S. maltophilia growth was detected in the blood cultures taken from the catheter of 12 patients hospitalized in the pediatric intensive care unit (PICU) of Van Training and Research Hospital between November 2021 and February 2022, and the files of these patients were scanned retrospectively.

Since the clinics of the patients with *S. maltophilia* growth were not compatible and there was no growth in the transplantations made with the catheter tip semi-quantitative culture method, it was assumed that the agent might have resulted from the contamination of medical instruments.

Three samples each from the blood culture bottles in which the cultures were cultivated and the syringes used in blood collection were sent to the laboratory. The blood culture bottle was incubated under sterile conditions in the laboratory. At the end of five days, no signal was obtained from the bottles removed from the incubation, blood agar, EMB (Eosin methylene blue agar) and chocolate agar were inoculated and incubated for 48 hours at 37 degrees, it was shown that no growth was detected.

2 cc sterile tryptic soy broth was drawn into each disposable sterile heparin injector and the lumen of the injector was washed, dilutions were prepared, and 100 microliters of tryptic soy broth was inoculated on blood agar EMB agar and chocolate agar and incubated at 37 for 24 hours. Isolated organisms were identified by Gram stain, colony morphology, biochemical tests and VITEK II. Antibiogram was applied to the identified *S. maltophilia* strains according to EUCAST (European Committee for Antibiotic Susceptibility Tests) 2021 criteria.

Surveillance

Microbiological data obtained from the intensive care unit where the outbreak strain was detected were examined two weeks before the outbreak, during the outbreak when the patients were positive for the outbreak strain, and for four weeks following the outbreak. Cases of *S. maltophilia* infection or colonization were counted weekly. Each patient was counted only once and included in the analysis.

Controlling the Epidemic

All heparin injectors sent by the manufacturer for use in the PICU were collected and returned. Later, it was determined that *S. maltophilia* reproduction was stopped with the use of heparin injectors produced by another company. For control and follow-up, samples were taken from new heparin injectors and sent to culture and no growth was found. It was evaluated that this false outbreak was brought under control with the collection of old heparin injectors used in the PICU. In addition, the production of heparin injectors with the employees of Company (Z) was also reviewed.

Statistical Analysis

Data obtained from our study, especially the laboratory values of the patients, were subjected to statistical analysis. First, the Shapiro-Wilk test was used to evaluate whether or not the data were suitable for normal distribution and it was observed that the data were suitable for normal distribution

(p= 0.271). Therefore, the paired t test, one of the parametric tests, was used. With this test, laboratory values obtained from the patients on days zero, three and seven were compared. In addition, basic characteristics of patients such as age, sex and clinical status assessment were also evaluated with descriptive analyses. For statistical analysis, version 28.0 of the SPSS package program was used. The limit of significance was accepted as p< 0.05 for all statistical analyses.

Results

Demographic and Epidemiological Characteristics of the Patients

In our pediatric intensive care unit, 225 patients were followed up during the study period, and *S. maltophilia* growth was detected in the control blood cultures taken from the catheter in 12 (5.33%) of them immediately after the catheter was inserted. Of these patients, 121 (53.7%) jugular and three (1.33%) femoral catheters were inserted. It was determined that the catheter cultures were taken with the same brand (E brand) heparin injectors.

Mean age of the 12 patients included in the study was 70.58 ± 81.02 months, seven (58.3%) were males. Nine (75%) of the patients included in the study received invasive mechanical ventilation, two received high-flow nasal cannula oxygen therapy and one received respiratory support with tracheostomy. Of the patients, six (50%) were hospitalized due to pneumonia, three (25%) postoperatively, two (16.7%) due to non-vehicle traffic accident (NVTA) and one (8.3%) due to chronic renal failure. Six patients had comorbid conditions, of whom five had syndromic conditions (cerebral palsy in two patients, microcephaly in one patient, metabolic disease in one patient, and spinal muscular atrophy in one patient) and one had chronic renal failure. None of the patients had a comorbid condition such as cystic fibrosis, malnutrition, or immunodeficiency that could predispose to non-fermentative gram-negative bacterial sepsis. Cultures taken with contaminated heparin injectors (E brand) from the catheters inserted in the first hour of admission to the intensive care unit in five of 12 patients, on the third day of hospitalization in three, and in the other four on the 8th, 10th, 30th and 32nd days, respectively, were transferred to microbiology. Mean hospital stay of the patients in the intensive care unit was 27.17 ± 34.41 days. Eleven (91.67%) of the patients were discharged with good recovery. One patient (NVTA) died due to non-sepsis causes (Table 1).

