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TRANSMISSION OF PRIONS BY REUSABLE MEDICAL DEVICES: EVALUATION OF PROFESSIONAL PRACTICES AND MANAGEMENT OF RISK IN MOROCCO

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ABSTRACT

Introduction: Creutzfeldt-Jakob disease is a neurodegenerative disease of humans, caused by unusual infectious pathogens called prions or UnConventional Transmissible Agents (UCTA). Prions possess common properties of resistance to the usual methods of inactivating microbiological agents. Reusable medical devices (RMD) in hospitals are one of the most common and dangerous modes of transmission. The objective of our investigation is to evaluate the professional practices related to the treatment of RMD and the management of the risk of transmission by the RMD to the hospital. **Material and Method:** This is a prospective and descriptive study of professional practices in hospital sterilization services and units, over a period of 2 months, from October 02, 2017 to December 05, 2017. Our survey covered 39 sterilization services and units of 34 public or private health facilities in 3 major cities in Morocco. The results are exploited using computer software, survey and statistical data analysis, the Sphinx plus V.5. **Results:** Our survey reveals that 56% of health facilities visited does not have a special sterilization process to combat UCTA. All hospitals use pressurized steam sterilizers. Prion Standard Protocol (PSP) parameters for inactivation of UCTAs (134 ° C for 18min with a pressure of 2.1Bar) are consistent in 94% of sterilization units and services. **Conclusion:** The hospital civil liability branch has been in a deficit position for several years, which calls into question the very

insurability of hospitals. New risks such as contamination with prion disease, the new variant of Creutzfeldt-Jakob disease, are making the situation worse. It is therefore more urgent than ever to introduce modern risk management.

KEYWORDS: Prion - UCTA - Creutzfeldt-Jakob disease - Reusable Medical Devices - Transmission – Sterilization.

INTRODUCTION

Described in 1920, Creutzfeldt - Jakob disease (CJD) is serious and rapidly fatal. It leads to dementia and coordination disorders of voluntary movements. It is a neurodegenerative disease of humans, which exclusively damages the central nervous system (CNS) with very long and variable incubation times. It is caused by unusual infectious pathogens called prions or UCTAs (UnConventional Transmissible Agents).[1] The term prion (acronym for Proteinaceous Infectious Particle ONly) refers to small infectious protein particles lacking the nucleic acid that causes transmissible spongiform encephalopathies (TSEs).[2][3] UCTAs have the characteristic of being resistant to many conventional methods of sterilization and disinfection. Prions remain a biological enigma and a public health problem. They constitute, by their physicochemical, biological and structural properties, an atypia in the realm of transmissible agents.[4] CJD is a very rare disease. The incidence is the same in all countries,[4][5] it is between 0.8 to 1.5 new cases per million inhabitants and per year.[6] The prions confer no immunity, the receptivity is total.[7] According to WHO, infectivity is primarily in the brain, optic nerve, posterior portion of the eye, spinal cord and lymphoid organs.[8] The transmissibility of these new agents, the long silent incubation periods, the difficulty of diagnosis, the absence of treatment, the difficulties of decontamination and the health and economic consequences are all alarming factors which explain an interest all in particular concerning prion diseases.[4]

CJD is classically presented in three distinct clinical forms, each with different symptoms. They are related to different origins: genetic, iatrogenic or sporadic.[9] The genetic origin is linked to a mutation on the gene that codes for the PrP protein (the mutation is dominant and the risk of transmission to a child is 50%).[9] The iatrogenic origin is linked to a medical act: brain tissue graft from a subject with CJD or surgical instruments (including reusable medical devices) contaminated insufficiently sterilized during surgery.[9] Currently the risk of transmission of Creutzfeldt-Jacob disease by reusable medical devices at hospital levels is the most common of the other types of transmission.

Given this critical situation, service managers and sterilization units must consider that all instruments / RMD pose an infectious risk. They must be prepared in accordance with the new recommendations on the sterilization of medical and surgical equipment to prevent the risk of transmission of UCTA / prions. Our study aims to evaluate the professional practices related to the treatment of RMD in the hospital and the management of the risk of transmission of the "PRION / CJD" UCTAS by the RMD. This survey is carried out in the sterilization units and services of public and private health establishments.

MATERIALS AND METHODS

This is a prospective and descriptive study of professional practices in hospital sterilization services and units, over a period of 2 months, from October 02, 2017 to December 05, 2017. Our survey covered 39 sterilization services and units of 34 public or private health facilities: UHC (University Hospital Center), RHC (Regional Hospital Center) and private clinics, distributed in 3 major cities of Morocco: Casablanca, Rabat and Marrakech.

