Original Article

Kidney Res Clin Pract 2023;42(1):117-126
pISSN: 2211-9132 • eISSN: 2211-9140
https://doi.org/10.23876/j.krcp.21.281

KIDNEY RESEARCH AND CLINICAL PRACTICE

Impact of needle type on substitution volume during online hemodiafiltration: plastic cannulae versus metal needles

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Background: Plastic cannulae have attracted increasing interest as an alternative to traditional metal needles with the aim of reducing cannulation-related complications. We investigated whether the substitution volumes during hemodiafiltration differ using these two types of needles in dialysis patients.

Methods: An intervention study involving 26 hemodialysis patients was conducted in Korea between March and September in 2021. Patients first received online hemodiafiltration using traditional metal needles, and thereafter plastic cannulae were used in a stepwise protocol. Repeated-measures design and linear mixed-effect models were used to compare substitution volumes between the two needle types with the same inner diameter.

Results: The mean patient age was 62.7 years, and their mean dialysis vintage was 95.2 months. Most patients (92.3%) had an arteriovenous fistula as the vascular access. The substitution volume increased as blood flow and needle size increased for both plastic cannulae and metal needles. The substitution volume was significantly higher with 17-gauge (G) plastic cannulae than with 16-G metal needles at blood flow rates of 280, 300, and 330 mL/min. Similar results were obtained for 15-G metal needles and 16-G plastic cannulae at a blood flow rate of 330 mL/min. However, the patient ratings of pain on a visual analogue scale were higher for plastic cannulae.

Conclusion: Higher substitution volumes were obtained at the same prescribed blood flow rate with plastic cannulae than with metal needles during online hemodiafiltration. Plastic cannulae are an option for achieving high-volume hemodiafiltration for patients with low blood flow rates.

Keywords: Hemodiafiltration, Hemodialysis, Ultrafiltration

Received: November 25, 2021; **Revised:** May 5, 2022; **Accepted:** May 17, 2022
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Introduction

Mortality remains high for hemodialysis (HD) patients despite continuous improvements in HD devices and membrane biocompatibility [1]. HD is based on diffusion across a semipermeable membrane, which allows adequate clearance of low-molecular-weight particles. However, simply increasing the HD dose to remove more of the small solutes does not improve survival [2]. Online hemodiafiltration (OL-HDF) provides additional clearance of larger toxins compared with standard HD. OL-HDF also offers effective removal of uremic substances over a wider range of molecular sizes, which has potential clinical advantages [3–5].

During the past few years, several prospective, randomized clinical trials (RCTs) have compared survival outcomes in patients receiving conventional HD and OL-HDF [6–9]. None of these RCTs have shown statistically significant beneficial effects of OL-HDF on mortality. However, in all of these RCTs, *post hoc* analyses showed that patients with the highest delivered convection volume had considerably lower risk of all-cause mortality than those receiving HD [10]. Achieving a high convection volume is not easy in older patients and those with fragile vessels, especially Asians. We previously conducted a study of the stepwise achievement of high convection volumes in patients receiving OL-HDF by changing the needle size and dialyzer surface area and found that high convection volume was feasible by increasing the needle size and dialyzer surface areas in patients with a low blood flow rate [11].

Two main types of needles are commercially available and used for HD: metal needles and plastic cannulae [12–14]. Metal needles are made of stainless steel and are either sharp or blunt [15]. Plastic needles are designed specifically for HD cannulation and contain a sharp metal needle housed within a flexible plastic sheath. The metal needle is used to access an arteriovenous fistula (AVF) and to guide the insertion of the plastic sheath into the vessel. Previous studies have reported that plastic cannulae have a lower risk of causing vascular injury, needle infiltration during cannulation, and hematoma compared with traditional metal needles [16–18].

There is some concern that high blood flow may have a negative effect on vascular access survival [19]. A recent study demonstrated that patients treated with plastic cannulae showed less negative arterial pre-pump pressures and lower venous pressures than those treated with metal needles at all prescribed blood flow rates [20]. In that study, the plastic cannulae had stable arterial and venous pressures at the prescribed blood pump flow rates in patients undergoing HD. Therefore, we assumed that patients treated with plastic cannulae can achieve higher substitution volumes (SV) than those treated with metal needles at the same pump speed when applied during OL-HDF. In this study, we investigated the impact of needle type on SV in patients using different needle types during OL-HDF.

