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Original Article

An evaluation of different steam disinfection protocols for cystic fibrosis nebulizers

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Abstract

Background: Contamination is a key element in cystic fibrosis. For this reason, nebulizer hygiene is an important, but complex and time-consuming task for cystic fibrosis patients. The aim of this study was to compare different steam disinfection and drying protocols.
Methods: One hundred nebulizer parts were inoculated with cystic fibrosis-related bacteria in high concentrations (*Burkholderia multivorans* 3.9×10^{10}/ml, *Staphylococcus aureus* 8.9×10^{8}/ml and *Pseudomonas aeruginosa* 2.1×10^{9}/ml). Tubes with *Mycobacterium abscessus* complex were additionally tested. Six steam disinfectors were compared. Different methods of drying were examined.
Results: All tested bacteria were efficiently killed by the different steam disinfectors tested. The risk of contamination depended on the method of drying.
Conclusions: Steam disinfection is a safe disinfection method. It is better to leave the nebulizers wet after steam disinfection than to manipulate them by active drying, which seems to be a source of recontamination.

Keywords: Aerosol drug therapy; Equipment contamination; Infection control; Infection prevention; Inhalers; Medical devices; Nebulizer; Inhalation; Hygiene; Cleaning; Steam disinfection; Mycobacteria; Compliance; Cystic fibrosis; Bacteria; *Pseudomonas aeruginosa*

1. Introduction

Survival and quality of life in cystic fibrosis (CF) have improved in recent years. This improvement was, however, associated with more complex treatment, resulting in a substantial burden for the patients. [1–3]. CF involves many time-consuming high-maintenance treatments, including airway clearance and nebulization. The daily duration of these treatments can be long. Moreover, the time needed for device disinfection must also be considered. So it is crucial to make cleaning steps as simple as possible to achieve optimal compliance and to reduce barriers to effective home nebulizer therapy and hygiene [4].

Home nebulizers are in widespread use among patients with chronic pulmonary diseases such as cystic fibrosis. Contamination of these devices has been well-documented [5–8]. Even though nebulizer disinfection is routinely recommended [9], advice varies among countries, manufacturers and organisations. As in our CF centre, steam disinfection has become increasingly regularly recommended, followed by drying with clean, ironed cotton towels prior to storing [10]. Steam disinfection is a very potent method for killing bacteria [11–13]. It reduces bacterial populations more effectively and is less complicated than other methods [14,15]. In comparison, chemical disinfection requires preparation of a solution which is a risk, both for contamination and faulty measurement. Temperature has an influence on chemical reactions, and protein or soap related errors can also occur. The disinfectant has to be stored correctly. Disinfecting solutions can be contaminated by microorganisms [16,17]. There are further considerations regarding the safety of these

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products for humans, such as hypersensitivity [18–20]. Finally, the nebulizer has to be rinsed with clean water to eliminate residual chemical substances[21].

Steam disinfection denaturizes bacterial proteins and therefore reduces bacteria significantly; however, not all manufacturers recommend it for their nebulizers. A study showed that steam disinfection has no influence on the functionality of eFlow® devices (Pari, Germany) [22]. Despite the use of steam disinfection, some of our patients' devices showed multiple, bacterial contamination at their annual nebulizer quality check (personal unpublished data). As concordance between bacteria isolated from the nebulizer and from patient sputa was rarely verified [4,8,23,24], the source of bacteria contaminating the nebulizer parts is poorly understood.

The aim of this study was (1) to investigate different modalities of steam disinfection and (2) to compare the efficacy of different steam disinfectors on various nebulizer or airway clearance devices.

