International Journal of IT-based Public Health Management
Vol. 5, No.1(2018), pp. 13-20
http://dx.doi.org/10.21742/ijiphm.2018.5.1.03

A Study on Microbial Culture Level of Hemodialysis Water Under the Influence of Disinfection Loop Types

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Abstract

Purpose: The purpose of this study was to analyze the culture level of microorganism in hemodialysis water that is affected by disinfection loop types and temperature difference.

Method: This retrospective study was performed between January 2010 and December 2014 in our hospital dialysis unit. We consecutively used (1) A method: monthly chemical disinfection, (2) B method: a combination of weekly 90℃ heat disinfection (maintaining hot water ≥ 90℃ entering the dis[1]tribution loop) and bimonthly chemical disinfection and (3) C method: a combination of weekly 95℃heat disinfection (maintaining hot water ≥ 85℃ returning from the distribution loop) and bimonthly chemical disinfection while checking bacterial count and endotoxin level every 4 weeks.

Results: The endotoxin levels at all sampling points of the water treatment system were lower than 0.005/ ml throughout the study. Bacterial counts were consistently <100 CFU/ ml except sometimes in A and B method. It is noteworthy that the application of weekly heat and bimonthly chemical disinfection reduced bacterial levels to acceptable levels, but an escape phenomenon of microbial growth was noted in B method. Bacterial growths were 28.31±123.13, 19.58±112.31 and 0.65±9.83 CFU/mL in A, B and C method, respectively. Bacterial growths in C method was significantly decreased than in A and B method (p<0.001). In Logistic regression analysis by disinfection method, bacterial contamination risk of dialysis water was associated with A (OR 33.151 p<0.001) and B (OR 19.107 p<0.001) disinfection method when compared with C disinfection method Conclusions: This study suggests that it is more important to maintain 85℃returning water temperature from the distribution loop than entering water temperature into that in disinfection of the RO water

Keywords: *Piping, Dialysis water, microbial Quality, Chemical disinfection, Thermal disinfection*

1. Introduction

1.1. Necessity and background of the research

These days with advancements in science and technique of medical treatment the quality of life has improved and our average life expectancy is getting longer. Also, the disease aspect has been changed from acute diseases to chronic diseases which need a long-term care and

Article history:
Received (August 09, 2017), Review Result (October 17, 2017), Accepted (November 28, 2017)

ISSN: 2205-8508 eISSN: 2207-3965 IJIPHM

cure. The Chronic Renal Failure(CRF) is a representative chronic disease and the people number registered in the Korean Society of Nephrology(KSN) is 80,674. Among them the dialysis people account for 80% of entire(KSN, 2015). The Hemodialysis for the people with the CRF(Chronic Renal Failure) is one of the Renal replacement therapy ; this is to periodically remove extra fluid, chemicals and wastes from the blood by filtering the blood through an artificial kidney ; which relieves the symptoms of the CRF patients(Jo Young-mun, Choi Myung-sim, Sung Gi-weol, 2011) and is related with a long-term survival and improving the quality of life(QOL). The necessary materials for the Hemodialysis are a hemodialyzer, dialysis-solution and dialysis-water etc. As more and more the domestic dialysis technique has been advanced like a world-class, many dialysis machines and dialyzers were developed (Kim Su-mi, 2011) and the importance and attention of the hemodialysis water and water-purity control is more emphasized. The conventional hemodialysis relatively has a effect for small molecule substances like urea and creatinine but falls short of removing the middle molecular substance. Because of just mentioned, these days an On-line hemo-diafiltration is used which is a merged way with the conventional hemodialysis and the hemodialysis. Because Its middle molecular substance clearance is excellent, so many hospital are using it(Jung Ji-min,2010). It has to use the ultrafiltration water and, therefore the importance of the hemodialysis-water is more emphasized.The International Organization for Standardization(ISO) established guidelines for the hemodialysis water and ordered each facility to strictly manage the water quality. Thus, there is a strict guideline and rule for the dialysis water in advanced countries like U.S., Europe and Japan(You Won-young, 2015). It is very important to strictly manage a filtration system and a loop for the safe hemodialysis because the dialysis water for the hemodialysis patients is provided through a loop after passing through a filtration system(No In-hye, 2002). In other words the disinfection is needed at least once a month and it is the most important to keep the filtration system being in sanitary. Cycle, way, antiseptic way(chemistry, heat or mix) and replacement time of filter and resin etc are up to a manual of the manufacturer(Shin Suk-Gyun, 2007). The proper cycle of the disinfection is decided according to principle, dynamics and degree of the re-contamination after the disinfection progress(Besarab A., DeLucia T., Picarello N., Jungkind D., 1993). To move the advanced water, Polyvinyl Chloride(PVC), Natural Polypropylene, Stainless steel and Glass are suitable as the quality of the loop. Among them, the PVC loop is the cheapest one and has been used the most(Shin Suk-gyun, 2007). Meanwhile, recently a Clean PVC loop is used the most which is relatively expensive and of which inner is laminated with Polyvinylidenefluoride(PVDF) like glass to prohibit bacterial growth. However there is no any guideline and rule, it is used differently for each medical institution and the management is conducted by the loop relevant company.Hence, the purpose of this study is to provide with a basic materials for the standardized guideline writing and management for the hemodialysis water as inspecting the hemodialysis water contamination in according to disinfection type.

