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Management of an Epidemic Outbreak of Burkholderia cepacia in A Hospital in The North of Italy

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Abstract

Burkholderia Cepacia (B. Cepacia) is a gram-negative bacterium responsible both for colonization and for a wide range of infections and clinical complications that significantly increase morbidity and mortality. B. Cepacia is able to survive and replicate into antiseptic solutions and invasive medical devices, thus representing potential reservoirs for hospital infections. Between April and August 2019 in the north of Italy, in two hospitals belonging to the same social health district (AULSS 8 Berica- West District), five cases of B. Cepacia sepsis were reported. This paper describes the epidemiological and microbiological investigation of the causal pathogen, the control measures adopted to contain the epidemic and the results obtained. The Infection Control Committee (ICC) assessed relevant demographic characteristics and potential risk factors of infected patients and collected environmental and equipment samples. Phenotypic and genotypic identification was carried out using microbiological methods of culture and the MALDI-TOF technique. The B. Cepacia sepsis involved four oncological patients and one cardiological patient who underwent an invasive procedure under ultrasound guidance from April to August 2019 at one of the hospitals involved. The analyses highlighted the positivity for B. cepacia in the ultrasound gel used for the eco-guided procedures. All samples were found to be sensitive to Meropenem. The infection control measures put into effect permitted an effective management of the outbreak and helped to reduce the risk of subsequent cases. The outbreak has revealed the need to draw up internal operating procedures that regulate punctually the grafting of invasive devices.

Keywords: *B. Cepacia; Gram-negative bloodstream infections; Hospital infections; Ultrasound gel; MALDI-TOF technique; Infection control measures*

Introduction

Burkholderia Cepacia (B. Cepacia) is an aerobic, gram-negative, catalase-producing, non-sporogenic, non- lactose fermenting bacterium. It belongs to a group of bacteria that includes at least 21 phenotypically similar but genetically distinct species called "Burkholderia Cepacia Complex". [1]

The identification of the species of B. Cepacia Complex is not easy using commercial phenotypic tests; the difficulty in differentiating the species or the Burkholderia from other similar gram-negative bacteria has led to high rates of misclassification or non-identification.

The MALDI-TOF mass spectrometry method (Matrix-Assisted Laser Desorption / Ionization-Time of Flight) is the best microbiological technique to correctly identify most of the species belonging to the B. Cepacia Complex. The confirmation of identification,

speciation and molecular typing of the B. Cepacia cultures should be performed in a reference microbiological laboratory. [1]

These bacteria are typically found in the ground and in moist soils. They have great metabolic versatility that allows them to adapt to a wide range of environments; morevover, their genome flexibility in acquiring and losing genes favors a peculiar variability in the pathologies caused. [1,2]

The species of the B. Cepacia Complex are opportunistic pathogens responsible both for colonization and for a wide range of infections and clinical complications that significantly increase morbidity and mortality. They can be very dangerous in the hospital setting, especially in intensive care units (ICU) where they can cause epidemics. [3]

The clinical presentation of the infection during epidemics is variable, causing mainly bacteraemia and "Cepacia Syndrome"-bacteraemia with rapid deterioration of lung function. [2-13]

It can also cause pneumonia [14,15], VAP [16,17], endophthalmitis [18,19], UTI [20,21], prostatitis [22],

arthritis [23], spondylodiscitis [24], meningitis [25], endocarditis [26], pyomyositis [27] and peritonitis. [28] The B. Cepacia Complex infections especially affect the fragile and immunocompromised hospitalized population. These bacteria tipycally involve subjects suffering from chronic lung diseases, such as cystic fibrosis and granulomatous disease, however their pathogenicity is not limited to such patients. [1]

The risk factors identified for B. Cepacia bacteremia among hospitalized patients without cystic fibrosis are: immunosuppression, comorbidity, prolonged hospitalization, presence of central indwelling catheters and other invasive medical devices, renal failure in hemodialysis, multiple bronchoscopic procedures and recent abdominal surgery. [1,11]

