

EFFECTS OF BIOFILM FORMATION ON HEMODIALYSIS MONITOR DISINFECTION

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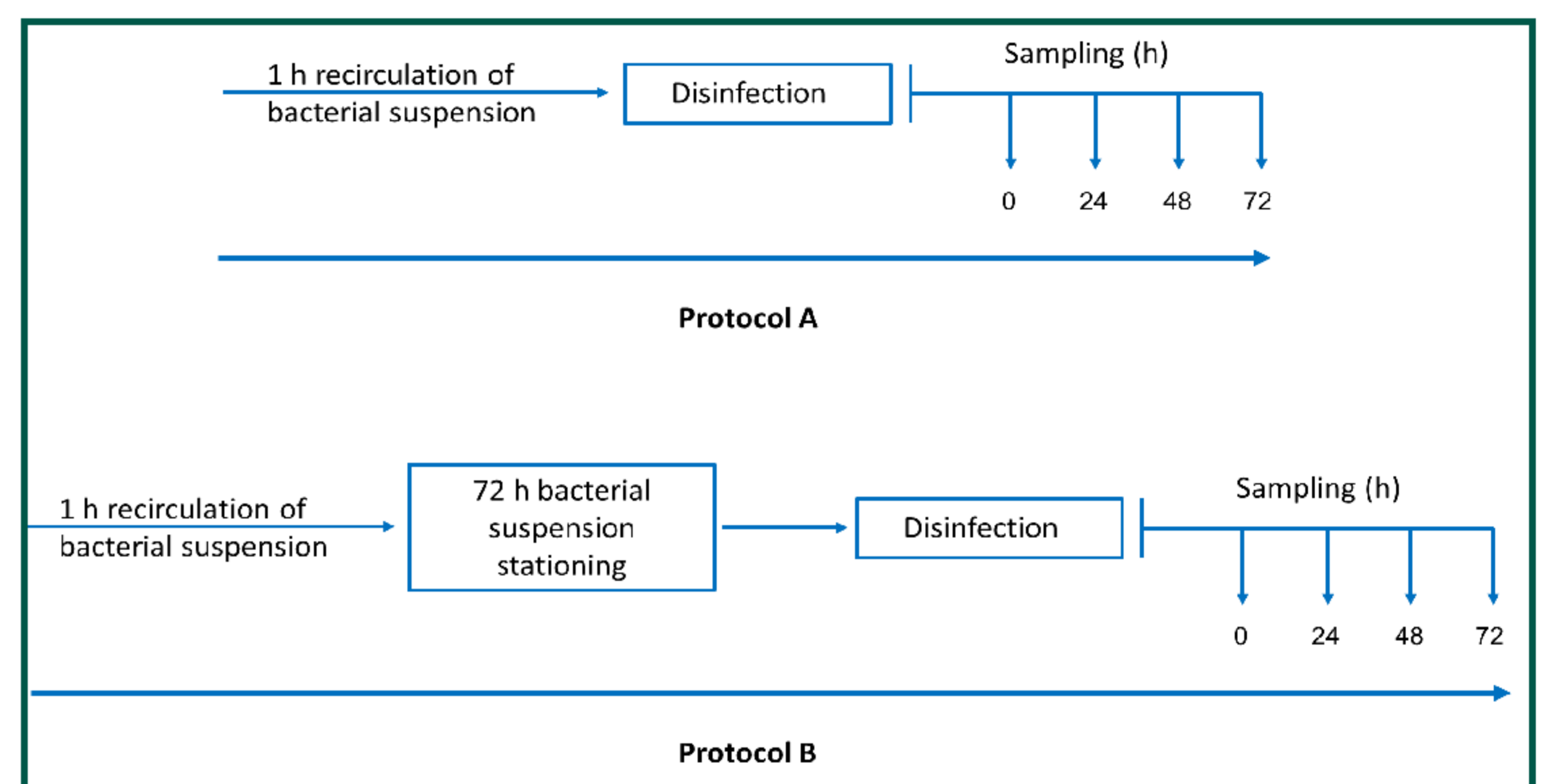
OBJECTIVES