1.2. The study purpose

This study is for the culture level of microorganism in hemodialysis water in according to the loop disinfection type. The detailed purpose is as follows. Frist. To analyze the culture level of microorganism in hemodialysis water that is affected by disinfection loop types.Second. To analyze the culture level of microorganism in hemodialysis water that is affected by temperature difference

1.3. The term definition

1) Hemodialysis water

The hemodialysis water is mixed with the processed Dialysis water with acetate and bicarbonate. The dialysis water is the prepared water for the CRF patients and was removed from chemical, bacteriological and endotoxin infection source(the Korea Centers for Disease Control and Prevention ,2011).

2) Hemodialysis water loop type

The hemodialysis water loop type have a function and rule to move the water created by the filtration system to an artificial kidney in the artificial kidney unit. The loop and storage tank must be cleaned once a month(the Korea Centers for Disease Control and Prevention ,2011).

3) Hemodialysis Water Microorganism Test

It is to inspect the microorganism number living in the hemodialysis water which affects the occurrence rate of an exothermic reaction. Namely, it is a general bacterial and endotoxin test for the hemodialysis(ISO,2014)

1.4. Limitation of the study

It is a retrospective research only for an artificial kidney unit in a general hospital, which means that there is a limitation of a generalization.

2. Literature review

2.1. The management criteria of the hemodialysis water

The most important thing is the water quality management of the hemodialysis in the hemodialysis unit and there are two standards of the water quality management. In the case of the South Korea, we follow “the Standard Guidelines for infection Management in the Dialysis Room” legislated by the Korea Centers for Disease Control and Prevention(KCDC). This guideline suggests that the bacteria in the water is lower than 200CFU/ml and the endotoxin is lower than 2EU/ml as a permission standard and also that the hemodialysis water must be in accordance with the AMMI standard.As a microbiological examination way, 1) the first is the bacteria test living in the dialysis water and of which samples are collected (1)at the spot that the dialysis water enters into a mixed tank, (2)at the end of the water gathering container that the water directly rises (3)and at the spot of each water distribution loop’s end before the dialysis water passes through the moving system. The collecting sample containers must be sterilized and have no any endotoxin and also, of which tap must be cleaned by the sterilized gauze with alcohol(must wait for alcohol evaporation) before use. And the detailed is as follow. Other antiseptics like cleanser must be prohibited. Also, after opening the water tap, flow the water for 60 seconds and collect at least minimum 50ml to do the test. In the microbiological examination, it is suggested that the culturing temperature is 35-36℃ and culturing time is 48 hours. After culturing, quantitatively inspect the formed colony count. 2) The second microorganism examination is the endotoxin test which is to sense gram-negative bacterium reacting the exothermic reaction in the dialysis water. This test is conducted in according to the endotoxin examination ways of the ISO(2002), ISO(2014), ASTMF748-06(2010) and the Korean Pharmacopoeia’s general test(the Ministry of Food and Drug Safety,

2014). For samples, collect (1)at the spot that the dialysis water enters into a mixed tank, (2)at the end of the water gathering container that the water directly rises and (3)at the spot of each water distribution loop end before the dialysis water passes through the moving system. The collecting sample containers must be sterilized and have no any endotoxin and also, the collecting method is the same with the microbiological collecting method. The testing way is as follow. React the endotoxin in the dialysis water with the LAL(Limulus Amaebocyte Lysate) commodified and measure the amount and time of becoming turbid before the liquid Lysate becomes a coagulum by the endotoxin which is included in the sample. And, there is a chemical standard. The examination is to measure the elements in the dialysis water. If the chemical pollutant in the water exceeds the acceptance criteria, side effects are appeared so, the chemical test must be needed. The micro substance acceptance criteria also follows the ISO standard.