A study investigated the outcome predictors among hospitalized patients without cystic fibrosis with B. Cepacia infection or colonization: disease severity and old age were the only two significant independent factors of mortality at 14 days. The highest mortality rates found in patients with B. Cepacia were not different from those usually seen in patients with any other type of ICU infection. In addition, this research showed that acquiring the pathogen at the moment of exacerbation of the underlying disease leads to a higher mortality rate. [1]

The mortality rate can differ and in some studies is reported to be up to 50% in patients with several underlying diseases and tracheal intubation. [3] So the authors concluded that prompt antibiotic treatment and supportive therapies are crucial to ensure adequate case management and favorable clinical outcomes for patients with bacteremia. [1]

The treatment of infections sustained by these microorganisms is often difficult because of their intrinsic resistance to aminoglycosides, first and second generation cephalosporins and polymyxin and the emergent global issue of pharmacological resistance further complicates clinical management. [11]

B. Cepacia susceptibility to antibiotics may differ in the various epidemics that occur internationally; it is mainly susceptible to trimethoprim-sulphamethoxazole, carbapenems (meropenem), ticarcillin and quinolones (ciprofloxacin). [29]

As reported in literature, the outbreaks duration varies from weeks to years and the identification of the source is often difficult, so in many cases it is not identified or not confirmed. [3]

The B. Cepacia Complex is able to survive and replicate into antiseptic solutions and invasive medical devices, thus representing potential reservoirs for infections in the hospital setting. [11]

Many studies have reported outbreaks of nosocomial infections of B. Cepacia caused by drug contamination (ultrasound gels, intravenous solutions, anesthetic agents, inhaled drugs, skin disinfectants) or devices (pre- filled syringes with saline solution and sterile products). [20]

B. Cepacia transmissions have also been reported due to contact between people, contact with contaminated surfaces or environmental exposure. [30]

Between April and August 2019 in the north of Italy, in two hospitals belonging to the same social health district (AULSS 8 Berica- West District), five cases of B. Cepacia sepsis were reported.

This outbreak led to an intense process of surveillance and research in order to identify any additional case and carrier of the pathogen, and to establish timely strategies with the aim of controlling the epidemic. This paper describes the epidemiological and microbiological investigation of the causal pathogen, the control measures adopted to contain the epidemic and the results obtained

Material and Methods

Hospital setting and patients

The AULSS8 Berica- West District is composed by 4 hospitals distributed on the territory of the Veneto Region – Italy. Between April and August 2019 five

cases of B. Cepacia sepsis were reported in two hospitals of this district: four in oncological patients and one in a cardiological patient.

The first four cases had very similar characteristics: they were all patients with an oncological pathology, who entered the Oncology Department of Montecchio Maggiore Hospital for the day hospital administration of chemotherapy treatment through implantable vascular access.

The fifth case involved a patient who was admitted to Cardiology Department of Arzignano Hospital for heart failure with pleural and pericardial effusions; during hospitalization he was subjected to bilateral thoracentesis and pericardiocentesis, and the presence of B. Cepacia was detected in the pericardial fluid. Considering that the last patient presented different clinical history and characteristics compared to the other ones, the Infection Control Committee (ICC, composed by representatives of Medical Direction, Risk Management, Infectious Diseases, Microbiology and Hospital Pharmacy) studied the cases to find a possible common point among these patients that could explain the acquisition of B. Cepacia.

After the identification of the first four cases of sepsis at the Oncology Department, an epidemiological and microbiological investigation was promptly started to identify the responsible pathogen and trace both the source and the way of transmission.

Epidemiological investigation

Relevant demographic characteristics and potential risk factors of infected patients have been assessed and analyzed: age, sex, underlying disease, clinical comorbidities, hospitalization, previous antibiotic treatments, surgical procedures, central venous access, permanent medical devices and drugs used.

Epidemic cases have been defined as patients with clinical suspicion of sepsis (fever, tachycardia, tachypnea, leukocytosis or leukopenia, with or without hypotension) with positive culture for B. Cepacia undergoing invasive procedure under ultrasound guidance from April to August 2019 at one of the hospitals of the AULSS 8 - West District.