Mean white blood cell (WBC) count, platelet count, procalcitonin and C-reactive protein after catheterization were 12.988 ± 5.65/mm^3, 334.916 ± 275.090/mm^3, 8.42 ± 24.7 ng/mL, 66.50 ± 71.5 mg/L on day zero, 11.358 ± 4.283/mm^3, 296.250 ± 204.646/mm^3, 2.81 ± 7.42 ng/mL, 29.80 ± 32.31 mg/L on day three, and 8.658 ± 3.697/mm^3, 286.083 ± 151.768/mm^3, 1.86 ± 5.02 ng/mL, 15.67 ± 18.13 mg/L on day seven. A statistically significant decrease was found in white blood cell values from the seventh day after the catheterization of the patients (p= 0.014). Mean platelet values of the patients did not increase after insertion of the catheter, on the contrary,

Table 1. Demographic and epidemiologic characteristics of the cases

Patient number	Age	Diagnosis	Comorbidity	Length of stay	Time of growth in the catheter	MV status	Outcome
1	10 months	Post-op craniosynostoses	Syndromic events	17 days	2nd day	Intubated	Discharged
2	6 months	Bronchiolitis-ARDS	None	70 days	32nd day	Intubated	Discharged
3	16 years 2 months	NVTA	None	17 days	First day	Intubated	Discharged
4	12 years 3 months	Post-op cyst hydatid	None	2 days	First day	Intubated	Discharged
5	1 year	Pneumonia	None	22 days	10th day	Intubated	Discharged
6	6 months	CP-aspiration pneumonia	Syndromic events	30 days	8th day	Intubated	Discharged
7	14 years	NVTA	None	20 days	First day	Intubated	Mortality
8	17 years 4 months	CRF-Uremia	CRF	6 days	First day	HFNC	Discharged
9	1 year	SMA-Pneumonia	SMA	120 days	30th day	Trakeostomi	Discharged
10	3 years	Pneumonia	Metabolic disease	8 days	2nd day	HFNC	Discharged
11	1 year 4 months	CP-Pneumonia	Syndromic events	4 days	1st day	Intubated	Discharged
12	2 years 8 months	Post-op ileal atresia	None	10 days	First day	Intubated	Discharged

NVTA: Non-vehicle traffic accident, ARDS: Acute respiratory distress syndrome, CP: Cerebral palsy, CRF: Chronic renal failure, SMA: Spinal muscular atrophy, MV: Mechanical ventilation, HFNC: High frequency nasal cannula.