Methods

Study design and population

We conducted an intervention study between March and September 2021. This study was performed in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Hallym University Kangnam Sacred Heart Hospital (No. 2020-03-023). Written informed consent was obtained from all patients before enrollment.

Patients with end-stage renal disease, aged >18 years undergoing chronic intermittent HD for ≥3 months in two dialysis centers of Kangnam and Chuncheon Sacred Heart Hospital in South Korea were included. Patients were eligible for inclusion if they were being treated three times per week with high-flux HD and were able to understand the study procedures and provide informed consent. The exclusion criteria were severe nonadherence regarding frequency and/or duration of HD treatment and a life expectancy of <3 months because of nonrenal disease.

Procedures

Blood flow rate and needle size and type were determined for all patients (Fig. 1). Metal needles (15-gauge [G] and 16-G with a needle length of 25 mm; JMS Singapore Ltd) and plastic cannula (Supercath Clampcath 16-G and 17-G with a cannula length of 25 mm; Togo Medikit) were used in this study. The needle size of the plastic cannula indicates the size of the introducer needle, which serves as an introducer for the cannula into the vessel. After removal of the introducer needle, the inner diameter of plastic cannula is the same as that of a metal needle that is one

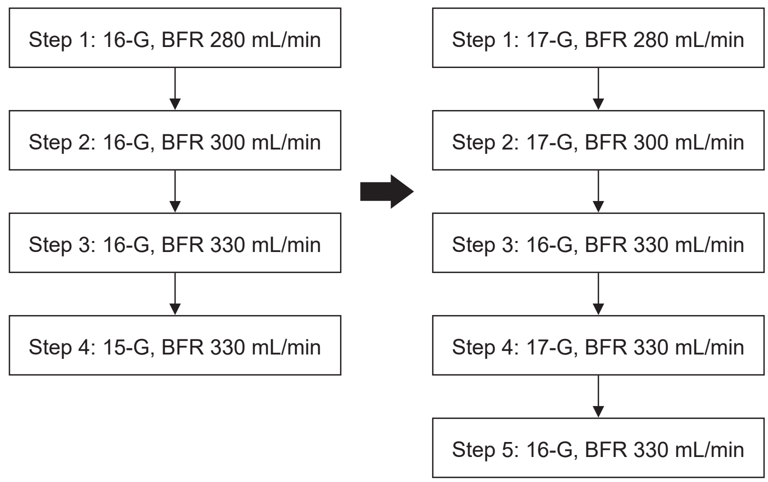


Figure 1. Study protocol.
BFR, blood flow rate; G, gauge.

gauge larger; e.g., a 16-G metal needle has the same inner diameter as a 17-G plastic cannula (Supplementary Table 1, available online). We compared SVs obtained using 15-G and 16-G needles. Metal needles were used at the start of the study protocol. The blood flow rate and needle size were increased in a stepwise manner. Each step was performed three times, and when a patient was able to tolerate one step, the next step was started. After reaching the last step with a metal needle, patients moved to the steps with a plastic cannula. The treatment times were fixed at 240 minutes. During the study, training of nursing staff on the study protocol was not required.

Postdilution HDF was performed using a 5008 CorDiax HDF machine (Fresenius Medical Care) with the AutoSub plus function. High-flux polysulfone dialyzers (surface area, 1.8 m^2, FX80; Fresenius Medical Care) were used. The dialysis and substitution fluid composition were standardized as follows: sodium, 140 mEq/L; potassium, 2 mEq/L; calcium, 3.0 mEq/L; and bicarbonate, 32 mEq/L. Unfractionated heparin was used for anticoagulation. Sterile and nonpyrogenic substitution fluids were produced by ultrafiltration of the ultrapure dialysate. Ultrapure quality was defined as a bacterial count of <0.1 colony forming unit/mL and endotoxin level of <0.025 endotoxin unit/mL [21].

Measurements

Demographic (age and sex), medical history (diabetes, hypertension, and dialysis duration), and clinical data were collected at baseline. Biochemical parameters were assessed before HD. Single-pool Kt/V was determined using two-point urea modeling based on the intradialytic decrease in blood urea concentration and intradialytic weight loss [22]. The reduction ratio of β2-microglobulin was calculated using the plasma concentrations of the solute before and at the end of HD [23]. The concentration at the end of HD was corrected for ultrafiltration. The SVs were automatically adapted and obtained based on pressure pulse attenuation and cross-membrane pressure assessment by the signal analysis, known as the AutoSub plus function [24]. A visual analogue scale (VAS) was used to assess the perception of pain caused by using plastic cannulae and metal needles. VAS is a validated, subjective measure for acute and chronic pain [25]. Scores are recorded by making a handwritten mark on a 10 cm line that represents a continuum between “no pain” (0 cm) and “worst pain” (10 cm) [26].