Inclusion criteria are all sterilization services and units heads (pharmacists, doctors and nurses). Exclusion criteria are all non-managerial and non-operational staff in sterilization units or services.

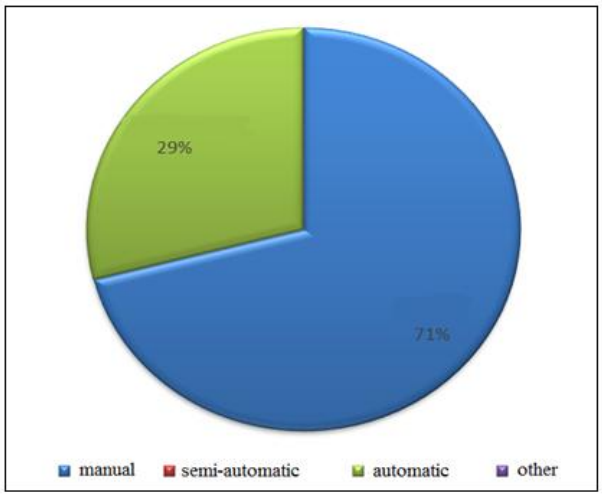
The evaluation of the management of the risk of UCTA transmission by reusable medical devices is done through a questionnaire. This questionnaire gathers 5 topics, in the form of small questions about the Professional Statutes, the Special Anti-Prion Sterilization Process, the Pre-Disinfection Process, the Biocleaning Process and the Sterilization Process. The results are exploited using computer software, survey and statistical data analysis, the Sphinx plus V.5.

RESULTS

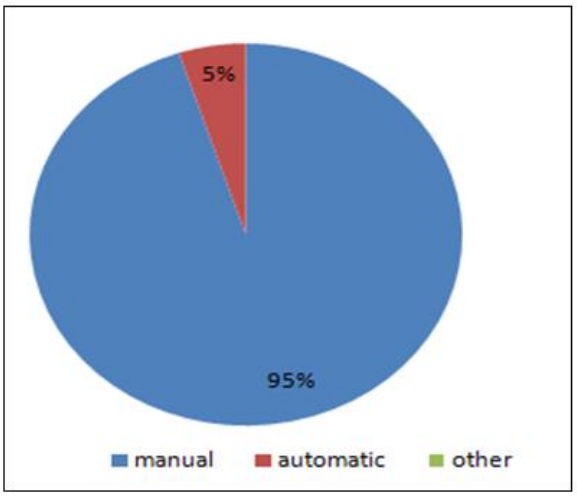
According to the results of our survey, 82% of the sterilization actors are nursing staff. Of these, 6% occupy sterilization units within surgical services and 76% occupy sterilization services. Only 18% of sterilization professionals are pharmacists. All the professionals of the sterilization units or services have more than 3 years of seniority. Of the 34 health facilities, 56% do not have a special sterilization process to control UCTAs. Only 44% of hospitals have one. Among these, only one service out of the 39 visited, 6% (Sterilization Service of the Mohammed V Military Hospital - Rabat), has a declaration form for RMD potentially contaminated with prions.

All services (99%) perform manual pre-disinfection. In 73% of the hospitals visited, the pre-disinfection tank is prepared by the sterilization service. Pre-disinfection is done either by disinfecting detergents (for 20 min) or by a halogen disinfectant (for 30 min), depending on the nature of the RMD, in 50% of cases. Pre-disinfection is done in 23% of the sterilization units using only disinfectant detergents for 10min, 25% use only halogen disinfectants for a minimum of 30 min. Pre-disinfection by quaternary ammonium with a soaking time of 10 min and used in a single service (2%). The majority of services, 90% do not have a special prion pre-disinfection process; only 10% (4 services) have one. These latter use JAVEL 6°Cl water for 30 minutes to 1 hour for the pre-disinfection.

Our survey reveals that manual bio-cleaning with manual traceability is done in 71% of hospital visited. Automatic bio-cleaning is done in 29% of health facilities, of which 24% have manual traceability and 5% have computerized traceability. The sterilization actors use chemicals with a dynamic bio-cleaning, thermal and hydraulic when it is a manual bi-cleaning. When it comes to automatic bio-cleaning, instead of chemicals, they use enzymatic products with dynamic, thermal and hydraulic bio-cleaning.