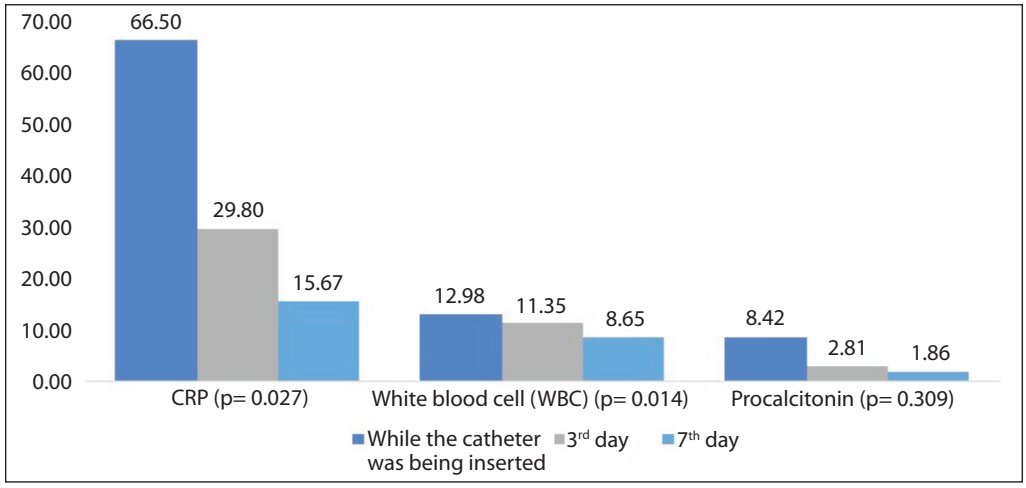

Figure 1. It is seen that patients' mean laboratory parameters do not show an increase from the day of catheter insertion until day seven, and on the contrary, the parameters show decrease and the picture is not compatible with clinical sepsis.

they showed a continuous decrease. However, no significant statistical difference was found between the days (p= 0.272). Procalcitonin values did not increase in the period after the insertion of the catheter, on the contrary, they showed a continuous decrease (p= 0.309). CRP values showed a statistically significant decrease in the days after the catheter was inserted (p= 0.027) (Figure 1).

White blood cell count (WBC), platelet count (PLT), procalcitonin (PROC) and (CRP) values of the patients on days zero, three and seven are shown in Table 2.

A complete physical examination was performed and medical records were reviewed in detail in patients with blood culture taken from the catheter. As a result of these evaluations, it was determined that the growth in the cultures of the patients was inconsistent with the clinical and laboratory findings, and no sepsis was detected in any of the patients.

Pseudo-Outbreak Description and Case Finding

After receiving blood culture reports from 12 positive catheters with *S. maltophilia*, the Infection Control Committee (ECC) conducted outbreak investigation and culture cultivation of the isolates. The outbreak curve revealed an unusual increase in *S. maltophilia* bacteremia exceeding the upper control limit [3 standard deviations (SD)] on the statistical process control chart (U plot, data not shown) from November 2021 to February 2022.

This situation was reported by HEK to Z company, which produces E brand heparin injectors, and it was ensured that the contaminated injectors were recalled from the market.

Table 2. Laboratory parameters of the patients on days zero, three and seven

Patient Number	WBC day 0	WBC day 3	WBC day 7	PLT-day 0	PLT-day 3	PLT-day 7	Pro-C day 0	Pro-C day 3	Pro C-day 7	CRP-day 0	CRP-day 3	CRP-day 7
1	15.600	10.700	9800	128.000	140.000	277.000				240	65	24
2	13.700	16.200	9200	81.000	184.000	255.000	1.48	0.82	0.63	86.00	20.51	11.10
3	21.000	13.000	9800	96.000	112.000	190.000	0.15	0.10	0.10	7.00	8.00	4.00
4	25.000	18.000	7800	679.000	600.000	450.000	2.42	1.10	0.8	67.00	47.00	27.00
5	10.860	7300	7800	805.000	457.000	600.000	0.07	0.101	0.030	1.46	0.20	0.10
6	8200	7800	4700	337.000	216.000	300.000	1.20	0.49	0.20	21.30	9.70	6.50
7	12.700	15.400	17.000	217.000	220.000	237.000	0.70	0.49	0.21	27.70	12.20	2.10
8	5400	6400	4900	102.000	111.000	103.000	0.310	0.300	0.200	1.21	7.80	7.20
9	12.000	15.000	13.000	750.000	650.000	450.000	1.45	1.20	0.80	65.00	43.50	45.50
10	8600	5600	4600	304.000	310.000	265.000	1.10	1.0	0.24	69.80	9.30	3.20
11	15.000	13.000	9800	455.000	500.000	250.000	0.65	0.15	0.25	45.70	23.0	3.20
12	7800	7900	5500	65.000	55.000	56.000	83.10	25.16	16.98	165.80	111.40	54.10

WBC: White blood cell, PLT: Platelet, ProC: Procalcitonin, CRP: C-reactive protein.
References ranges of our laboratory for procalcitonin and CRP are respectively as 0-0.046 ng/mL and 0.0-5.0 mg/L.