Microbiological investigation

After reporting the first four cases in Oncology, the ICC collected environmental and equipment samples from taps water, surfaces, medications and devices. The specimens were initially performed both on involved patients and at Oncology and Surgical Unit; later the research was extended to other departments and hospitals of the West District. Pads were used to take samples from the environment and test tubes were employed to contain liquids; the material was collected using sterile products and techniques.

The samples were sent and analyzed at the Microbiology Department; phenotypic and genotypic identification was carried out using microbiological methods of culture and MALDI-TOF technique.

Antibiotic susceptibility analysis was carried out on all samples collected showing bacterial growth of B. Cepacia.

All samples were found to be sensitive only to Meropenem except for: a blood culture sensitive also to trimetoprim sulfametoxazole and a central venous catheter culture sensitive also to ciprofloxacin, levofloxacin and piperacillin.

The committee organized periodical meetings to share and discuss the results.

Results

Oncology Department- Montecchio Maggiore Hospital

The B. Cepacia sepsis involved four oncological patients who entered the Oncology Department of Montecchio Maggiore Hospital for the day hospital administration of the chemotherapy treatment through implantable vascular access.

In two cases the onset of symptoms occurred simultaneously with the administration of the first dose of chemotherapy: a few minutes after the treatment they experienced fever with chills.

In the other two cases the onset occurred during the second therapy session even if it was discovered that they also had complained fever and chills on the day of the first chemotherapy, referred only to the general practitioner.

The bacterium B. Cepacia was isolated from the blood culture analysis, presenting in all cases the same phenotypic and genotypic characteristics.

Considering that the cases presented a similar clinical manifestation and that the colonies of bacteria detected in blood cultures appeared morphologically overlapping, it was hypothesized that the origin of the infection and the transmission dynamics could be common to all four patients.

All patients were subsequently admitted to medical wards for further diagnostic investigations and they received antibiogram-based antibiotic treatment.

Three patients were treated with intravenous meropenem because their blood cultures were found to be sensitive to meropenem while the central venous catheter culture of a fourth patient was also sensitive to ciprofloxacin, so the patient was treated

with oral ciprofloxacin.

Three patients recovered and were discharged from hospital between 12 and 18 days without any complication or consequence due to infection; one patient unfortunately died but the outcome was related to her underlying disease and not attributed to B. Cepacia bacteraemia. The clinical details of cases are autlined in Table 1.

The ICC carried out in July 2019 an inspection at Oncology Department with the aim of searching for potential exposures and probable pathogen acquisition mechanisms in the area where chemotherapy sessions were performed.

A microbiological investigation was carried out performing environmental samples in Oncology Department (water and surfaces). In order to analyze sources implicated in previous B. Cepacia outbreaks reported in the literature. [11] Table 2 reports enviromental sampling sites results.

None of the microbiological cultures showed the presence of B. Cepacia so further investigatios were carried out in order to find the source of infection and the transmission mechanism.

A medical records review was performed: the clinical history, the underlying pathology and any comorbidities, the execution of surgical procedures, the presence and duration of exposure to permanent devices and other potential risk factors were evaluated in order to find a common characteristic that could suggest the infective mechanism.

The analysis carried out highlighted that all the patients carried a Port-a-cath device positioned in the operating room at Arzignano Hospital.

Port placement is a small surgical procedure lasting 20-30 minutes that is performed under local anesthesia in the operating room, it consists of two phases: cannulation of the vein under ultrasound guidance and subcutaneous tank implantation. The device implantation must be performed under aseptic conditions, using sterile material and disinfecting the area surrounding the chamber.

Like all surgical procedures, the positioning of the Port can also give rise to complications, including the possibility of becoming infected with fever and chills at the time of use. [31, 32]

Surgical Unit- Arzignano Hospital

Suspecting an infection of the Port-a-cath, at the beginning of August 2019 an inspection was carried out at the Surgical Unit of Arzignano Hospital to verify the positioning of this device and some critical issues were highlighted from hygienical and caring point of view.

Microbiological samplings were performed on medical devices most probably involved in the transmission of the infection, including physiological bottles and ultrasound gel used for the eco-guided Port-a-cath implant procedure.

The analyses highlighted the positivity for B. Cepacia in the ultrasound gel. Table 2 reports enviromental sampling sites results.