Biofilms are composed of communities of microorganisms that adhere to almost any surface. In correct conditions of a hemodialysis apparatus, the probability of biofilm formation within its hydraulic circuit is very low. In particular situations, e.g. long periods of downtime or use of water with a high bacterial content, this probability increases considerably. The aim of this work was to evaluate the combined effect of two different disinfection methods: physical (descaling with citric acid at 70°C) and chemical (disinfection with Oxagal®), on reduction of bacteria contents in a hemodialysis monitor (FLEXYA® Dialysis Monitor). In particular, the effectiveness of the disinfection action despite the biofilm presence inside the hydraulic circuit was investigated.

METHODS

The hydraulic circuit of FLEXYA was intentionally contaminated according two different contamination protocols, A and B described below, using a 10^8 CFU/ml suspension of *Pseudomonas aeruginosa*. For the bacteria determination, sample of water volume was aspirated at 0, 24, 48 and 72 h after disinfection from different sampling sites of the hydraulic circuit: on dialysate outlet (before entry in the hemodialyser), immediately after heating tank, after mixing and after the recirculation circuit. Samples were filtered through a 0,45 µm membrane filter. The filter was placed in culture at 32°C for 5 days on Reasoner 2A agar plates.

STUDY DESIGN



Protocol A: without biofilm

The monitor was contaminated by recirculating 500 ml of the bacterial suspension for 1 hour at 37°C. The hydraulic circuit, washed with deionized water for 5 min at 500 ml/min, was disinfected with the two different procedures: physical followed by a chemical disinfection with 60 hour of stationing. The monitor was finally, turned off and samples were taken at 0, 24, 48 and 72 h of non-use.

Protocol B: with biofilm

The monitor was contaminated by recirculating 500 ml of the bacterial suspension for 1 h at 37°C, then switched off leaving the bacterial suspension inside the circuit for 72 h in order to allow biofilm formation. The monitor was washed with deionized water for 5 min at 500 ml/min and later, was disinfected with a physical followed by a chemical disinfection with different time of stationary phase: 60, 36, 24 and 12 hours. For each stationary phase duration, samples were taken at 0, 24, 48 and 72 h of non-use.

RESULTS

Protocol A – Effect of disinfection on CFU formation: there were no significant differences between the different sampling points at any time interval. The combination of two disinfection procedures reduced CFU contents. Bacterial regrowth was completely abrogated.

Protocol B – Effect of disinfection on biofilm: also for protocol B, there were no differences between the sampling points at any of the time intervals. Moreover, the combination of two disinfection procedures reduced CFU levels and biofilm regrowth.

Bacterial content in the hemodialysis monitor evaluated in presence and in absence of biofilm and different time of stationary phase is shown in Figure 1.

Sample time, h	Stationary phase				
	12 h	24 h	36 h	60 h	no biofilm
0	8,6±6,7	1,8±0,5	11,5±11,7	27,3±43,1	7,0±1,1
24	3,8±5,2	0,2±0,3	0,6±0,9	0,3±0,2	0,2±0,2
48	194,7±314,8	0,3±0,3	0,4±0,5	0,3±0,3	0,08±0,03
72	395,9±558,5	0,3±0,3	0,6±0,7	0,2±0,2	0,08±0,03