Environmental Surveillance and Observational Study of the Pediatric Intensive Care Unit

Cultures were planned to be taken from all 21 handwash sinks in the ICU, four faucets in the care room, sink and potable water in the ICU kitchen, a nurse station adjacent to a sink used for both hand washing and cleaning of contaminated medical equipment, from the hands of nurses, from the hands of healthcare workers who have come into contact with the patient; however, cultures were taken from heparinized injectors upon receiving reports of outbreaks of heparin injectors from surrounding hospitals (E brand) in the current time period. Interviews with healthcare professionals about the blood sampling process revealed that healthcare professionals always wore sterile gloves, followed the rules of antisepsis in drug preparation and patient contact. However, it was learned that heparin injector was used while blood cultures were taken from the catheter (E brand) from some patients.

No growth was detected in another patient who slept in the next bed and received the same nurse care and who used a close sink with the patient who had growth. This showed that there was no cross contamination. Catheter blood cultures were sent 138 times within 120 days. Heparin injector was used for 12 of these catheter blood cultures. It was determined that >100.000 CFU of *S. maltophilia* was grown in catheter blood cultures taken with heparin injectors. All of our heparin injectors used in the PICU are from the same company and are the same brand. Three samples were sent from these heparin injectors, and it was determined that there was >100.000 CFU *S. maltophilia* growth. There was no growth of *S. maltophilia* in any of the blood cultures taken with normal syringes.

Backtracking Research (Manufacturing of Heparinized Saline Flush Injectors)

The pharmacy that the manufacturing company has a contract with and the manufacturing company Z jointly undertake the production of these injectors. Company Z delivers heparin solutions to the pharmacy to prepare heparin raw material powder and heparin gel. The pharmacy prepares heparin gels from the materials sent by the company, places them in sterile bags and sends them to company Z. The company uses automated equipment to pump heparinized gels into sterile syringes. Filled syringes are packed and labeled. All these processes are done in a clean room. During our meetings with the company, the records of the "finished product test" required for the sterilization control of packaged medical supplies could not be reached.

The expiry dates of the contaminated syringes in our possession were checked, and it was seen that none of them had passed their expiration date. During the meeting with company Z, it was learned that packaged heparin injectors were sterilized using ethylene oxide with low temperature pressure. It was recommended to check sterilization validation stages of the company for packaged and lumen medical devices.

Discussion

We tracked down 12 cases of *S. maltophilia* culture growth in our PICU unit, which occurred with intrinsically contaminated, heparinized blood gas sampling syringes prepared in a pharmacy warehouse. In our study, both detailed physical examinations and clinical follow-ups of the patients with growth in the blood culture taken from the catheter were performed strictly and especially in the follow-up with laboratory parameters. In the follow-ups from the time of insertion of the catheter, no increase was observed in the blood values of the patients, especially in the infection parameters, on the contrary, all of the white blood cell, platelet, procalcitonin and CRP values showed a decreasing trend. This is compatible with physical examination and clinical follow-up and supports the absence of clinical sepsis findings in the patients. It was noticed that this situation also occurred in the adult intensive care unit of our hospital, other inpatient services and even throughout the province, that is, the number of *S. maltophilia* growths in the culture was quite high. Hospitals with all affected patients across the province were contacted, and it was determined that these heparinized blood gas injectors, which caused the outbreak, were purchased from company Z, and that there were many unopened heparin injectors in these hospitals. In a report published by the US Food and Drug Administration (FDA), it has been stated that manufacturers avoid various regulatory rules in order to produce cheap materials, which may pose a significant problem (11). As reported by the FDA, the fact that cheap material manufacturers avoid some rules and also reduce the quality of the material poses a significant risk in terms of patient health. We think that cheapness of hospital supplies cannot be a reason for preference, and it is more important for patient health to have sterilization control documents for medical supplies.