Having thus identified the source of infection, the Medical Direction in agreement with the ICC has immediately released directives to face the outbreak and a series of corrective actions were applied to improve the care process.

The Port-a-cath of the four patients were promptly removed and replaced and the patients were admitted to hospital in order to be monitored and receive antibiotic treatment.

One of the Ports has been preserved for microbiological investigations, both the external part of the catheter and the internal part of the tank have been sampled resulting positive for B. Cepacia as patients' blood and the ultrasound gel.

Cardiology Department- Arzignano Hospital

At the end of August 2019, the ICC was contacted after the detection of B. Cepacia positivity in another patient at the Cardiology Department of Arzignano Hospital.

The patient had been hospitalized for heart failure with pleural and pericardial effusions; during hospitalization he was subjected to bilateral thoracentesis and pericardiocentesis and the presence of B. Cepacia was detected in the pericardial fluid. Consequently, he was readmitted to General Medicine ward to receive intravenous treatment with meropenem, the only antibiotic to which B. Cepacia showed antibiogram sensitivity. He was successfully discharged at home after 20 days, without long-term morbidities related to the infection.

From the subsequent investigations it was noticed that the pericardiocentesis was performed in CICU (Coronary Intensive Care Unit) with an eco-guided technique; therefore, also this patient, like the other cases, had been subjected to an invasive procedure with the use of ultrasound gel.

This case raised awareness that the problem of B. Cepacia contamination potentially involved all the departments in which invasive procedures were performed under ultrasound guidance. The clinical details of the case are outlined in Table 1.

Investigation and actions undertaken

Since B. Cepacia has been detected in patients and in the gel but not in the environment, corrective actions and safety measures focused on this substance.

The Hospital Pharmacy examined the supply records of medical products and recovered the production lot of the contaminated gel. All the departments provided with this batch were identified but it was no longer in use.

To further microbiological investigations, two sealed containers from the storehouse were analyzed, resulting both negative for the presence of B. Cepacia.

The ICC prompt recalled the available gel stock in each department of the four West District hospitals and it was isolated in the Pharmacy warehouse to be random analyzed. The number and the quantity of the stored gel were determined: 41 containers and 220 bottles were recalled, for a total of about 163 kg of gel involved. The microbiological samples carried out so far showed B. Cepacia positivity for gel samples from the Medicine and Neurology Department of Arzignano and Senology Department of Montecchio Maggiore.

The 5-liter gel packs were replaced with 250- or 150-ml containers of another manufacturing company; furthermore, from that moment on, it was decided to use sterile gel for invasive procedures and non-sterile one for practices on intact skin.

An epidemiological surveillance was started to monitor the situation and promptly identify any additional case of B. Cepacia infection or colonization: the total acquired number of PORT / PICCs inserted at the Arzignano Surgical Unit from April (month of the first case recorded) to September (month of ultrasound gels withdrawal) was about seventy.

The ICC decided to proceed with vigilant surveillance and immediately perform blood cultures if any patient with implantable vascular access would have presented symptoms of bacteremia during a chemotherapy session.

Furthermore, a notification of the contaminated devices was sent both to the manufacturing company and the Italian Ministry of Health in order to solicit the research of B. Cepacia also in other products and care settings.

To date, no further new cases of infection have been detected.

Table 1: Demography and clinical features of patients with Burkholderia Cepacia

Patient	Age	Sex	Underlying disease	Comorbidities	Invasive eco-guided procedure	Blood culture positive date of b.cepacia	Hospital admission for sepsis	Treatment received	Outcome: survived
1	57	F	Breast cancer	Metastases (lung, brain, lymph node, skeletal). Chronic C hepatitis	Port-a-cath (11 April 2019)	16 April 2019 (first Port use)	NO	Ciprofloxacina per os	NO
2	61	M	Lung cancer	Metastases (lymph node, skeletal). Peripheral vasculopathy. IPMN	Port-a-cath (30 May 2019)	6 June 2019 (first Port use)	YES	Meropenem ev	YES
3	71	M	Prostate cancer	Metastases (lymph node, skeletal). DM 2. Hypertension	Port-a-cath (6 June 2019)	11 July 2019 (second Port use)	YES	Meropenem ev	YES
4	73	F	Colon-rectal cancer	Metastases (liver, uterus). AF	Port-a-cath (8 July 2019)	30 July 2019 (second Port use)	YES	Meropenem ev	YES
5	82	M	Heart failure	Pericardial and pleural effusion. DM2. Dyslipidaemia. Hypertension. BPCO. CKD	Pericardiocentesis (14 August 2019)	14 August 2019	YES	Meropenem ev	YES

