

Effect of differences in disinfection methods on the durability of endotoxin-retentive filters

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Objectives

As a result of improvements to dialyzer performance there is apprehension about the risk of endotoxin or endotoxin fragments present in dialysis fluid passing into the blood. Since it has been suggested that repeated cytokine induction by trace amounts of endotoxin, etc., may be related to such complications of long-term dialysis as chronic inflammation and dialysis-related amyloidosis, dialysis fluid purification is absolutely essential to hemodialysis therapy. It is said to be possible to remove viable bacteria and endotoxin by using endotoxin-retentive filters (ETRFs), but because there have also been reports of inclusion of microbiological contaminants in dialysis fluid that are incapable of being removed by ETRFs, maintaining a high level of purification upstream before flowing into the ETRF is ideal. Nevertheless, consciousness of dialysis fluid purification varies greatly from country to country, region to region, and institution to institution, and today quite a few institutions ensure a high degree of dialysis fluid purity by inserting an ETRF into the dialysis circuit. ETRFs are usually replaced at the replacement intervals recommended by the manufacturer. When ETRFs are used in clinical practice, however, the ways and environments in which they are used vary from institution to institution. The purpose of this study was to assess the effect of differences in disinfection methods on ETRF durability.

Methods

We assessed the following three disinfection methods on 92 ETRFs (EF-02, Nikkiso Co., Ltd., Japan) that were inserted, two per machine, into the dialysis circuits of 46 versatile hemodialysis machines (DBG-03, Nikkiso Co., Ltd., Japan): method A, hot water disinfection with Citrix-50H + Na hypochlorite disinfection (17 machines, 34 filters); method B, Citrix-50H acid washing + Na hypochlorite disinfection (14 machines, 28 filters); method C: hot water disinfection with citric acid + Na hypochlorite disinfection (15 machines, 30 filters). The observation period was from 2015/1/18 to 2015/7/18. We defined an ETRF failure as the occurrence of a warning of a dialyzer check-filter (CF) leak test failure and assessed the times until the failures occurred. We divided ETRF service time at the time of failures into CF1 upstream and CF2 downstream, and recorded each of them. We defined the service time of the ETRF as the time during which the dual pump was in operation. Differences between failure rates were evaluated by the chi-square test, and a probability value under 5% was used as the criterion for statistical significance. Mean service times were calculated by the Kaplan-Meier method.

Results

The mean service times according to disinfection method were: method A, CF1 1866 hours, CF2 1878 hours; method B, CF1 and CF2 both 2073 hours; method C, CF1 1649 hours, CF2 1648 hours. When disinfection method B was used, no ETRF failures were seen during the observation period. The proportions of CF1 in which failure occurred during the study period were: method A 53% and method C 71%, and the proportions of CF2 were: method A 41% and method C 71%, and the differences were significant according to the chi-square test. (Fig.1) The survival rates at the 750-h replacement time recommended by the manufacturer based on survival curves plotted by the Kaplan-Meier method were: methods A and B, CF1 and CF2 both 100%, and method C, CF1 and CF2 both 93%. (Fig.2)

