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Original article

Influence of the vascular access punction needle caliber in the efficacy of online hemodiafiltration

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ABSTRACT

Introduction and objective: Higher infusion volumes (IV) in online hemodiafiltration (OL-HDF) are associated with better survival. The IV depends mainly on blood flow (Qb). The objectives of our study were to evaluate the influence of the caliber of arteriovenous fistula (AVF) puncture needles on the total convective volume and other characteristics of OL-HDF, and to investigate possible adverse effects.

Material and methods: Prospective intervention study analyzing six sessions of postdilution OL-HDF with 14G needles and six sessions with 15G needles in the same patients, to compare results of efficacy and safety. The monitor, the dialyser, the arterial and venous pressures, the conductivity and the flow of the dialysis fluid were kept equal in each patient. Efficacy through mean blood flow for maximal blood and venous pressures of −220 mmHg and 220 mmHg respectively, total convective volume, and percentages of creatinine, urea and β2-microglobulin reduction, were measured. Adverse effects such as measured pain with an analog scale, postdialysis coagulation times and complications were analyzed.

Results: A total of 34 patients, 55 ± 16 years old, 63% male, were studied. The use of 14G needles was associated with higher Qb (471.1 ± 36.7 ml/min vs 354.8 ± 25.8 ml/min, $p < 0.001$) and higher total convective volume (29.7 ± 5.7 liters with G14 vs 24.1 ± 3.6 liters with G15, $p < 0.001$) compared to 15G needles. The percentages of creatinine, urea and β2-microglobulin reduction were significantly higher in the 14G needles sessions (73.94 ± 6.03%, 82.54 ± 6.41% and 84.07 ± 4.83%) than 15G needles sessions (70.31 ± 6.67%, 78.80 ± 6.52% and 81.45 ± 5.16%), $p = 0.031$, 0.029 and 0.047 respectively. On the analog pain scale, no significant differences were found between both needles (4.03 ± 2.09 with 14G and 3.57 ± 2.04 with 15G, $p = 0.386$). No significant differences between the coagulation times of arterial and venous punctures with the two types of needles were found. As complications, only two punctured bleedings that required new coagulation were recorded, one with a 14G needle and one with a 15G needle.

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Conclusion: The use of 14G needles improves the efficacy of OL-HDF without increasing the associated adverse effects. In light of the results, widespread use of 14G needles in OL-HDF whenever possible can be recommended.

Influencia del caliber de la aguja de punción de acceso vascular en la eficacia de la hemodiafiltración en línea

Palabras clave:
Hiperuricemia
Progresión de la enfermedad renal
Reducción de la masa renal
Nefrectomía

RESUMEN

Introducción y objetivo: Mayores volúmenes de infusión (VI) en la hemodiafiltración en línea (HDF-EL) se asocian a una mejor supervivencia. Los VI dependen principalmente del flujo de sangre (Qb). Los objetivos de nuestro estudio fueron evaluar la influencia del calibre de las agujas de punción de la fístula arteriovenosa (FAV) sobre el volumen convectivo total y otras características de la HDF-EL e investigar posibles efectos adversos.

Material y métodos: Estudio prospectivo de intervención en el que se analizaron 6 sesiones de HDF-EL posteriores a la dilución con agujas de 14 G y 6 sesiones con agujas de 15 G en los mismos pacientes, para comparar los resultados de eficacia y seguridad. El monitor, el dializador, la presión arterial y venosa, la conductividad y el flujo del líquido de diálisis se mantuvieron iguales en cada paciente. Se evaluó la eficacia a través de mediciones del Qb medio para la presión arterial y venosa máximas de −220 y 220 mmHg, respectivamente, el volumen convectivo total y los porcentajes de reducción de creatinina, urea y microglobulina β2. Se analizaron efectos adversos tales como el dolor medido con una escala analógica, los tiempos de coagulación posteriores a la diálisis y las complicaciones.