2.2. The disinfection method for the hemodialysis water loop filter device

As ways of the hemodialysis water loop disinfection, the first is a chemical disinfection with chlorine bleach or percetic acid and the second is a heat disinfection by heating water at 80℃. However, recently it is prohibited to use the chlorine bleach to prevent the water pollution but the chemical disinfection is quarterly conducted with the 1.73% Percetic acid(Hemo clean) including perectic acid. However, the guidelines for the time and method of the disinfection haven't been set up yet for the each dialysis unit. The heat disinfection for the hemodialysis loop management was firstly applied for a domestic purification system in the dialysis unit in 2010. However, among 520 hemodialysis centers, most of them still don't have the heat disinfection system for the loop disinfection. Although they have it, they don't have the detailed guidelines for loop disinfection type, loop quality, size and installation standard.

3. Study method

3.1. The study design

This study is for the hemodialysis unit of the Superior general hospital in I city. It is a retrospective research to find out if the hemodialysis water is contaminated or not which was collected through the entire hemodialysis device and R/O for 5 years from January, 2010 to December, 2014.

3.2. The study object

The hospital's hemodialysis unit had 45 hemodialysis devices, purification system and distribution system etc. Used hemodialysis devices wer from G company and the installation of the high flow dialyzing diaphragm(polyflux 14S, polyflux 170H, polyflux 210H) was conducted with the cooperation of the G company.

3.3. The study tool

1) General Bacteria Test

The general bacteria test of the hemodialysis water follows the ISO standard(2014). Its standard is that more than 100CFU/ml means contamination and lower than 100CFU/ml means noncontamination

2) Endotoxin Test

In according to the ISO standard(2014) more than 025EU/ml means contamination and lower than 0.25EU/ml means non contamination.

3.4. Method of collecting data

This study got a deliberation from IRB(approval number : 20 1412-HR0-89). The period of the collecting data was from January, 2010 to December 2014. And the medical records of hemodialysis water result which are related with the infection management in the dialysis unit was collected with a retrospective way. We collected the water of the 45 dialysis machines and 50 porters, in which the hemodialysis water rises, and requested the test every month. The general bacteria test was conducted in the laboratory. And in the case of the endotoxin, two samples for each 3 months were sent to a specialized company for the test. Also, in the case of the chemical test(micro substance test), in according to the ISO standard(2014), the test for 23 items was regularly conducted by a specialized company once a year.The hemodialysis unit of this institution installed 45 dialysis machines and new reverse osmosis purification system after moving a new place. The microorganism culturing test was conducted every month with collecting samples, the endotoxin test was quarterly conducted and the micro substance test was regularly conducted once a year.As the disinfection method, at first, Type A : the chemistry disinfection for the verse osmosis purification system and loop disinfection was conducted from January, 2010 to 30th December, 2010 once a month by using Percetic acid(Hemocraim). Type B : The second way was conducted from January, 2011 to 30th December, 2012. The heat disinfection at 90℃ was conducted in the evening on the every saturday and the chemistry disinfection was conducted once bimonthly with the heat disinfection. Type C : The third way was conducted from 1st January, 2013 to 30th December, 2014. The heat disinfection at 95℃ was conducted in the evening on the every Saturday and the chemistry disinfection was conducted once bimonthly with the heat disinfection.

3.5. Data analysis method

The SPSS 18.0 Program was used for the data analysis and the statistical test of entire data was conducted in a significant level 5%. To compare an bacteria emission of the hemodialysis water according to the loop disinfection types, so the One-way ANOVA was used. And for the post test, the Scheffe was used. The Logistic Regression was used to find out if the hemodialysis water was contaminated or not according to the disinfection types after clarifying under 100CFU/ml as non-contamination and more than 100CFUml as contamination.

4. Study result

4.1. The microorganism culturing level according to loop disinfection types

In this study to analysis the hemodialysis microorganism culturing level according to the loop disinfection types, the One-way ANOVA result is like <Table 1>

Table 1. The microorganism culturing level of the hemodialysis water according to the loop disinfection types.