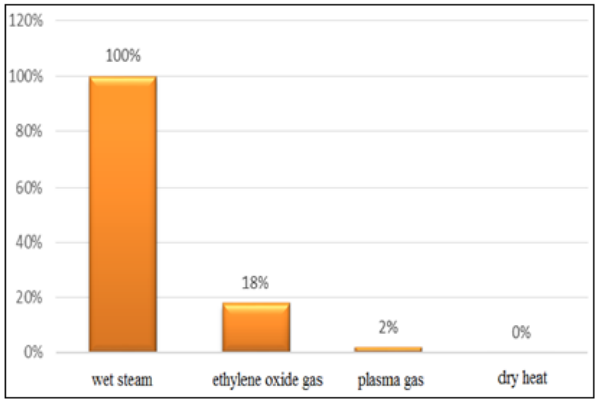
Type of Bionettoyage used at sterilization units



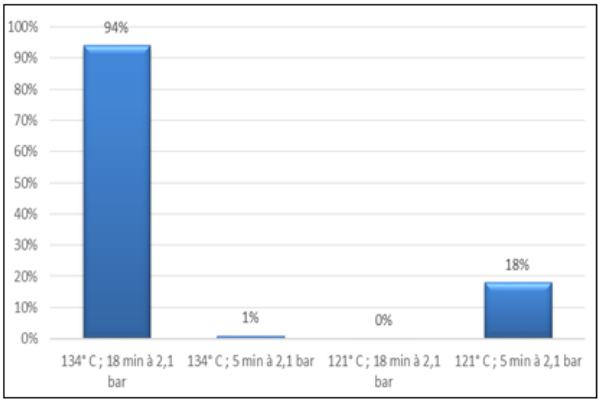
Traceability of Bionettoyage at sterilization units

All hospitals use pressurized steam sterilizers. Ethylene oxide gas sterilizer is used in 18%. Only one hospital uses plasma gas sterilization. Dry heat sterilization is no longer used. The Standard Prion Protocol (SPP) parameters for inactivation of UCTAs (134 ° C for 18min with 2.1Bar pressure) are compliant in 94% of sterilization units and services. Only one health facility (2%) has parameters that do not conform to the SPP. Sterilization of heat-sensitive RMD by steam sterilizers with a temperature of 121°C for 5 min is done in 18% of the visited

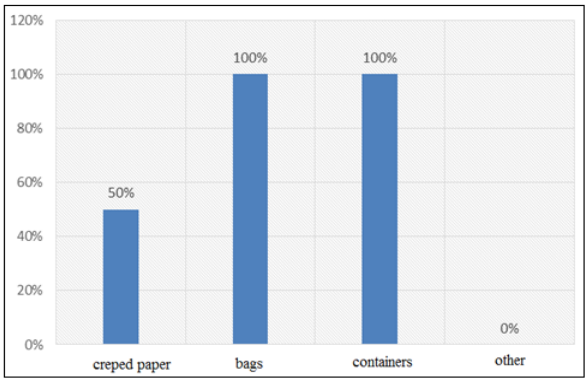
hospitals. RMD packaging is done in containers and bags in all hospitals. Packaging with crepe paper is used in 50% of hospitals. The vast majority (95%) of sterilization units and services use manual traceability of the sterilization process. Traceability by the computer system is done in 5% of hospitals.



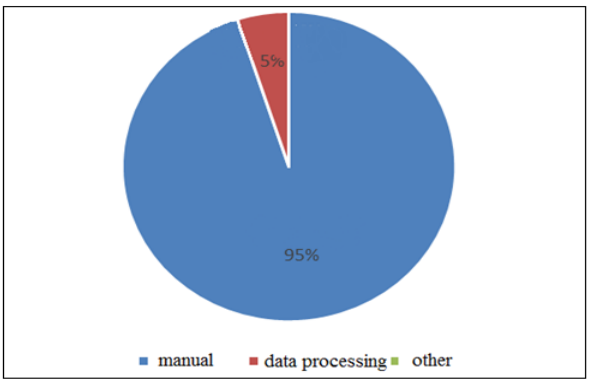
Percentage of use of different sterilization methods



Parameters retained for sterilization for inactivation of prions



Different preservative packaging of the sterile condition



Traceability of sterilization

DISCUSSIONS

Whatever the sector of activity, the training of the personal is an obligation for every employer who has to apply the code of work. In fact, the Labor Code provides for the right of employees to "benefit from programs to combat illiteracy and continuous training" (Article 23). On-the-job training, which includes in-service training, has been governed since 2002 by Moroccan Decree No. 2-73-633 of May 22, 1974 establishing the Vocational Training Tax. When it is provided by physical persons or corporation other than the government, vocational training is mainly governed by Law No. 13-00 and Decree No. 2-00-1018 on Private Vocational Training.[10] The vast majority of the personal sterilization units visited is nurses. This requires the initiation of continuing education and awareness of staff on the risk of

transmission of UCTAs by RMDs and the important role of the application of the new rules and sterilization techniques to fight against any disease caused by prion.[11]

The absence of a special sterilization process to control UCTA in more than half of the visited hospital exposes patients to the risk of cross-contamination.[12] These establishment still respect the recommended parameters of the sterilization step (134°C for 18 min at 2.1Bar).[13] This is due to the absence of awareness or negligence of this type of transmission and the absence of continuing education. The absence of the declaration form for potentially prion-contaminated RMD in hospital poses a problem for the management, sorting and treatment of RMD. Only one service (the sterilization service of the Mohammed V Teaching Military Hospital - Rabat), possesses this form of declaration of the RMD potentially contaminated with the prion.