Resultados: Se estudió un total de 34 pacientes, de 55 ± 16 años de edad, el 63% de los cuales eran hombres. El uso de agujas de 14 G se asoció a un mayor Qb (471,1 ± 36,7 frente a 354,8 ± 25,8 ml/min; p < 0,001) y a un mayor volumen convectivo total (29,7 ± 5,7 con G14 frente a 24,1 ± 3,6 L con G15; p < 0,001) en comparación con las agujas de 15 G. Los porcentajes de reducción de creatinina, urea y microglobulina β2 fueron significativamente mayores en las sesiones con agujas de 14 G (73,94 ± 6,03%; 82,54 ± 6,41% y 84,07 ± 4,83%) que en las sesiones con agujas de 15 G (70,31 ± 6,67%; 78,80 ± 6,52% y 81,45 ± 5,16%) con p = 0,031; 0,029 y 0,047, respectivamente. En la escala analógica del dolor no se observaron diferencias significativas entre ambas agujas (4,03 ± 2,09 con 14 G y 3,57 ± 2,04 con 15 G; p = 0,386). No se observaron diferencias significativas entre los tiempos de coagulación de las punciones arteriales y venosas con los 2 tipos de aguja. Como complicaciones, solo se registraron 2 sangrados debidos a la punción que requirieron nueva coagulación, uno con una aguja de 14 G y otro con una de 15 G.

Conclusión: El uso de agujas de 14 G mejora la eficacia de la HDF-EL sin aumentar los efectos adversos asociados. En función de estos resultados, se puede recomendar el uso generalizado de agujas de 14 G en la HDF-EL siempre que sea posible.

Introduction

Hemodialysis techniques mainly based on the diffusion of molecules through a semipermeable membrane ensure the clearance of low molecular weight particles. In recent years, the use of extrarenal purification techniques that add convective transport of molecules is increasing significantly due to its greater ability to purify medium and high molecular weight toxins. According to the latest published trials, on-line hemodiafiltration (OL-HDF) with high volumes of infusion (at least 24 L of total infusion), compared with conventional hemodialysis, is associated with a decrease in cardiovascular and overall mortality risk.[1,2] In these studies it is evident that higher volumes of infusion in HDFOL are related to better survival.

A high volume of total infusion in each session of OL-HDF requires a high blood flow, for which it is necessary to ensure adequate vascular accesses, cardiac function and vascular conditions. Once the best possible arteriovenous fistula (AVF) has been performed, the only way we can influence blood flow improvement is by changing the size of the puncture needle of the fistula.[3,4]

There are no comparative studies of the different dialysis needle sizes. Gauge 15 needles (15G) are used in most clinical

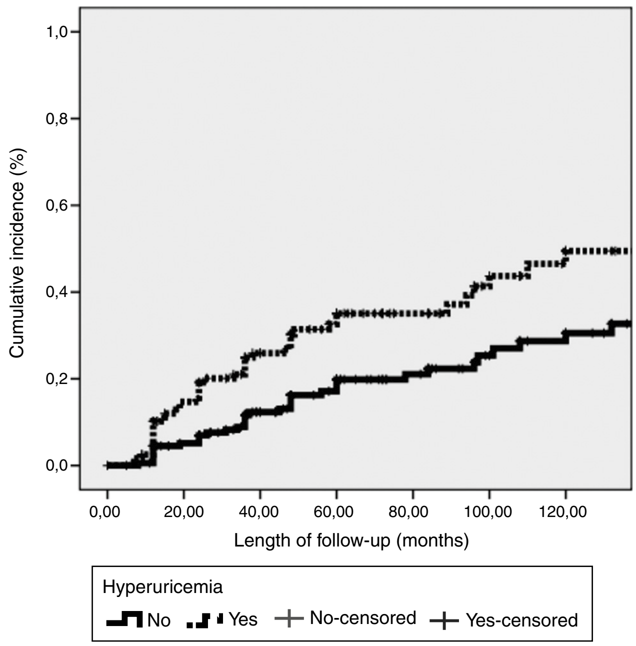

Fig. 1 – Relationship between hyperuricemia (>7 mg/dl of uric acid level) and renal disease progression (Cox regression model).