Table 2: Environmental sampling sites results

SOURCE OF THE SAMPLES	MICROBIOLOGICAL MATERIAL	NUMBER	RESULT	MICROORGANISM
Patient				
1	blood	1	**pos**	B. Cepacia
1	blood	1	**pos**	B. Cepacia
1	Port a cath	1	**pos**	B. Cepacia
2	blood	1	**pos**	B. Cepacia

2	blood	1	**pos**	B. Cepacia
3	blood	1	**pos**	B. Cepacia
4	blood	1	**pos**	B. Cepacia
4	Port a cath	2	**pos**	B. Cepacia
	Environment			
Oncology Dep.	taps	6	neg	
Oncology Dep.	nurses work counter, sink, pumps, nursing cart	11	**pos**	other microorganisms
Surgical Unit	physiological solution	1	neg	
Surgical Unit	antiseptics, hand sanitizers	13	neg	
Surgical Unit	multiple surfaces in the operating room	16	**pos**	other microorganisms
	Ultrasound Gel			
Surgical Unit	5L gel container	1	**pos**	B. Cepacia
Surgical Unit	5L gel container	1	**pos**	B. Cepacia
Cardiology Dep.	5L gel container	1	**pos**	B. Cepacia
Cardiology Dep.	250ml gel bottle	1	**pos**	B. Cepacia
Cardiology Dep.	5L gel container	1	neg	
Hospital Pharmacy	5L gel container	1	neg	
Hemodialysis	5L gel container	1	neg	
Hemodialysis	250ml gel bottle	1	**pos**	B. Cepacia
Day Services Centre	5L gel container	1	neg	
General Medicine Dep.	5L gel container	1	neg	
General Medicine Dep.	5L gel container	1	**pos**	B. Cepacia
General Medicine Dep.	5L gel container	1	neg	
Neurology Dep.	5L gel container	1	**pos**	B. Cepacia
Endocrinology Dep.	5L gel container	1	neg	
Radiology Dep.	5L gel container	1	neg	
Rehabilitation Dep.	5L gel container	1	neg	
Rehabilitation Dep.	5L gel container	1	neg	
Rehabilitation Dep.	5L gel container	1	neg	
Senology Dep.	250ml gel bottle	1	**pos**	B. Cepacia

Discussion

B. Cepacia sources of infection

The investigation conducted on these cases of B. Cepacia sepsis revealed that the contaminated ultrasound gel used in the eco-guided procedures was the source of this outbreak.

The growth of the same microorganism in the patients' cultures and in the gels, ones demonstrated the source of infection that was also confirmed by the sharp end of the outbreak after the withdrawal and replacement of the ultrasound gel.

Previous studies have linked the outbreaks of B. Cepacia to different contaminated products in addition to the ultrasound gel; the medical products' contamination can occur in an extrinsically (introduced while the device is in use) or intrinsically (ie already present when the device is received in the hospital). [1-30]

The West-District outbreak was probably caused by an intrinsic acquisition during the manufacturing process: water pollution during production, bacterial resistance to preservatives and non-sterilization are common causes of B. Cepacia contamination and could occur throughout the entire production process. Indeed, in the USA the CDC (Centers for Disease Control and Prevention) recalled some products with defects in the manufacturing process that have caused nosocomial B. Cepacia infections. [20]

As reported in literature, ultrasound gel has been previously identified as a source of B. Cepacia infection [3,4,7,8,22,30,33,34]: this bacterium is able to hydrolyse parabens, esters of p-hydroxybenzoic acid with antimicrobial properties commonly added as stabilizers in gel and this characteristic allows it to colonize and proliferate in this medical substance. [8]