S. maltophilia is an important nosocomial pathogen that has been reported to cause infections, colonization and epidemics previously (12-15). In addition to *S. maltophilia*, it has been reported that many other microorganisms such as *P. aeruginosa* can cause colonizations, epidemics and pseudo-outbreaks (16-18). Cross-contamination or disruptions in disinfection processes may be the cause of outbreaks caused by these factors (19,20). However, disruptions in sterilization processes in medical supplies can also pave the way for epidemics or pseudo-epidemics with these factors. Numerous infectious outbreaks have been reported in the literature due to contamination of products that should be sterile (17,21-23). When the epidemic reports related to all these sterilization defects are examined, Gershman et al., in their retrospective review of 80 patients from six states between December 2004

and March 2006, reported bloodstream infection due to *Pseudomonas fluorescens* in patients exposed to a pharmacy-prepared contaminated heparinized saline flush (17). In 2005, four of the patients treated in an oncology clinic in Missouri were reported to the American Center for Disease Control and Prevention (CDC) to have a bloodstream infection caused by *P. fluorescens*. It was determined that the common feature of these patients was exposure to heparinized saline intravenous flush injectors, which were determined to be contaminated with *P. fluorescens* by the microbiology laboratory of the hospital. The investigation revealed that these injectors were prepared by a Texas pharmacy and a manufacturing company (Company A), preloaded into the syringes with intravenous flush, and distributed by the same company (Pinnacle Medical Supply, Rowlett, Texas). It was determined that it was applied to patients in Missouri to prevent coagulation that may occur in central venous catheters. Five days after this notification, the American Food and Drug Administration (FDA) issued a nationwide warning, calling for caution in the use of all heparin/saline flushes preloaded on the syringes with intravenous flush, and immediately afterwards, the relevant company ordered the recall of all products in the market. Within two weeks of this date, state and local health departments and the CDC were notified that a total of 36 *Pseudomonas* strains infections were detected in patients treated with heparin/saline wash from more than one lot in four different states (23). David Blossom et al. in their research, detected bloodstream infections in which *Serratia marcescens* grew in a total of 162 patients in nine states of the USA in 2007 in healthcare facilities where heparin and/or saline injectors were used. In the review of these patients, it was determined that all patients had in common the use of prefilled and unopened heparin and/or saline syringes manufactured by Company X. *S. marcescens* growth was confirmed in the cultures made from these unopened and prefilled syringes administered to these patients. It was revealed that there was a genetic relation between *S. marcescens* grown in the culture in 70 (84%) of a total of 83 blood samples sent to CDC by seven states and *S. marcescens*, which was reported to be grown from injectors used in these patients. In the inspections carried out by the US Food and Drug Administration (FDA), it was determined that Company X did not act in accordance with the quality system regulations, and the outbreak probably occurred for this reason (24). Parallel to these, in 2001 Rachel Civen et al. reported an outbreak of *S. marcescens* infection following betamethasone injection in California, USA. The authors stated that the cause of this outbreak was the contamination of betamethasone prepared in the pharmacy. Meningitis occurred in five of the 11 cases affected by this outbreak, and three of them were mortal. Brain abscess and hip joint infection were also reported in other patients. The authors stated that this serious *S. marcescens* infection was due to the improper preparation of betamethasone in a pharmacy and that national standards applicable to pharmaceutical compositions were needed to reduce the risk of such outbreaks. The authors also noted that high-risk compounded sterile products must undergo final product sterility testing before dispensing into pharmacies. As a matter of fact, after this outbreak, the California Board of Pharmacy required pharmacies preparing sterile formulations to obtain a special license (22). Outbreaks due to all these contaminated medicinal products are similar to the one that occurred in our PICU. However, in the above-mentioned literature samples, while the bacteria were given to the patient from the contaminated product, there was no transfer of bacteria to the patient's blood in our cases. The patient's blood was infected in the syringe from which the sample was taken.