trials, although gauge 14 (14G) thicker needles are available. The tendency to use needles of 15G instead of 14G is based on the unfounded belief of a risk on vascular access with little benefit over the technique of dialysis. The objective of our study was to evaluate the influence of needle gauge size on vascular access in total convective volume, toxin clearance and other characteristics of OL-HDF. As secondary objectives we investigated possible adverse effects, such as coagulation times of vascular access, along with the collection of episodes of postcoagulation bleeding and assessment of pain related to puncture (Fig. 1).

Material and methods

Prospective, unicentric, non-randomized, two-stage intervention study to compare the efficacy of AVF puncture needle caliber on the efficacy of postdilutional OL-HDF, maintaining all session characteristics similar in both phases of the study.

Population under study

Prevalent patients in a chronic hemodialysis program that submit the inclusion criteria: >18 years, acceptance of informed consent to participate in the trial, presence of functioning AVF. Exclusion criteria: revocation of informed consent, current or in the last month hospital admission.

Timeline

Upon acceptance of the study, each patient was given the information sheet and informed consent. Following the signing of informed consent, the study included two phases: Phase A – Patients were evaluated for two weeks in post-dilution OL-HDF with 14G needles. After two weeks (six sessions), data on the characteristics of the dialysis session, efficacy data and possible adverse effects were collected. The automatic systems dialysis monitors available in the unit were used (Fresenius 5008 Cordiax autosub plus® and Artis with ultracontrol®). The blood flows (Qb) were the maximum possible as long as the arterial and venous pressures of the circuit did not exceed −220 mmHg and 220 mmHg respectively. Normally prescribed parameters for each patient were not modified: FX1000 was the standard dialyzer used, heparin prescription, dialysis time and dialysis fluid flow (Qd) were not modified according to the usual pattern of each patient. Phase B – Each patient initiated the treatment in OL-HDF with identical characteristics that in the previous phase, modifying only the type of puncture needle (15G). After two weeks (six sessions) of treatment, the same parameters as in phase A were assessed.

Efficacy of the session was measured by: mean blood flow, total convective volume (total infusion volume + net ultrafiltration volume) and percentage of creatinine, urea and β2 microglobulin reduction (Percentage reduction = (predialysis concentration − postdialysis concentration) × 100/Predialysis concentration), for which pre and post dialysis blood tests were performed.

Adverse effects were analyzed as pain measured with analog scale (FPS),[5] which was filled by patients after the block of two weeks with each needle. Coagulation times of the AVF in each puncture were analyzed. Finally, the occurrence of complications possibly related to the change of puncture needle (hematomas, rebleeding) was monitorized.

Statistical analysis

Qualitative variables are presented by frequency distribution. Quantitative variables are presented by mean and standard deviation or median and interquartile range according to normal distribution valued by Kolmogorov–Smirnov test. The comparison of variables between phases A and B was performed using Student's *t*-test. A *p*-value <0.05 was accepted as significant. Statistical analysis was performed with SPSS version 20®.

Ethical aspects

This study has been carried out in accordance with the international ethical recommendations for conducting human research in the last revision of the Declaration of Helsinki, as well as those established in the Norms of Good Clinical Practice and current legislation. It has been presented and approved for its realization by the ethical commission (CEIC) of the Gregorio Marañon Hospital.

Results

Thirty-four patients, 55 ± 16 years old, 63% of whom were male, were studied. The baseline characteristics of the sample are summarized in Table 1.

Table 1 – Baseline characteristics and cardiovascular factors between patients with renal disease progression (group A) vs patients without renal disease progression (group B).