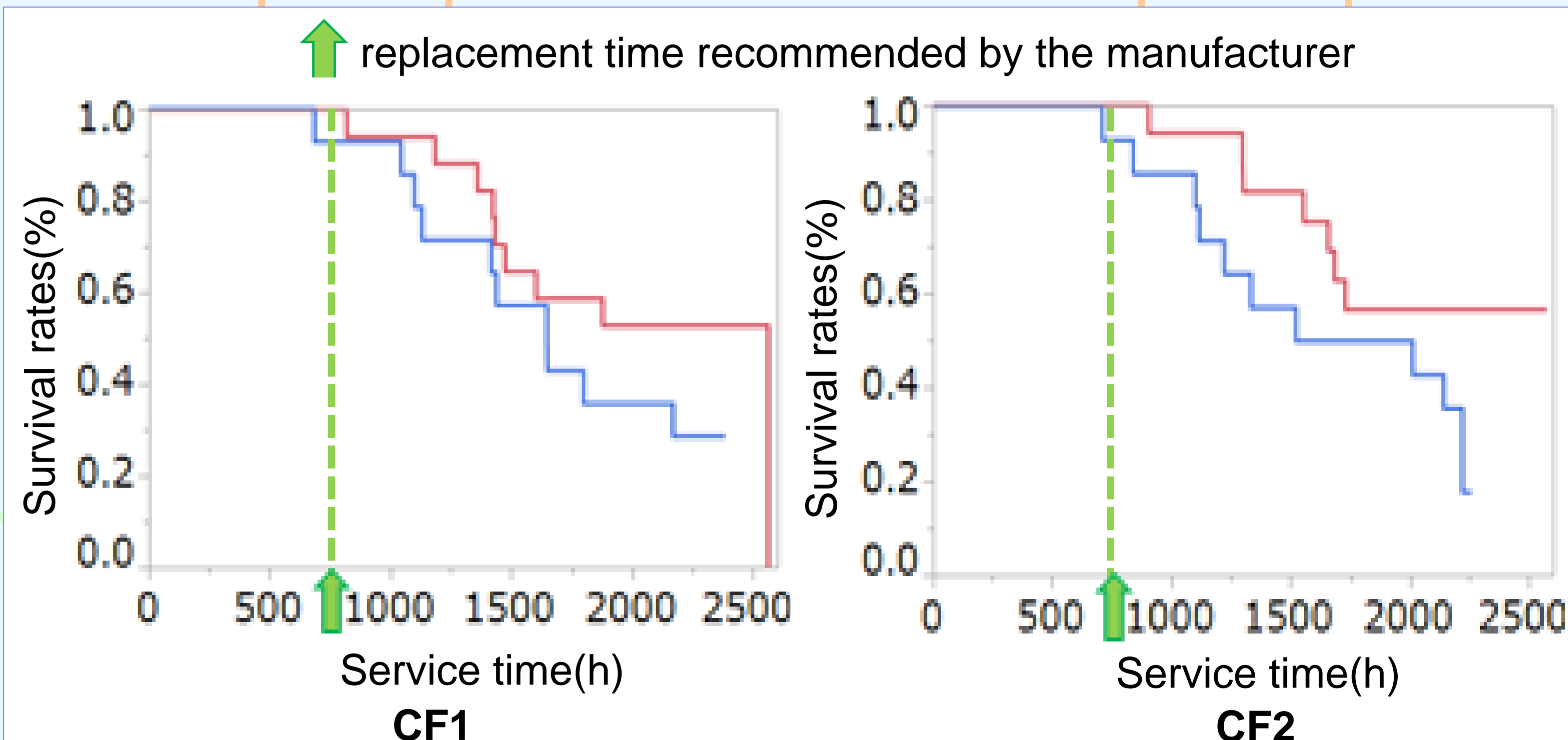


Fig.2 Survival rates plotted by the Kaplan-Meier method.

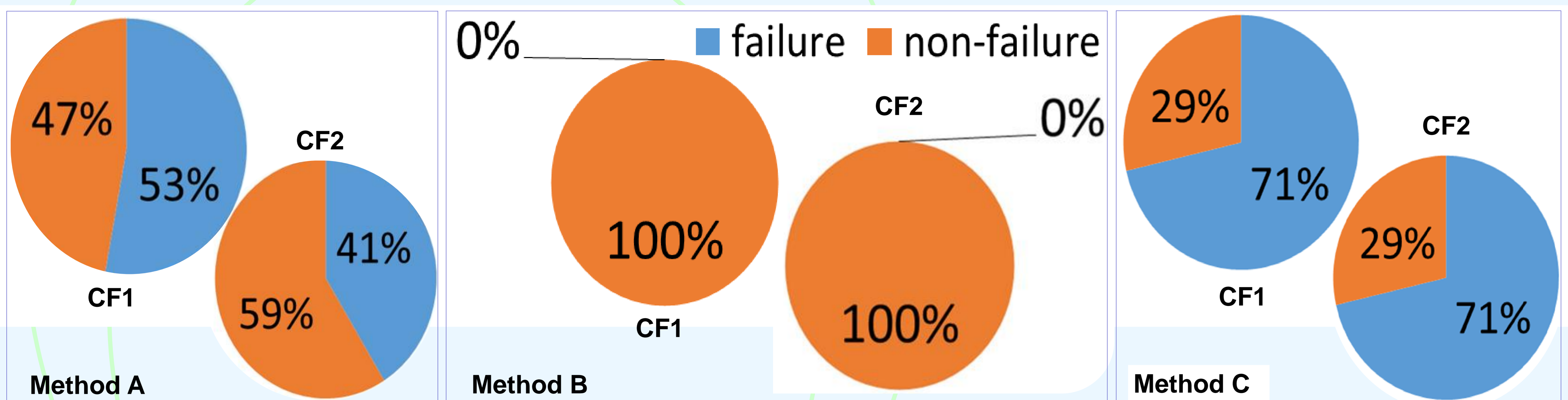


Fig.1 The proportions of ETRF filters in which failure occurred during the study period.

Discussion

The failure rate at 750 hours was highest, 7.1%, with disinfection method C, suggesting that the durability of EF-02 is lowest when citric acid hot water disinfection is used. In addition, the results of the chi-square test showed that differences in durability developed according to the disinfection method that was used.

Conclusions

The results of this study revealed that the durability of EF-02 is inadequate when disinfected by the citric acid hot water method. ETRFs are important devices for dialysis fluid purification, and manufacturers are expected to develop ETRFs whose performance is sufficient to be used with confidence during their service period. Moreover, for safer use it is recommended that ETRF durability be appropriately evaluated and managed in the environment in which they are used in each institution.