2. Material and methods

2.1. Protocols

Six different protocols (Table 1) for steam disinfection of nebulizer parts, mimicking situations that might occur if a patient has to handle steam disinfection alternating with dry inhalation, on a regular basis, were investigated after artificial inoculation of the nebulizer parts:

- Protocol 1: immediate steam disinfection, using tap water (pH 10, 7°dH, no bacteria) and instant drying with paper towels.
- Protocol 2: immediate steam disinfection, using tap water, with the nebulizer parts then left in the moist environment, defined by leaving it in the steam disinfector with the lid continuously closed for 96 h after steam disinfection.
- Protocol 3: air drying for one hour prior to steam disinfection using tap water, with the nebulizer parts then left in the moist environment of the steam disinfector for 24 h.
- Protocol 4: nebulizer stored in a box for four months before inoculation, extended drying time (48 h) before steam disinfection using tap water, followed by a long exposure (72 h) to the moist environment of the steam disinfector.
- Protocol 5: extended drying time (48 h) before steam disinfection using tap water contaminated with 31,000 CFU/ml, *Pseudomonas aeruginosa* and subsequent long exposure to the moist environment of the steam disinfector (48 h).
- Protocol 6: drying time of 96 h before steam disinfection using tap water contaminated with 31,000 CFU/ml *P. aeruginosa*, and subsequent extended exposure (four days) to the moist environment of the steam disinfector, followed by active drying with paper towels (6a) or no active drying (6b).
- CF bacteria control: immediate steam disinfection after use, using tap water, immediate resuspension and cultivation.
- Mycobacteria abscessus complex: immediate steam disinfection of mycobacterial mass with Petra 3 and Avent 3-in-1 disinfectors, using tap water, immediate resuspension and qualitative cultivation.
- Mycobacteria control: immediate steam disinfection of mycobacterial suspension with Petra 3 and Avent 3-in-1 disinfectors using tap water, immediate resuspension and quantitative cultivation.

For each of the six protocols, 100 parts of nebulizer and airway clearance devices [seven sets of eFlow®rapid (Pari, GE), two sets of LC plus (Pari, GE), three sets of RC-Cornet® (RC, GE), three sets of I-Neb® (Phillips, NL), three sets of VRP-Desitin (Tyco, GE), three sets of nasal douche (Pari, GE), two sets of PEP I (Pari, GE), four sets of Pep/RMT (AstraTech, SE) and four sets of Vortex (Pari, GE)] were contaminated using cotton swabs with a mix of 5 ml of each standard suspension, containing bacteria grown overnight on Columbia agar and inoculated into NaCl 0.9% at a density of 3.0 McFarland (Table 2) and additionally, 5 ml of anonymized liquefied patient sputa, containing bacteria (Table 3).

The CF bacteria controls consisted of three plastic tubes filled with 0.5 ml of three different standard suspensions, respectively (Table 2)

For *Mycobacterium abscessus* complex: one glass tube and one plastic tube, each filled with 60 μg of living bacterial mass of either (1) *M. abscessus abscessus* or (2) *M. abscessus massiliense* or (3) *M. abscessus bolletii* were investigated. The mycobacteria strains were patient isolates confirmed by the German National Reference Center for Mycobacteria (FZ-Borstel). Mycobacteria control: one glass and one plastic tube, each filled

Table 1
Duration of the different phases and the mode of sampling for each protocol.

Protocol	Phase 1: Air drying before disinfection	Disinfection	Phase 2: Moist storage after disinfection	Sampling	Phase 3: Active paper drying	Sampling
1	0 h	Yes	0 h	No	Yes	Yes
2	0 h	Yes	96 h	Yes	No	No
3	1 h	Yes	24 h	Yes	No	No
4	48 h	Yes	72 h	Yes	No	No
5	48 h	Yes	48 h	Yes	No	No
6a	96 h	Yes	96 h	No	Yes	Yes
6b	96 h	Yes	96 h	Yes	No	No
CF bacterial control	0 h	Yes	0 h	Yes	No	No
M. abscessus complex	0 h	Yes	0 h	Yes	No	No
Mycobacterial control	0 h	Yes	0 h	Yes	No	No