	Group A ($n = 170$)	Group B ($n = 154$)	p
Age (years)	60.5 ± 17.0	59.4 ± 17.1	0.62
Sex male (%)	105 (62%)	72 (47%)	0.005
Nephrectomy (n) (%)	85 (50%)	95 (62%)	0.022
HTA (n) (%)	126 (74%)	109 (71%)	0.61
Diabetes mellitus (n) (%)	24 (14%)	19 (12%)	0.74
Previous cardiovascular event (n) (%)	34 (20%)	21 (14%)	0.14
RAAS blockers (n) (%)	53 (31%)	54 (35%)	0.34
Diuretics (n) (%)	71 (42%)	48 (31%)	0.05
Alopurinol (n) (%)	45 (27%)	47 (28%)	0.68
Systolic BP (mmHg)	141 ± 20	138 ± 21	0.12
Dyastolic BP (mmHg)	80 ± 12	80 ± 12	0.56
Pulse pressure (mmHg)	62 ± 18	57 ± 17	0.025
Creatinine (mg/dl)	1.36 ± 0.40	1.37 ± 0.40	0.87
MDRD-4 (ml/min/1.73 m²)	54.5 ± 20.8	51.9 ± 19.3	0.25
Albuminuria tertiles			
<10 mg/day	68 (40%)	84 (54%)	
10–100 mg/day	48 (28%)	41 (27%)	0.02
>100 mg/day	48 (28%)	20 (13%)	
Hyperuricemia (>7 mg/dl)	69 (40%)	51 (33%)	0.41
CRP (mg/l)			
Total cholesterol (mg/dl)	202 ± 39	206 ± 49	0.47
Follow-up time (months)	62 (38–100)	59 (35–96)	0.08

No differences in LDL and HDL-cholesterol and statins use were found between groups.

Differences in efficacy between use of 14G and 15G needles are shown in Table 2. The use of 14G needles was associated with higher Qb ($p < 0.001$) and higher total convective volume ($p < 0.001$). The percentages of creatinine, urea and β2-microglobulin reduction were significantly higher in the sessions with 14G needles than with 15G needles ($p = 0.031$, 0.029 and 0.047 respectively).

Adverse effects with 14G and 15G needles are shown in Table 3. On the analog pain scale, no significant differences were found between both needles ($p = 0.386$). There were also no differences between coagulation times of arterial and venous punctures. As complications, only two punctured bleedings that required new coagulation were recorded, one with a 14G needle and one with a 15G needle. No patient had vascular access infection or any other complication.

Discussion

Our study demonstrates that puncture of AVF with 14G needles, compared to 15G, results in increased OL-HDF

Table 2 – Baseline characteristics and cardiovascular factors in patients with renal disease progression Group A_1: lower than 1.6 ml/min/1.73 m^2 and Group A_2: higher than median.

	Group A1 ($n = 87$)	Group A2 ($n = 83$)	p
Age (years)	59.4 ± 17.2	61.7 ± 17.90	0.393
Sex male (n) (%)	53 (61%)	53 (64%)	0.754
Nephrectomy (n) (%)	51 (60%)	33 (40%)	0.021
HTA (n) (%)	62 (73%)	64 (77%)	0.378
Diabetes mellitus (n) (%)	10 (12%)	14 (17%)	0.379
Previous cardiovascular event (n) (%)	17 (20%)	17 (20%)	0.851
RAAS blockers (n) (%)	24 (28%)	29 (25%)	0.576
Diuretics (n) (%)	33 (39%)	38 (46%)	0.277
Alopurinol (n) (%)	21 (18%)	18 (15%)	0.062
Systolic BP (mmHg)	140 ± 20	143 ± 21	0.381
Dyastolic BP (mmHg)	81 ± 11	78 ± 14	0.106
Pulse pressure (mmHg)	58 ± 17	64 ± 19	0.035
Creatinine (mg/dl)	1.40 ± 0.4	1.30 ± 0.3	0.295
MDRD-4 (ml/min/1.73 m²)	53.5 ± 21.6	55.7 ± 20.1	0.491
Albuminuria tertiles			
<10 mg/day	39 (46%)	29 (35%)	
10–100 mg/day	26 (30%)	22 (26%)	
>100 mg/day	19 (22%)	28 (34%)	0.08
Hyperuricemia (>7 mg/dl) (n) (%)	28 (33%)	41 (49%)	0.040
Total cholesterol (mg/dl)	208 ± 43	196 ± 35	0.07

Table 3 – Uni and multivariate analysis (Cox regression) for progression of chronic kidney disease.