Manual pre-disinfection is an operation that concerns all RMD intended to be sterilized. It involves immersing in a properly diluted solution of a suitable disinfectant detergent, all materials that will be treated in the laundry room. This dipping is done as soon as possible and as close as possible to the operating room. If the distance between the operating room and the laundry room is reduced, soaking can be done in the laundry room. In this case, the instruments must be transported in a closed container. Moving in the corridor of the block, the instrument table with fields and instruments soiled from the operating room until sterilization is to be avoided.[11] Of the sterilization services and units visited, the majority use manual pre-disinfection. The pre-disinfection tank is prepared by the sterilization services in 73% of the cases. Depending on the products used, the soaking time is 15 to 30 minutes. Among the services that have a special anti-prion process, pre-disinfection of heat-sensitive RMD uses 6°Cl bleach for 30 to 60 min. This process is effective for the complete inactivation of UCTA.[14] The results of the survey published on December 28, 2015 by Patrick BREACK on the sterilization conditions of surgical instruments in the Maghreb region and Africa shows that overall, all these measures seem well respected.[11]

The majority of sterilization services visited (71%) use a manual bio-cleaning (washing). Manual brushing is a very important source of microbial contamination because it produces a multitude of contaminated droplets and aerosols at each gesture. They are deposited throughout the local, but above all, the person who performs this work and who collects on this occasion a very important contamination. Staff protection is rarely provided when it should be a rule.[11] The ideal situation would be that after rinsing, the material should be

placed in an ultrasonic wash tub as appropriate and in the baskets that will be installed in the washer-disinfector.[11]

All health institution visited use pressurized steam sterilizers for heat-resistant RMD. Low temperature sterilization (ethylene oxide gas) is performed in 18% of hospitals for the sterilization of thermosensitive RMD. Parameters associated with steam sterilization under pressure (autoclave) are time, temperature and pressure.[11] These sterilization parameters are predefined by the automatisms of the devices. In Morocco, the values used to inactivate UCTA are 134°C for 18 minutes with a pressure of 2.1Bar. To reach this sterilization tray, the device must make successive voids and steam injections that cannot be modified without altering the effectiveness of the sterilization. The complete duration of the cycles must absolutely be respected, even if it is of the order of 75 min. Our survey revealed that 94% of sterilization units and services met these parameters. The control and maintenance of the autoclaves makes it possible to ensure that these values are maintained over time. The term conditioning also applies to packaging that serves to protect the sterile condition. All services visited use containers and bags to protect this sterile condition. Crepe paper is used in 50% of sterilization units. In all cases, the quality and integrity of the packaging are the essential criteria.[11] The method of packaging must comply with the standards in force to maintain this sterile condition. To eliminate the probability of UCTA transmission risk associated with conditioning. The purpose of traceability is to identify a failure in the process of a process to provide a cure and to quickly understand what effect this failure may have had on the situation encountered.[11] In the case of an investigation concerning a post-operative infection, the traceability of the sterilization step will make it possible to rule out, or not, a fault in the washing, the packaging or the sterilization. Its legal value is important because in the absence of evidence, the reliability of the process is systematically challenged.[11] In our case, 95% of sterilization units visited have manual traceability, and 5% have traceability by computer system. The results of the survey published on December 28, 2015 by Patrick BREACK on the conditions of sterilization of surgical instruments in the Maghreb region and Africa shows that in the cases observed, use simple methods such as use of notebooks, numbering, labels, or techniques by integrating computer functions in the different devices, washer disinfectors and sterilizers in particular.[11] In all cases, the value of traceability rests on the rigor of the staff who must constantly apply strict rules, well assimilated, which he fully understood the justification. Therefore, before initiating a traceability process, it is essential to train staff to understand the entire process and its importance to patient safety.[11]

CONCLUSION

Sterilization is a complex and expensive process that requires skills, coaching and control. Major deficiencies occur at each of these levels in many of the situations encountered: lack of continuous training and awareness of the staff about the risks of UNTA, lack of a special sterilization process and a national strategy to fight against CJD, poor management and treatment of RMD contaminated or potentially contaminated with prion, non-existence of a RMD report card potentially contaminated by the prion. All this casually exposes patients to the risk of transmission of Creutzfeldt-Jacob Disease.

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