The Effect of Low-Flux and High-Flux Filters on Adequacy and Complications during Hemodialysis of Patients

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ABSTRACT

In case of inadequacy, hemodialysis, as one of the most common treatments for chronic renal failure, increases the blood toxins, complications, hospital stay, costs, and death. High-Flux filters can be effective in increasing hemodialysis adequacy if the patients tolerate and do not display complications. Therefore, this article aimed to study the efficiency of these dialyzers in increasing the dialysis adequacy compared with the complications and tolerance of hemodialysis patients. This is a single-group quasi-experimental study during which all 22 patients underwent hemodialysis three times a week for four hours for six months. They consented to participate in the study. They underwent dialysis for 4 sessions with Low-Flux filter and then 4 sessions with High-Flux filters. In each session, the patients were investigated by a checklist during the hemodialysis. In the fourth session, dialysis adequacy was measured for each patient. The mean score of dialysis adequacy in Low-Flux stage was 0.83 ± 0.48. It was 1.02 ± 0.064 in High-Flux stage, though. According to the Paired Sample Test, the difference was significant (p=0.006). According to the McNamara’s test, the incidence of nausea and vomiting, headache, muscle cramps, etc. was not significant between Low-Flux and High-Flux modes (P>0.05). Systolic blood pressure changes were increasing in both mentioned modes which was not statistically significant (P>0.05). Conclusion: In addition to increasing the dialysis adequacy, using High-Flux filter is a better choice than Low-Flux filter due to no complications for hemodialysis patients.

Keywords: Dialysis Adequacy, High-Flux, Hemodialysis Complications.

INTRODUCTION

Chronic Renal Failure (CRF) is a pathologic process with multiple causes which causes unstoppable and irreversible reduction in nephron number and function¹. In 2010, CRF was known as one of the three causes of death with the largest increase from 1990 to 2010². End Stage Renal Disease (ESRD) is the severe form of CRF which causes death if alternative renal therapies including dialysis and kidney transplant are not performed³. The number of ESRD patients worldwide was estimated 3346000 at the end of 2014. With an annual increase of 6%, it has become one of the important therapeutic dilemmas around the world. The number of dialysis patients was 2.662 million in 2014. It means that 89% of all dialysis patients use hemodialysis. Hemodialysis is expected to remain the most important therapy for ESRD patients⁴. Despite the continuous improvement in technology and hemodialysis care, a high mortality rate is still reported for the hemodialysis patients⁵. Lack of dialysis adequacy is one of the important factors of increasing mortality rate⁶. Various parameters increase the dialysis adequacy including dialysis fluid flow increase, the use of high-ultrafiltration filter, blood-flow increase, longer duration, and higher frequency
of dialysis\textsuperscript{7}. Some of these solutions such as longer duration of hemodialysis for more than 4 hours are costly and not tolerable\textsuperscript{6}. Blood-flow increase can also cause inadequacy due to the type of vascular access and certain factors such as hypotension and muscle cramps, followed by dialysis intolerance\textsuperscript{8}. Dialysis fluid flow increase cannot be much effective in dialysis adequacy\textsuperscript{9}. Therefore, using High-Flux filters seems more appropriate. Despite the superior ability of the High-Flux filters for withdrawing medium molecular-weight toxins, the advantages of these filters are still the subject of debate\textsuperscript{9}. 60\% of patients are dialyzed with High-Flux filters worldwide\textsuperscript{8}. High-Flux membranes with larger pore size allow larger molecule cleansing by reducing the induction of inflammatory mediators. Numerous studies showed that using these filters is associated with mortality rate reduction and clinical outcome improvement\textsuperscript{7}. The study by Kreusser showed that the survival increased by High-Flux filters. No significant difference was found concerning the effect of both filters on laboratory parameters\textsuperscript{10}. The study by Narimani\textsuperscript{11} (2015) and Eshvandi\textsuperscript{12} (2012), however, proposed the use of High-Flow filters in order to increase the dialysis adequacy. The studies by Lee et al. (2013) and Makar et al. (2011) showed that using High-Flux filters is a better choice for the patients undergoing long hemodialysis \textsuperscript{12,13}. Some studies, however, showed that using High-Flux filters is not practical in all sessions for all patients because it is not cost-effective and tolerable\textsuperscript{7}. The study by Kavian Nejad et al. (2015), however, showed that the incidence and severity of complications such as nausea, vomiting, hypotension, fever, chills, headache, muscle pain, and muscle cramps were not significant in dialysis patient using High-Flux and Low-Flux filters. The patients who underwent High-Flux filters reported greater comfort and tolerability\textsuperscript{15}. Yet, the study by Raj Maneshi (2014) showed that although High-Flux filters are associated with higher urea clearance efficiency than Low-Flux filters in zero ultrafiltration, and low blood and dialysis fluid flow conditions, they are not safe concerning the hemodynamic instability and disequilibrium syndrome in high risk patients\textsuperscript{16}. Due to the disputes over the complications and advantages of High-Flux filters and lack of studies concerning consideration of the complications of these filters and efficiency at the same time for improving the dialysis adequacy, this article aimed to compare High-Flux and Low-Flux filters concerning the dialysis adequacy and complications at the same time.

