FISTULA CATHETER: A NEW ALTERNATIVE FOR VASCULAR ACCESS PUNCTURES

Olga Martínez Ocaña, Jaime Rodríguez Estaire, Beatriz Ruiz Sanz, Juan A. Martín Navarro, Eva Mérida Herrero.
ICN San Luciano. Madrid. Fresenius Medical Care.

INTRODUCTION

Adequate vascular access (VA) is an essential requisite for optimal dialysis[1]. Internal arteriovenous fistula (IAVF) is the most chosen vascular access for hemodialysis (HD) patients. It is not the sole vascular access, as the most selected alternative is the expanded polytetrafluoroethylene graft (PTFE)[2]. Damage to IAVFs and grafts caused by the puncture of conventional needles or by the movement or flexion of the arm during dialysis, can be the main factor in VA longevity. Another factor related to solute clearance to keep in mind during HD is blood flow and to obtain an adequate blood flow it is important to take into account the needle caliber[3]. It is for all these reasons that we think that both the VA puncture and the use of an appropriate needle caliber are essential issues for HD quality. In this sense, a new type of puncturing cannula has been recently developed, the fistula catheter, a fluoroplastic catheter that can prevent the graft of FAVI internal wall from damaging in case the patient moves or flexes their arm. Moreover, it has a smaller puncture gauge, but a bigger caliber inside the VA, allowing stable flows and raising blood flow to reach the highest effectiveness in the purification of toxins. All these features open interesting perspectives due to increased tolerability, more adequate dialysis and fewer complications.

OBJECTIVES

General Objective:

To compare fistula catheter with conventional needle during dialysis session.

Specific Objectives:

To ascertain whether the fistula catheter can determine dynamic parameters, such as Venous Pressure (VP), Arterial Pressure (AP) and Transmembrane Pressure (TMP).

To ascertain if the caliber of the fistula catheter affects the real blood flow rate and the quantity dialyzed liters, as well as dialysis effectiveness.

To find a relationship between the use of the fistula catheter and the dose of heparin, the time of haemostasis and the occurrence of complications, such as post-session bleeding and extravasations.

To compare pain tolerance for punctures with fistula catheter and with conventional needle.

MATERIAL AND METHODS

Description of the Fistula catheter

The Supercath AZ fistula catheter shown in Image 1, is a highly biocompatible tri-beveled internal metal needle for puncturing Image 2, covered by a fluoroplastic sealless blunt tipped catheter with a central opening (lumen of the catheter) and side slots in the catheter tip. Image 3.

Image 1

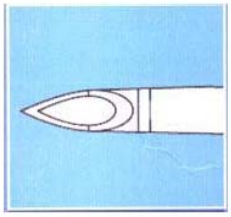


Image 2

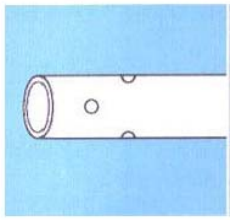


Image 3

The caliber of the internal needle is 16G and the internal gauge of the catheter is 14G. It is equipped with a non return valve, to prevent blood from dripping and a telescopic cover that avoids accidental puncturing. To follow the puncture technique, grab the fistula catheter between the connector and the non return valve to avoid the metal needle to retrocede while puncturing the vessel Image 4. Once the vein has been punctured, advance the catheter through the VA lumen while removing the metal needle.
Image 5. Fix the fistula catheter to the skin. Image 6.


Image 4


Image 5


Image 6

Method
A three month prospective trial was realized modifying the type of puncturing cannula as follows:
18 sessions with conventional 15G needle and 18 sessions with Supercath AZ 16G fistula catheter
Patients were selected among the 132 patients of our center following renal replacement treatment with conventional HD
Criteria for enrollment were the following:

1. Patient with autologous IAVF, with normalfunctioning arterial or venous access in the elbow joint and with a PTFE graft, for 3 months.
2. Stable patient without hospital admission in the last 6 months.
3. Vascular access of a minimum blood pump flow of 300 ml/min with a VP≤ 200 mm Hg and a minimum usage time of 10 months.