Statistical analyses

Data are expressed as mean (±standard deviation, SD) for continuous variables and as numbers of patients and percentages for categorical variables. Linear mixed-effect models were used to analyze associations between the increase in steps and SV, factors related to SV, and comparison of SV according to the needle type and size. Differences in VAS, Kt/V, and the reduction ratio of β2-microglobulin for each step were also analyzed using linear mixed-effect models. A *post hoc* Tukey test was used to compare differences in the response variables between the groups. Each subject in the models was used as a random factor. The model to identify factors related to SV was adjusted for serum albumin level and hematocrit, which are factors used to estimate convection volume in patients during OL-HDF [27]. Statistical analyses were performed using R software (version 4.0.5; R Foundation for Statistical Computing, Vienna, Austria; https://www.R-project.org/). All p-values were two-sided, and p < 0.05 was considered to be significant.

Results

Baseline characteristics

A total of 26 patients were included in the study, and all patients completed each step. Patient characteristics are summarized in Table 1. The mean age was 62.7 years, 23.1% were women, the average dialysis vintage was 95.2 months, and 57.7% had diabetes. The mean hematocrit was 31.5%, and the mean serum albumin concentration was 3.9 g/dL. A high percentage (92.3%) of patients had an AVF as the vascular access. The mean blood flow was 285 mL/min.

Table 1. Baseline characteristics of the study subjects

Characteristic	Data
No. of participants	26
Age (yr)	62.7 ± 11.1
Male sex	20 (76.9)
Body mass index (kg/m^2)	24.6 ± 3.7
Predialysis SBP (mmHg)	148.4 ± 22.0
Predialysis DBP (mmHg)	70.5 ± 14.1
Duration of dialysis (mo)	95.2 ± 57.8
Diabetes	15 (57.7)
Hypertension	17 (65.4)
Vascular access, AVF	24 (92.3)
Blood flow rate (mL/min)	285 ± 16.1
Hemoglobin (g/dL)	10.4 ± 0.7
Hematocrit (%)	31.5 ± 2.3
Albumin (g/dL)	3.9 ± 0.3
Calcium (mg/dL)	8.8 ± 0.7
Phosphorus (mg/dL)	5.1 ± 1.1
Single-pool Kt/V	1.8 ± 0.3

Data are expressed as number only, mean ± standard deviation, or number (%).
AVF, arteriovenous fistula; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Substitution volumes at each step

The mean (SD) values for each step and trends for the changes in SV in the different steps are shown in Fig. 2. Positive linear trends could be seen for each step. As blood flow and needle size increased, the SV increased using both plastic cannulas (β coefficient, 0.80; 95% confidential interval [CI], 0.61–0.97; p < 0.001) and metal needles (β coefficient, 1.14; 95% CI, 0.95–1.33; p < 0.001).