	Crude		Adjusted	
	HR	*p*	HR	*p*
Age (year)	1.02 (1.00–1.03)	0.012		
Gender (female)	0.51 (0.32–0.82)	0.005		
MDRD (ml/min/1.73 m²)	1.02 (0.99–1.01)	0.80		
Pulse pressure (mmHg)	1.02 (1.01–1.03)	0.001	1.02 (1.01–1.03)	0.001
Nephrectomy (yes)	0.54 (0.35–0.85)	0.032		
Diuretics (yes)	1.67 (1.07–2.59)	0.023		
Alopurinol (yes)	1.54 (1.04–2.78)	0.046		
Hyperuricemia (>7 mg/dl) (yes)	1.89 (1.22–2.92)	0.004	1.67 (1.06–2.63)	0.025
Diabetes mellitus (yes)	2.04 (1.14–3.63)	0.016		
Albuminuria				
<10 mg/day	Reference			
10–100/day	1.19 (0.68–2.09)	0.53	1.04 (0.58–1.84)	0.90
>100 mg/day	2.39 (1.42–4.02)	0.001	2.14 (1.26–3.64)	0.005

postdilution efficacy as a result of increased blood flow, without increasing the incidence of adverse effects.

Three clinical trials (CONTRAST, Turkish and ESHOL), four meta-analyzes and the French REIN registry have been published, relating postdilution high infusion volumes OL-HDF (24-liter cutoff point) with a decrease in cardiovascular and overall mortality, compared with conventional hemodialysis.[1,2,6–11]

To achieve 24 liters of infusion volume in four hours of postdilution OL-HDF, 100 ml/min infusion volume is required, which needs a blood flow of at least 400 ml/min (accepting an infusion rate of 25%). Assuring the best functional status of the patient, the best vascular access achieved and optimization of hemoglobin levels, the only tool available to improve blood flow is the modification of the hemodialysis needle. In most clinical trials and observational studies 15G needles are the one achieved or needle gauge is not mentioned. There are different studies on the material of the puncture needle or the position and other biomechanical characteristics of the needles, but there are no comparative studies of different puncture needle gauges demonstrating the benefit or prejudice of one or the other.[12,13]

In our study we compared the use of smaller caliber (15G) needles with larger caliber (14G) needles. Monitors with automatic reinfusion system were used, based on the characteristics of the pressure wave emitted by the blood flow through the dialyzer, avoiding possible intervention bias. Between the two phases of the study, the dialyzer, heparin dose, dialysis bath flow, or any of the other characteristics of OL-HDF that could influence infusion volume were not modified.

The change of caliber performed a higher mean blood flow under equivalent pressure conditions. This higher mean blood flow leads to greater volume of total infusion, which leads to greater efficacy, valued by higher percentage reduction of molecules.

Possible adverse effects of a larger gauge needle were studied, but no increased puncture pain, longer coagulation time or more episodes of bleeding were found in the sessions studied. The limitations of our study are: unicentric study with a small sample size, and lack of follow-up of the long-term AVF, with study of the vascular wall. However, despite the inclusion of only six dialysis sessions in each phase of the study, significant differences were found.

As a conclusion of our study we can affirm that the use of 14G needles improves the efficacy of postdilution OL-HDF without increasing the associated adverse effects, therefore the generalized use of 14G needles in HDFOL whenever possible can be recommended.

Conflict of interest

The authors declare that they have no conflicts of interest.

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