Criteria for exclusion were the following:

1. Patient with central catheter.
2. Patient with allergies to ethylene oxide sterilized needles.
3. Patient with vascular complications in the last three months.

Using these criteria 10 patients were enrolled in this study, 9 men and 1 woman, with an average age of 69 years (58- 88 years) All patients were following a conventional HD program, 3 days per week, with an average duration of 232, 5 min (210- 240 min), and a high permeability membrane, an average blood pump flow of 384 ml/min (350 – 400 ml/min), with FRESENIUS 4008 S monitor. As for flux bath, 8 patients had 500 ml/min and 2 patients de 800 ml/min. 1 patient had PTFE graft and 9 patients had IAVF, of which 3 radio-cephalic and 6 humero-cephalic. To evaluate this trial a data logbook was designed, to collect values as initial and final AP, VP, and PTM, blood pump flow, real blood flow, dialyzed liters, set ultrafiltration, hypotension episodes, extravasation and bleeding near the needle or the catheter; and Kt foe each session, calculated with the OCM function of a FRESENIUS 4008 S monitor. Each patients was scanned every 6 sessions to measure Kt/V (monocompartimental Daugirdas 2^{nd} generation) and to measure the recirculation rate. Pain was measured according to a subjective graded range where 0=no pain, 1=light pain, 2=moderate pain and 3=severe pain[3]. Comfort too was measured according to a subjective graded range (0-4) where the higher value meant more comfort. Basal haemostasis time was measured and recorded together with the haemostasis times of each session. Also the status of arterial and venous chambers was valued using a numerical quantitative grade where 0=coagulated chamber, 1=chamber with clot 2=clean chamber. The same occurred with the status of the dialyzer, valued with numerical grade, where 0=coagulated dialyzer, 1=very dirty dialyzer, 2=dialyzer with many capillaries, 3=dialyzer with few capillaries and 4=clean dialyzer.

Statistical analysis
Average and standard deviation were calculated for each value with the SPSS 17.0 computer program, using the paired data analysis with parametric and non-parametric test (Student's t-test and the Wilcoxon W test).

RESULTS

The general characteristics of the 10 enrolled patients are recorded in table 1.

Sex	M: 9 (90%) W:1 (10%)
Age (Average±SD)	69,3±10,36 years (58-88 years)
Time in HD (months) (Average+SD)	77,8± 92,07 (10-276 months)
Nº of sessions per week Average Time	3 232,5±12,74 min (210-240 min)
Cause of TRF	Unknown: 2 (20%) Nephrosclerosis: 2 (20%) Diabetic Nephropathy: 2 (20%) Glomerulonephritis: 3 (30%) Malignant Hypertension: 1 (10%)
Comorbidity	Hypertension: 100% Ischaemic heart disease: 30% PVD (Peripheral Vascular Disease): 30% PTH 2º: 100% Previous transplant: 30%
Dialyzer	FX 60: 8 (80%) FX 80: 2 (20%)
Flux Bath (ml/min)	500: 8 (80%) 800: 2 (20%)
Vascular Access	Prosthesis: 1 (10%) IAVF: 9 (90%): RC: 3 (30%) HC: 6(60%)
Anticoagulation	Heparin sodium: 9 (90%) Low molecular weight heparin: 1 (10%)
UF per session Needle/Catheter (1)	2.339,33 / 2.346,50 ml/session

(1) No statistically significant differences were detected for UF per session between the compared 2 groups.

Table 1: General Characteristics of the patients:

Table 2 show initial and final results (Average + SD) of dynamic parameters such as AP, VP, and TMP while comparing conventional needle and Supercath AZ fistula catheter. An interesting finding among these data is that puncture with Supercath AZ catheter caused a statistically significant decrease in AP and VP (p<0,001). Images 6 and 7 TMP value also decreased, without reaching statistical significance.