According to the Spaulding classification used since 1968, all medical supplies are divided into three groups as 'critical', 'semi-critical' and 'non-critical' materials according to the infection risk they carry. The sterilization and disinfection method to be applied is done accordingly (2,25). Critical medical supplies are sterilized in an autoclave (steam sterilization) if possible. If the vehicle is made of heat-sensitive materials (for example, plastics), sterilization can be performed with low temperature sterilization method [ethyleneoxide gas (ETO), hydrogen peroxide plasma, etc.]. The most important advantage of the ETO sterilization method, which is also used in our injectors, is its good penetration into medical packages and lumens (26). In packages made with paper and plastic combinations of lumen medical devices, they should allow the penetration of sterilant into the packaging material, protect against contact contamination during use, provide an effective barrier against microbial penetration, and maintain the sterility of the processed material after sterilization (27). Physical, chemical and biological controls that prove the effectiveness and safety of sterilization should be provided (3,4). A biological control, "microbiological verifications", indicates the "sterility confidence level" of medical supplies and is a statement of adequacy and safety of sterilization of the product before it is distributed to the market (28). Satisfactory quality control and monitoring of the sterilization processes is important in maintaining the safety of sterile materials in the sterile medical supplies department. The quality monitoring process of each sterilization technique depends on chemical, biological and physical parameters in accordance with the Association for the Advancement of Medical Instrumentation (AAMI), International Standards Organization (ISO) and European Norms (EN) (29,30).

In our study, a pseudo-outbreak situation caused by heparin injectors, which were applied to patients and should have been sterile, was reported. It was also determined that the outbreak in our study was seen in large numbers in our hospital and in our city, in the COVID ICU, Adult ICU and operat-

ing room units. After this false outbreak, necessary feedback was given to the infection control committees throughout the hospital and the province, and after the injectors of the relevant brand were collected and necessary sterilization controls were provided, it was determined that the growth status of this agent in the culture disappeared, which confirmed that the epidemic agent had originated from the syringes whose sterility was not adequately provided. No such new outbreak has been documented in the process after ensuring that the necessary infection control measures are taken. Our study also highlights the public health importance of informing all patients and hospitals exposed to contaminated intravenous products since patients are at risk of infection as long as the catheter is inserted.

Sterilization control should be ensured in order to enable that all medical materials have successfully completed the sterilization stages and sterilized with an effective and appropriate technique for medical equipment. False outbreaks and even fatal outbreaks may occur with contaminated medical devices due to deficiencies in sterilization controls or insufficient sterilization. Therefore, sterilization controls must be made before the market and especially before patient use, and all of these must be recorded. Especially for critical materials, "sterilization control certificate" is of vital necessity. In our study, we saw that sterilization was applied effectively and suitably for the material in the meetings with the company Z, but we could not reach the "finished product test" or "sterilization control document" of the company.

Conclusion

Healthcare-associated infections may occur due to medical equipment and devices used for patients. It should be kept in mind that not every growth in patient blood draw samples will show a real outbreak, the patient should be evaluated clinically and with laboratory analysis, and there may be such a false outbreak in case of non-compliance. The existence of "sterilization control documents" showing that sterilization control level tests have been carried out should be confirmed before medical materials are used.

Limitations and Advantages of the Study

Our study has certain limitations. First, genetic typing of *S. maltophilia* grown in culture was not performed in our patients. Deficiencies in notification and surveillance chains can be considered as another limitation. On the other hand, we think that our study will make an important contribution to the literature as it reports a pseudo-outbreak related to a medical device that should have been sterile in this way. In addition, in our study, blood was drawn only from the catheter with pre-filled contaminated syringes, and no intravenous bolus was administered to the patients using the injectors, which is the main reason why bloodstream infection did not occur.

Ethics Committe Approval: Ethical approval was obtained from Van Training and Research Hospital Clinical Research Ethics Committee with the decision numbered 2022/13-04 on 15.06.2022.

Informed Consent: Patient consent was obtained.

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Author Contributions: Concept- EB; Design- EB, MB; Supervision- EB, EUB; Resource- FA, MB, SY, ZE; Data Collection and/or Processing- MB; Analysis and/or Interpretation- EB; Literature Search - EB, EUB; Writing- MB; Critical Review- EUB, ZE.

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