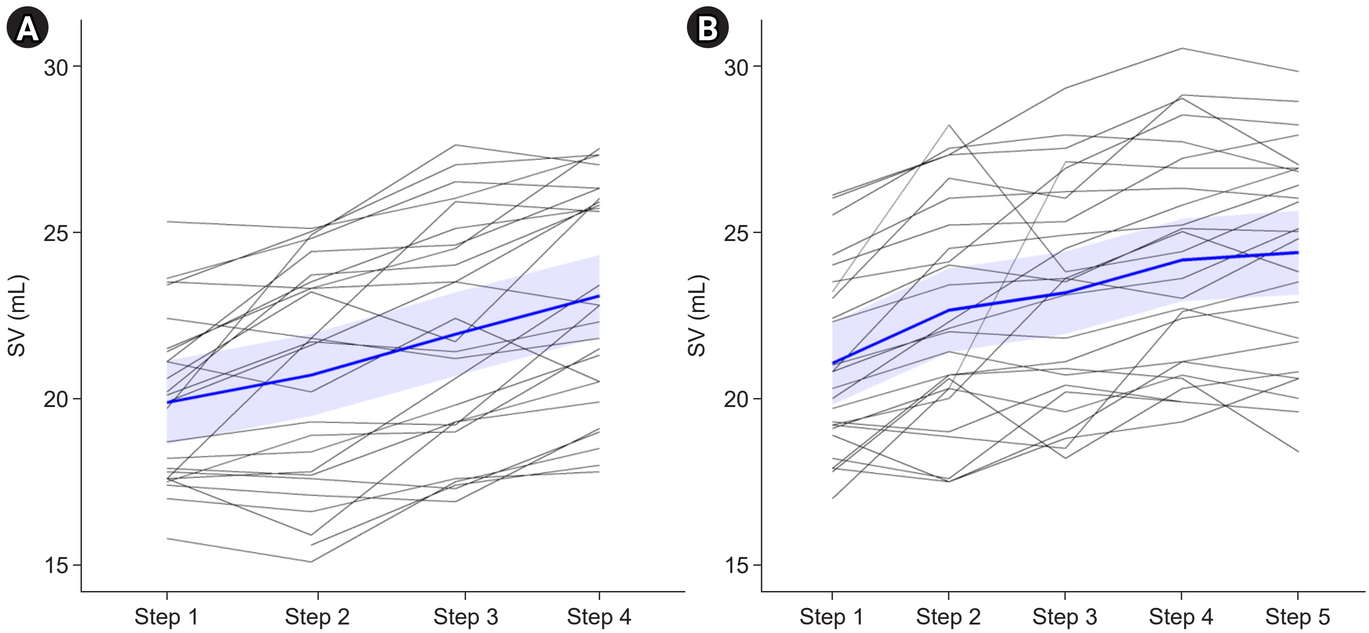
Next, we used a linear mixed-effect model to identify factors associated with the SV. After adjusting for serum albumin concentration and hematocrit, high SV was significantly associated with the use of plastic needles (vs. metal needle: β coefficient, 1.69; 95% CI, 1.33–2.05; p < 0.001), blood flow rates of 300 mL/min (vs. 280 mL/min: β coefficient, 1.29; 95% CI, 0.79–1.78; p < 0.001) and 330 mL/min (vs. 280 mL/min: β coefficient, 2.64; 95% CI, 2.14–3.13; p < 0.001), and use of 15-G needles (vs. 16-G needles: β coefficient, 0.67; 95% CI, 0.26–1.08; p < 0.001).

Comparisons of substitution volumes

The comparison of SVs for plastic cannulae and metal needles is shown in Fig. 3. For 16-G needles, the SVs were significantly higher when using plastic cannulae than metal needles at blood flow rates of 280 (estimated difference, 1.39; standard error [SE], 0.37; p < 0.001), 300 (estimated difference, 1.88; SE, 0.38; p < 0.001), and 330 (estimated difference, 2.32; SE, 0.38; p < 0.001) mL/min. For 15-G needles, the SVs were higher for plastic cannulae than for metal needles, but the significance was borderline (estimated difference, 1.17; SE, 0.38; p = 0.05).

Visual analogue scale of perceived pain according to needle type

The comparison of pain VAS scores according to needle type is shown in Fig. 4. For 15-G needles, the VAS score for pain was higher for plastic cannulae than for metal needles (3.76 ± 1.46 vs. 2.62 ± 1.53; p < 0.001). For 16-G needles, the VAS score was also higher for plastic cannulae than for metal needles (3.94 ± 1.73 vs. 2.73 ± 1.40; p < 0.001).



SV (mL), mean±SD	19.7 ± 1.7	20.7 ± 3.3	21.9 ± 3.5	13.1 ± 3.3	21.1 ± 2.7	22.6 ± 3.3	13.2 ± 3.3	24.2 ± 3.3	24.4 ± 3.2

Figure 2. Spaghetti plot of SVs plotted separated for metal needles (A) and plastic cannulae (B). The smooth lines (blue) show the linear trend of SVs using locally estimated scatterplot smoothing analysis.
SD, standard deviation; SV, substitution volume.