Therefore, it is strictly recommended to suspect ultrasound gel and test it along with other medical devices, particularly during a B. Cepacia outbreak. [33]

In previous Pseudomonas Aeruginosa and Klebsiella Oxytoca outbreaks, the US Food and Drug Administration ordered to recall contaminated gels and recommended the use of sterile ultrasound gel for invasive procedures while the use of non-sterile products for procedures performed on intact skin and on low-risk patients. [8]

The lack of regulations and precise guidelines

governing the use of the gel in clinical practice is unfortunately an established problem: some researchers emphasize the importance of using only sterile gel near susceptible sites and they recommend the introduction of routine sterility checks, even for usually non-sterile products if used in critical areas, particularly when stabilized with parabens.[33]

In conclusion, although the sterility of substances that come into contact with intact skin, such as ultrasound gel, is generally not required, B. Cepacia contamination should not be underestimated, especially in fragile and complex patients.[33]

Limitations: Hygienic and caring criticalities

It is necessary to underline that, although in this case the infection was probably the result of a gel contamination during production, no case would have occurred if the indications to maintain the sterility during the insertion of the devices would have been followed, as the gel should never come into contact with the patient's skin.

According to the latest guidelines, the use of ultrasound technique for the placement of implantable catheters is encouraged, as it guarantees a better success rate at first attempt, reduces the failures and the risk of complications. However, it is mandatory to ensure sterility, otherwise all benefits aimed at patient safety are nullified by the risk of microorganism transmission.[35]

Furthermore, in order to guarantee patient's safety, it is necessary that the vascular accesses insertion procedure is correctly performed.

Infection control measures

Following B. Cepacia cases, strict infection prevention measures have been adopted and systematic control practices have been undertaken to avoid a further spread of the outbreak.

The infection control actions included: removal of all 5-liter ultrasound gel containers and replacement with single 250 or 150 ml bottles from another manufacturer; use of sterile gel for invasive procedures; use of sterile pre-filled syringes for PICC and Port washing; staff training on proper hand hygiene and on appropriate behaviour in the operating room; field training course on vascular access management and medication; accurate sanitization of the environments and all equipment and definition of the responsibility for the disinfection of critical devices; review and sharing of hospital protocols on healthcare infection prevention; monitoring the implementation of the improvement actions.

All these strategies are in line with an internationally shared infection control policy: studies concerning previous B. Cepacia outbreaks have shown that adherence to these good care practices has allowed to avoid the transmission of the pathogen, further limit the spread and end the outbreak. [1,3,11,20,30]

Additional tools that have proved to be fundamental for successful case management were: regular meetings to discuss prevention and control measures and recommendations; collaboration among the departments involved in the outbreak; continuous epidemiological and microbiological surveillance coordinated by ICC.

Conclusions

In this outbreak the cases were defined as patients with clinical suspicion of sepsis (fever, tachycardia, tachypnea, leukocytosis or leukopenia, with or without hypotension) with positive culture for B. Cepacia who underwent ultrasound-guided invasive procedure from April to August 2019 at one of the hospitals of AULSS 8 Berica - West District.

The sepsis can be considered the epiphenomenon of a widespread hygienic and caring problem and it highlighted the fundamental role that sanitation and asepsis play in guaranteeing patient safety and quality of care.

This outbreak gave also the opportunity to investigate the way in which assistance is provided to users, allowing the identification of some critical issues related to safety and the management of care processes. It represented a stimulus to identify strategies and corrective measures to support and provide high quality care services.

This infectious event fortunately involved only a few patients, but this didn't allow to conduct a significant statistical analysis to assess any associated risk factors.

No mortality was associated with the infection probably because of the immediate and appropriate antibiotic treatment of the subjects involved

To conclude, the infection control measures put into effect (sanitation improvement, staff training on hygiene and asepsis, early diagnosis, epidemiological and microbiological investigation, and collaboration between the stakeholders) have permitted effective management of the outbreak and have helped to reduce the risk of subsequent cases and future outbreaks.

In addition, the outbreak has revealed the need to draw up internal operating procedures that regulate punctually the grafting of invasive devices. These

procedures are currently being drafted.

Conflict of Interest Statement

None declared.

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