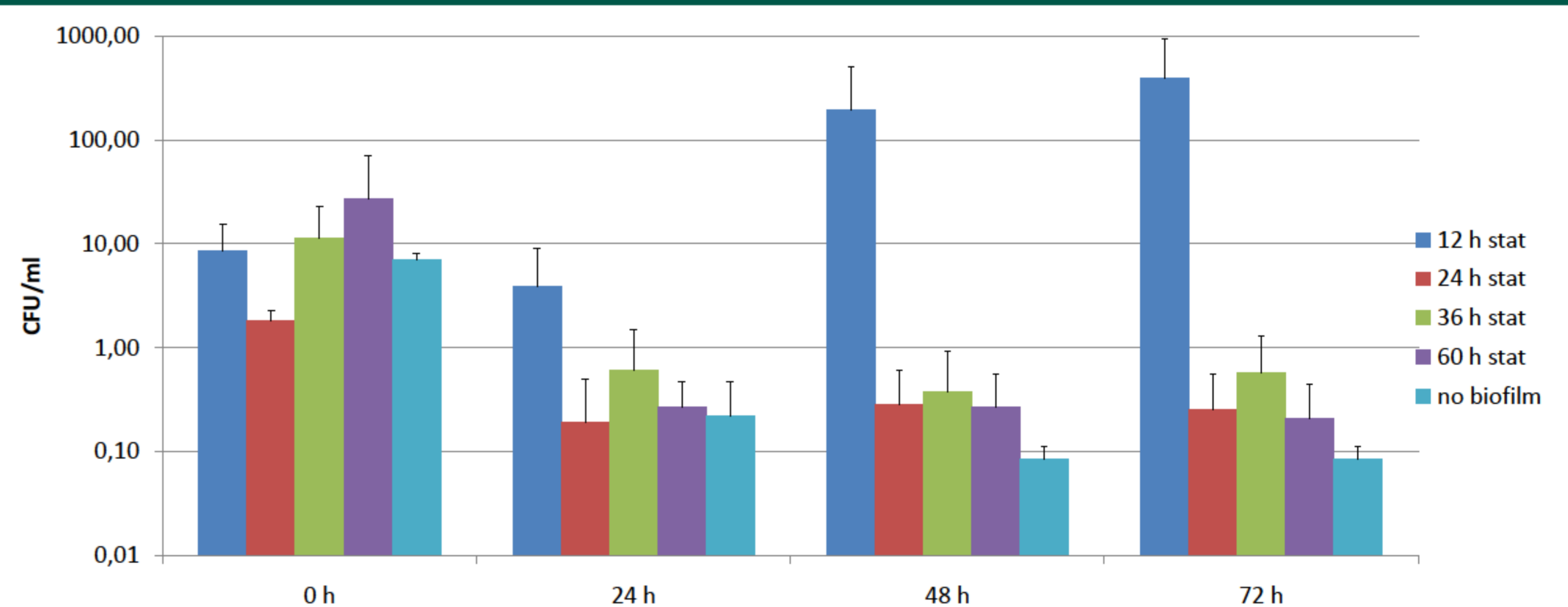


Figure 1: Bacterial content (CFU/ml) in the hemodialysis monitor evaluated in presence and in absence of biofilm and different time of stationary phase (baseline: 10^8 CFU/ml). Samples were taken at 0, 24, 48 and 72 h of non-use

CONCLUSIONS

This results shows that the combination of two different disinfection methods, physical and chemical, is able to disinfect the hydraulic circuit even in situations of serious bacterial contamination. It also shows that 24 hours of disinfectant stationary phase are sufficient to completely break down the bacterial contents in the hydraulic circuit.

REFERENCES

- [1] Man NK, Degremont A, Derbord JC, Collet M, Vaillant P. Evidence of bacterial biofilm in tubing from hydraulic pathway of hemodialysis system. *Artif Organs* 1998; 22: 596–600
- [2] Vincent FC, Tibi AR, Darbord JC. A bacterial biofilm in a hemodialysis system. Assessment of disinfection and crossing of endotoxin. *ASAIO Trans* 1989; 5: 310–313
- [3] Cappelli G, Ballestri M, Perrone S, Ciuffreda A, Inguaggiato P, Albertazzi A. Biofilms invade nephrology: effects in hemodialysis. *Blood Purif* 2000; 18: 224–230
- [4] The International Electrotechnical Commission (IEC): Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and haemofiltration equipment; IEC 60601-2-16 Edition 3.0 2008-04