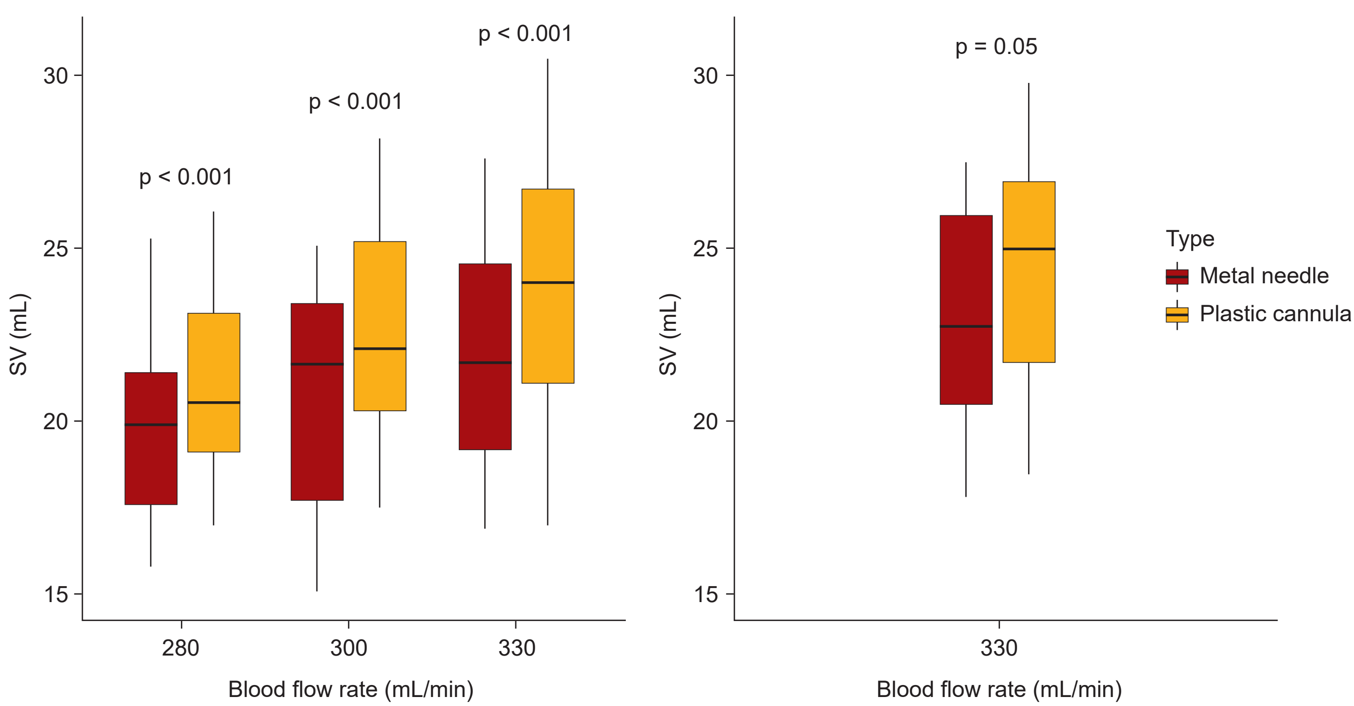


Figure 3. SVs by needle size and type. (A) 16-Gauge (G) metal needle vs. 17-G plastic cannula. (B) 15-G metal needle vs. 16-G plastic cannula.
SV, substitution volume.

Kt/V and β2-microglobulin reduction ratio

We compared the changes in Kt/V and β2-microglobulin reduction ratio between needle types (Table 2). For metal needles, the Kt/V and β2-microglobulin reduction ratio tended to be higher for step 4 compared with step 1 ($p < 0.001$). For plastic cannulae, the Kt/V was significantly higher for step 5 compared with step 1. The change in the β2-microglobulin reduction ratio did not change significantly between steps 1 and 5 ($p = 0.70$). In step 1, plastic cannulae showed higher Kt/V ($p = 0.01$) and β2-microglobulin reduction ratio ($p = 0.01$) than metal needles. Between step 4 of metal needles and step 5 of plastic cannulae, the difference in Kt/V was not significant ($p = 0.05$), and β2-microglobulin reduction ratio with metal needle was significantly higher than with plastic cannula ($p = 0.003$).