**MATERIALS AND METHODS**

This is a single-group quasi-experimental study in order to determine the effect of High-Flux and Low-Flux filters on hemodialysis adequacy and complications of 22 hemodialysis patients visiting the hospitals in Zabol, Iran in 2016. The sample size was calculated based on the following statistical formula and a guideline\textsuperscript{1}:

\[
N = 2\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \delta^2 / \delta^2 = 22 \quad z_{1-\alpha/2} = 1.96 \quad z_{1-\beta} = 1.28
\]

Then, the study was carried out in three stages. In the first stage, the patients were selected considering the inclusion criteria: ESRD, three times dialysis in a week each four hours, at least six months after hemodialysis treatment, fistula or arterio-venous graft, tolerance of dialysis, capability of participation in the study, lack of pulmonary heart and acute disease, ultrafiltration fewer than 3 liters, 15-65 years old, and hemoglobin greater than 10 mg per deciliter. After briefing and explaining the objectives, the consent was taken. In the second stage, all patients underwent the dialysis for 4 sessions with Low-Flux filter and 4 sessions with High-Flux filter in the third stage. Prior to every hemodialysis, the patients were investigated concerning the exclusion criteria (anti-cramping medication intake, nausea and vomiting, and blood pressure four hours before the hemodialysis, blood pressure greater than 140.90 and less than 100.60 mm Hg at the start of hemodialysis, smoking one hour before the start of hemodialysis, nausea and vomiting, muscle cramps before each hemodialysis, changes in diet during the study). If they had any of above mentioned exclusion criteria, they were excluded until the next hemodialysis. All patients were directly observed concerning the complications from the beginning until the end of hemodialysis. Notably, B. Braun hemodialysis machine, the temperature of 37 degree dialysis solution, bicarbonate dialysis solution, fixed concentration of dialysis solutions, 140 mEq per liter sodium concentration, and 250 ml/min blood flow were used for all the subjects. Other variables were kept constant for every patient such as hemodialysis shift, ultrafiltration, the consumption or lack of consumption of caffeinated beverages prior to and during the hemodialysis, diet, antihypertensives prior to the dialysis. A blood sample was taken at the beginning and end of the fourth session in each stage in order to determine the dialysis adequacy. The sample was taken from the arterial line prior to the dialysis after connecting the dialysis needles. The final sample was taken at the end of hemodialysis before disconnecting the machine. First, the speed was reduced to 50 ml per minute. Then, the blood sample was taken 15 to 30 minutes after speed reduction from the dialysis line. Samples were sent to the laboratory immediately. BUN test result before and after the fourth session in each dialysis and the weight before and after the dialysis in the fourth session were used to determine the dialysis adequacy using KT/V with Daugirdas2.
RESULTS