Loop disinfection types	Mean ±SD	F	*p*	Scheffe
A type a	28.31± 123.13	37.358**	<.001	c<a,b
B type b	19.58± 112.31			
C type c	0.65± 9.83			

* *p*<.05, ** *p*<.01

● A type : only chemistry disinfection(once a month)

● B type : heat disinfection at 90℃(once a week) + chemistry disinfection(once biweekly)

● C type : heat disinfection at 95℃(once a week) + chemistry disinfection(once biweekly)

4.2. The result of contamination or not of the hemodialysis water according to loop disinfection types

The analysis result of the Logistic Regression is like <Table 2> to find out if the hemodialysis water is contaminated or not according to the loop disinfection types. After we clarified that under 100CFU/m is non-contamination and more than 100CFU/m is contamination, we researched if the hemodialysis water is contaminated or not according to the disinfection types. As a result, the type A is Wald=32.994, p<.001 and type B is Wald=22.249, p<.001, which means there is statistically a significant difference. Therefore, the odds ratio of the type A is 33.151. The type A has a high rate of being contaminated 33.151 times than type B(heat disinfection at 90℃ once a week + chemistry disinfection once biweekly) and C(heat disinfection at 95℃ once a week + chemistry disinfection once biweekly)Also, the odds ratio of the type B is 19.107. Type B(heat disinfection at 90℃ once a week + chemistry disinfection once biweekly) has a high rate of being contaminated 19.107times than Type C(heat disinfection at 95℃ once a week + chemistry disinfection once biweekly).As a result of the Hosmer and Lemeshow test, the chi-square statistic is under 0.001, so it is represent that the Logistic Regression is suitable. According to this model, when we set up that the cut value more than 0.5 is contamination and the cut value lower than 0.5 is non-contamination, the accuracy of the whole classification appears high for 98.4%.

Table 2.The result of the hemodialysis water is contaminated or not according to the loop disinfection types

Types	B	S.E,	Wald	*p*	Exp(B)
A type	3.501	0.610	32.994	<.001	33.151
B type	2.950	0.625	22.249	<.001	19.107
C type	-6.423	0.578	123.553	<.001	0.002

Hosmer and Lemeshow test : χ^2<.001, *p*=1.000

Accuracy of the whole classification = 98.4%

● A type : only chemistry disinfection(once a month)

● B type : heat disinfection at 90℃(once a week) + chemistry disinfection(once biweekly)

● C type : heat disinfection at 95℃(once a week) + chemistry disinfection(once biweekly)

6. Result

This study is a retrospective research to find out the hemodialysis microorganism culturing level according to the loop disinfection types. we analyzed the hemodialysis water microorganism number collected by R/O and the hemodialysis machines for 5 years from January, 2010 to December, 2014 in the hemodialysis unit of the superior general hospital in I city once every a month.As a result of the study, according to the loop disinfection, the virus of type B(heat disinfection at 90℃ once a week + chemistry disinfection once biweekly)(19.58±123.31) is found fewer than type A(only chemical disinfection once a month)(28.31±123.13) in the microorganism culturing level. Also, although the heat disinfection is conducted, the virus of the type C(heat disinfection at 95℃once a week + chemistry disinfection once biweekly)(0.65±9.83) is found fewer than type B in the microorganism culturing level(F=37.358, p=.001). Also, after clarifying that under 100CFU/ml is non-contamination and more than 100CFU/ml is contamination, we found whether there is a difference or not for hemodialysis water contamination/non-contamination according to the loop dis infection types. And there is a significant difference statistically of type A(Wald= 32.994, p<0.001)(only chemical disinfection once a month) and type B(Wald=22.249, p<0.001)(heat disinfection at 90℃ once a week + chemistry disinfection once biweekly)(19.58±123.31). The contamination rate for the hemodialysis water of the type A is higher 33.151 times than type B. And the contamination rate for the hemodialysis water of the type B is higher 19.107 times than type C.The management standard for the hemodialysis water quality has been stated but there has been no standards for related factors such as loop disinfection, loop quality, size and installation standard.However, because these factors affects the whole hemodialysis water, the detailed guidelines have to be needed. Therefore, through this study, we want to provide with the basic materials for practical guidelines of the hemodialysis water management with our attention of it. Furthermore the study is considered that this study will contribute to the medical practice improvement for the domestic hemodialysis through the scientific and systematic approaching

7. Suggestion

Based on the study, we suggest as follows to manage the hemodialysis water in the hemodialysis unit.

1. We suggest to install the Heating system when the each hospital installs the refined system for the dialysis unit.

2. We suggest that the hospital strictly disinfect and monitor the loop disinfection time and temperature because the temperature is changed depending on the loop length and size during the heat disinfection.

3. We suggest to develop a education program for continuing education for improving the recognition of the medical provider.

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