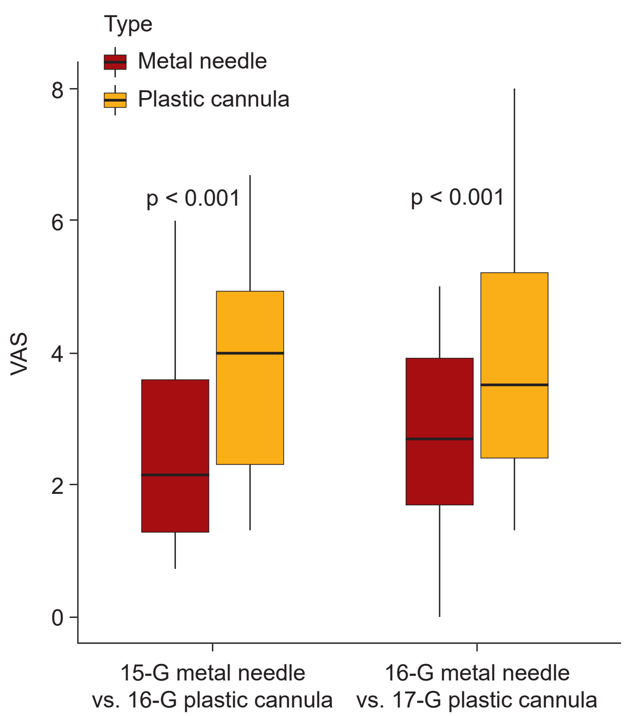


Figure 4. VAS pain scores.
G, gauge; VAS, visual analogue scale.

Discussion

In this study, we found that the SVs were higher using plastic cannulae than metal needles in patients undergoing OL-HDF. With both types of needles, the SVs increased with higher blood flow rates and needle size. However, plastic cannula insertion was perceived by the patients to be more painful than metal needle puncturing. We used a stepwise protocol to the adjust blood flow rate and needle size. The first step involved a low blood flow rate and high needle gauge. Thereafter, the blood flow rate was increased and a lower gauge needle was used. All participants tolerated each step. In the protocol for the use of metal needles, the 15-G metal needle was not applied at a blood flow rate of 300 mL/min. The choice of gauge may be based on AVF vintage and expansion, patient tendency for bleeding, and patient preference [28]. Except for the initial cannulation, most guidelines do not recommend a specific gauge but instead recommend that the needle gauge matches the blood flow rate [29]. However, there is concern that larger needles are associated with complications of vascular access. We used 15-G metal needles only at the highest blood flow rate in our protocol.

Traditional sharp metal needles used to cannulate vascular access can harm the vessel or even infiltrate into the vessel wall during cannulation or during HD treatment. With plastic cannulae, the risk of vessel damage during HD or infiltration may be reduced because the cannula is soft and made of flexible material and the introducer needle is smaller than a metal needle. Studies have found that the

Table 2. Kt/V and β2-microglobulin reduction ratio according to the needle type

Variable	Metal needle	Plastic cannula	p-value
Step 1			
Kt/V	1.64 ± 0.28	1.78 ± 031	0.01
β2-microglobulin reduction ratio (%)	70.56 ± 10.12	75.49 ± 8.31	0.01
Steps 4, 5			
Kt/V	2.02 ± 0.44	1.92 ± 0.35	0.05
β2-microglobulin reduction ratio (%)	82.01 ± 3.81	75.14 ± 10.28	0.003

Data are expressed as mean ± standard deviation.

use of plastic cannulae results in lower rates of vessel damage, infiltration, and hematoma, and less stenosis of the vascular access [16,18,30]. Early cannulation with a plastic cannula, which means use of vascular access before 10 days from creation, did not affect vascular access patency in a retrospective cohort study in Japan [31].

OL-HDF is currently the most advanced and promising alternative to conventional HD. Previous large RCTs and observational studies have failed to show a consistent significant beneficial effect of OL-HDF on all-cause mortality [6–9,32,33]. However, the results of a pooled analysis of individual data from the RCTs and meta-analysis showed significant all-cause and cardiovascular survival benefits of HDF over HD when high convection volumes were achieved [10,34,35]. Treatment time, blood flow rate, and filtration fraction are stronger determinants of the convection volume than individual characteristics [36]. In feasibility studies, high-volume HDF was possible for >80% of HD sessions with modification of these factors [24,36]. However, the blood flow rate applied in these studies was >350 mL/min, which cannot be achieved easily in patients with fragile vascular access. In Asian patients, a low blood flow rate is the main obstacle to high-volume HDF. In this regard, our study suggests that the use of plastic cannulae may be an option for increasing SVs in patients whose blood flow rate is <350 mL/min.