The results showed that 59.1% of the patients were female and 40.9% were male. The mean age was 43±3.212. The mean score of dialysis adequacy was 0.83±0.48 in Low-Flux stage and 1.02±0.064 in High-Flux stage. According to the paired-sample test, the difference was significant (p=0.006). Findings showed that the mean systolic blood pressure in Low-Flux filter was 129.86±2.8, 133.36±4.1, 134.13±4.13, 138.86±5.38 prior to, at the beginning of, in the middle of, and at the end of the dialysis, respectively. Concerning the High-Flux filter, they were 7.63±3.66, 131.9±3.125, 137.36±5.25, 133.13±6.17 prior to, at the beginning of, in the middle of, and at the end of the dialysis, respectively. As it can be seen, systolic blood pressure increased during the dialysis while using both filters. The changes were not significant, however (p>0.05). None of the patients had hypotension during 8 sessions. According to the results of the paired-sample test, no significant difference was found between the mean systolic and diastolic BPs during the dialysis in both filters (p>0.05). During the first, second, third, and fourth dialysis sessions, 4.5%, 9.1%, 9.1%, and 4.5% of the patients using Low-Flux filters experienced muscle cramps, while 13.6%, 18.2%, 22.7%, and 22.7% of the patients using High-Flux filters experienced muscle cramps. According to the Mc Nemar's test, the muscle cramp incidence was not significant between two filters (p>0.05). A total of 4 patients had lower headache after using High-Flux filter compared to the Low-Flux filter, while five had more headache after using High-Flux filter. According to Mc Nemar's test, no significant difference was found concerning the headache (P>0.05). According to Mc Nemar's test, the incidence of nausea and vomiting was not significant in both filters (p>0.05).

Table 1: Mean Systolic and Diastolic Blood Pressure before and after Intervention

<table>
<thead>
<tr>
<th>Blood Pressure</th>
<th>Mean ±St. Deviation (Low-Flux)</th>
<th>Mean ±St. Deviation (High-Flux)</th>
<th>Paired-Sample Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>134.13±4.13</td>
<td>137.36±5.25</td>
<td>t=1.1 df=21 p&lt;0.05</td>
</tr>
<tr>
<td>Diastolic</td>
<td>77.04±2.38</td>
<td>85.50±3.58</td>
<td>t=1.6 df=21 p&lt;0.05</td>
</tr>
</tbody>
</table>

Table 2: Incidence of Complications before and after the Intervention

<table>
<thead>
<tr>
<th>Filter</th>
<th>Muscle Cramps (%)</th>
<th>Headache (%)</th>
<th>Nausea</th>
<th>McNemar's Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session</td>
<td>1 2 3 4 1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>Low-Flux</td>
<td>4.5 9.1 9.1 4.5</td>
<td>18.2 18.2 18.2 27.2</td>
<td>9.1 4.5 13.6 0</td>
<td></td>
</tr>
<tr>
<td>High-Flux</td>
<td>13.6 18.2 22.7 22.7</td>
<td>27.3 9.1 22.7 22.7</td>
<td>4.5 0 0 0</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Mean KT/V before and after the Intervention

<table>
<thead>
<tr>
<th>KT/V</th>
<th>Mean ±St. Deviation</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Flux</td>
<td>0.83±0.48</td>
<td>21</td>
</tr>
<tr>
<td>High-Flux</td>
<td>1.02±0.064</td>
<td>21</td>
</tr>
<tr>
<td>Paired-Sample Test</td>
<td>T=3.03</td>
<td>P=0.006</td>
</tr>
</tbody>
</table>