In preliminary clinical observations, flow images at venous cannulation sites show distinct patterns for the two types of needles [37]. Images of metal needles show that the jet flow effect appears to be a solid stream projected toward the vessel wall. In contrast, images of plastic cannulae show that this effect appears more diffuse and extends from the side holes to the tip of the cannula toward the center of the vessel lumen. A study of hemodynamics found that the plastic cannula helps to maintain stable blood flow and reduces dynamic arterial and venous pressure despite the smaller diameter of the inner introducer needle compared with a metal needle [20]. There were lower negative arterial pre-pump pressures and lower venous pressures during HD with the use of plastic cannulae compared with the metal needles at all prescribed blood pump flow rates. The real blood flow rate is somewhat lower than the set value, and a higher the blood pump speed is correlated with a wider difference [38,39]. This phenomenon is explained by partial collapse of the tubes at more negative pre-pump pressures, which may be more prominent in HDF because it has more negative pre-pump pressure than conventional HD. These findings support our results showing that plastic cannulae can achieve higher SVs than metal needles. A plastic cannula has four sides with round holes all along the circumference of the tip, which improves steady blood flow during dialysis and prevents occlusion of the cannula by the vessel wall [30]. The VAS pain scores were higher for plastic cannulae than metal needles in this study. Previous studies have reported inconsistent results for the pain response during cannulation using plastic cannulae and metal needles [16,30]. Choi et al. [16] reported that plastic cannula insertion is more painful than metal needle puncturing. The larger outer diameter of the plastic cannula might be one of reasons for the high VAS pain scores of plastic cannulae. Furthermore, the insertion techniques differ between plastic cannulae and metal needles [17]. Because of the complicated cannulation technique, miscannulation can occur when trying to insert a plastic cannula, which might also cause pain. Adequate training of nursing staff is needed for the use of plastic needles in clinical practice. For example, Choi et al. [16] noted that nursing staff felt that plastic cannulae were much easier to use after a training period.

SVs with 16-G plastic cannulae were higher than ones with 15-G metal needles. However, the 15-G metal needles also give high SVs, so the difference in SVs by needle types was not significant (24.4 ± 3.3 with 16-G plastic cannula vs. 23.1 ± 3.3 with 15-G metal needle at blood flow rate of 330 mL/min). High convection volumes are advantageous to small molecule removal. We found that Kt/Vs were significantly improved in both metal needles and plastic cannulae as steps increased. However, β2-microglobulin reduction ratios were not significantly increased with plastic cannulae in higher step. The mean β2-microglobulin reduction ratios at the first step were higher with plastic cannulae than with metal needles, due to the high SVs of plastic cannulae. However, the β2-microglobulin reduction ratio with plastic cannulae at the fifth step did not significantly increase, despite high SVs, compared with the first step. Furthermore, the β2-microglobulin reduction ratio with plastic cannulae was lower than with metal needles at later steps. The relationship between convection volume and removal amount of middle molecules is unclear [40]. β2-microglobulin reduction ratio according to needle type should be investigated in future studies.

This study has several limitations. First, we used a repeated-measures design with the same participants for the response variable. There are several threats to the internal validity of this design because when patients are tested several times, their scores tend to regress toward the mean and may change during the course of the experiment. However, this study design helps to make a study more efficient and keeps the variability low while allowing for smaller-than-usual subject groups. Second, we enrolled a small number of patients from a single center, and therefore, our results are not generalizable. However, there are few data on the effects of needle type on SV during OL-HDF. Our findings suggest that plastic cannulae can be considered as a modifying factor for high-volume HDF. Third, we did not measure the dynamic venous pressure and effective blood flow rate at the cannulation site. Further studies are needed to compare the hemodynamic effects of these two types of needles.

In conclusion, SVs during OL-HDF differed between the two types of needles. Higher SVs were achieved with plastic cannulae than with metal needles. This may reflect the ability of plastic cannulae to maintain a stable blood flow rate with less negative pressure, but further studies are needed to confirm this result. Our findings suggest that plastic cannulae can be used for patients who cannot achieve high-volume HDF because of a low blood flow rate.

Conflicts of interest

All authors have no conflicts of interest to declare.

Funding

This research was supported by Hallym University Research Fund 2021 (HURF-2021-29).

Data sharing statement

The data presented in this study are available on request from the corresponding author.

Authors' contributions

Conceptualization: AJC, HCP, YRS, JWY, YKL
Data curation: ShK
Formal analysis: AJC, JKK, YKL
Investigation: GC
Methodology: DHK, GHS
Project administration, Supervision YKL
Resources: HBC
Software: AJC
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