DISCUSSION

The findings showed that the mean age of hemodialysis patients was 43±3.212, while it was 38.3 in the study by Shahdadi et al. (2010). The difference can be associated with better control of patients diagnosed with blood pressure and diabetes in the last 5 years compared to the past. The mean dialysis adequacy in Low-Flux stage was 0.83±0.48. It was, however, 1.02±0.064 in High-Flux stage. According to the paired-sample test, the difference was not significant (p=0.006). The study by Narimani et al. showed that KT/V is significantly higher in High-Flux filter than Low-Flux filter (p=0.13). The study by Narimani, however, showed that the dialysis adequacy was optimal in both groups. In our study, the dialysis adequacy was less than 1.2 in dialysis with Low-Flux filter. After using High-Flux filter, 36.3% of the patients had greater adequacy, which might be associated with the fact that one group was used before intervention (Low-Flux filter) and after the intervention (High-Flux filter) in order to remove the intervening variables that could affect the dialysis efficacy. Narimani et al., however, used two different groups for each of the filters. The findings of the study by Moslem et al. (2008) showed that the mean KT/V was 1.34±0.43 in Low-Flux group and 1.44±0.32 in High-Flux group and 80% of the patients had greater-than-1.2 dialysis adequacy. Eshvandi et al. (2012) studied the dialysis adequacy using High-Flux filter in hemodialysis patients. They showed that using these filters was beneficial to significantly increase the dialysis adequacy. Co ra et al. (2015) compared the effects of High-Flux and Low-Flux filters. The results showed that a significant decrease was found in BUN after dialysis, phosphorus, sodium, PTH and potassium using the High-Flux filter. Another study by Maker et al. (2010) investigated the effect of Low-Flux and High-Flux filters on PTH of children undergoing hemodialysis. The results showed that PTH is significantly lower in patients undergoing hemodialysis with High-Flux filter than those with Low-Flux filter (p<0.001). The study by Raj Maneshi et al. (2013) on the comparison of urea clearance in Low-Flux and High-Flux filters and blood flow reduction and dialysis liquid flow showed that there was a significant increase in urea clearance in all set-blood flows in High-Flux filter than Low-Flux filter.
to the disequilibrium syndrome. Maneshi advised to use Low-Flux dialyzers for critically ill patients, patients receiving the first treatment, children, and the elderly. In our study, however, no significant difference was found between two filters concerning the hypotension, nausea and vomiting, headache, muscle cramps, etc. (p>0.05). The incident of the complications in Low-Flux filters was as follows: Nausea (6.8%), vomiting (1.1%), muscle cramps (6.8%), and headaches (20.4%). The study by Razeghi Nejad et al. showed that nausea and vomiting, muscle cramps, and headaches incidence were 8%, 16%, and 8% using Low-Flux filter, respectively. The study by Kavian Nejad et al. showed that they were 6.7%, 13%, and 10% which were consistent with our study, respectively. The incident of the complications in High-Flux filters was as follows: Nausea (1.1%), vomiting (0%), muscle cramps (19.3%), and headaches (20.4%). Similar to our study, the incidence of nausea and vomiting, muscle cramps, and headaches incidence was 16.7%, 16.7%, and 23.3%, respectively. No significant difference was found between our study and the one by Kavian Nejad concerning the incident of the complications. Therefore, it seems that, in addition to dialysis adequacy increase, using High-Flux filter is a better choice than the Low-Flux filters due to lack of complications for hemodialysis patients. Most clinical guidelines also emphasize on High-Flux dialysis. This is consistent with our study and the one by Kavian Nejad. Notably, blood pressure with both filters decreased significantly by extending the duration of the hemodialysis in the study by Kavian Nejad, while it was not significant in our study, which is likely associated with the fact that filters with material and drug clearance can affect the antihypertensive drug clearance. Similar to the study by Kavian Nejad, the changes of blood pressure was not significant between the two filters (p>0.05). Lee et al. (2013) investigated the patients undergoing Low-Flux hemodialysis with High-Flux dialysis for three years. The parameters included blood pressure, hemoglobin, albumin, PTH, calcium, phosphorus, and KT/V. The results showed that only the mean blood pressure, serum levels of phosphorus, iPTH, and the dosage decreased, while hemoglobin increased. These filters had better clinical results to modify the anemia, blood pressure and reducing phosphorus levels of serum. Similarly, our study proposed that High-Flux filters are better choices for hemodialysis patients.

CONCLUSION

Our findings showed that High-Flux filters were one of the most effective, efficient, and safest methods to enhance the dialysis adequacy due to lack of significant difference in complications during dialysis and blood-pressure changes.

REFERENCES