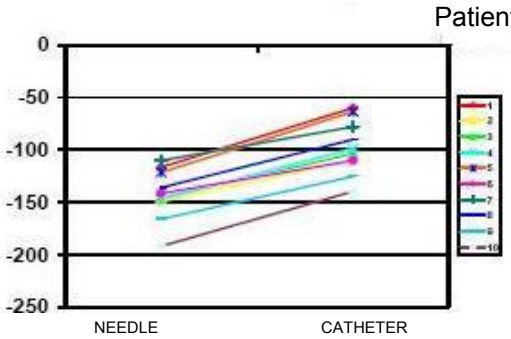


Image 6:Average Final Arterial Pressure

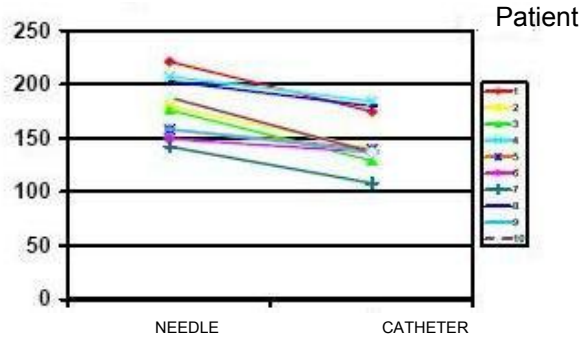


Image 7: Average Final Venous Pressure

	NEEDLE	SUPERCATH AZ	p
Initial AP	-130±25	-82±27	**<0,001**
Final AP	-142,7±24	-98±25	**<0,001**
Initial VP	176,4±25	144,5±21,5	**<0,001**
Final VP	178,2±26	146,8±24,6	**<0,001**
Initial TMP	43,3±9,2	36,64±10,1	**0,02**
Final TMP	42,6±17,3	33,9±10,73	**0,01**

Table 2. Differences in VP, AP and TMP dynamic parameters depending on the used cannula.

As for the status of the arterial and venous chambers and of the dialyzer at the end of the session, table 3, it was better with the use of Supercath AZ, even though there were no statistically significant results. Also, it is important to report that we observed a decrease in the heparin dose in patients punctured with the fistula catheter, again without statistical significance.

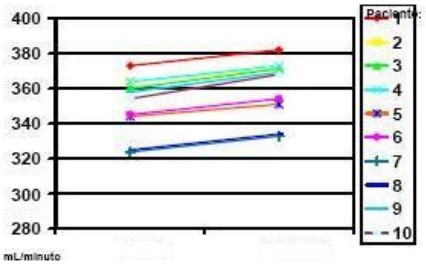
	NEEDLE	SUPERCATH AZ	p
Arterial Chamber status	1,98±0,6	2	NS
Venous Chamber status	1,9±0,18	2	0,1
Dialyzer status	3,48±0,6	3,85±0,21	NS
Dose of heparin	15,0±15,2	12,78±13,01	**0,1**

Table 3. Differences in the status of chambers and dialyzer and the heparin dose.

The second important result is the significant increase observed in real blood flow after puncturing with Supercath AZ, (p<0,01). Image 8 Likewise, using the fistula catheter, the dialyzed liters per session have increased together with the Kt value, while recirculation rate decreased, without reaching statistical significance. As for Kt/V, no change was observed. Moreover, with the Supercath AZ no collapse of blood flow was recorded, while it was observed using conventional needles. Table 4.

	NEEDLE	SUPERCATH AZ	p
Blood pump flow	384,5±21,4	384,5±21,4	NS
Real blood flow	351,1±16,5	360,6±16,87	**<0,01**
n. dialyzed liters	80,92±6,6	83,22±7,34	**0,08**
session KT	47±3,86	48,85±3,48	**0,03**
Average KT/V	1,64±0,29	1,64±0,26	NS
Recirculation	7,13±7,86	3,96±2,7	NS
Collapse (1)	7,63	0	NS

(1) occurrences for every 100 dialysis sessions.
Table 4. Comparing dialysis effectiveness.



NEEDLE CATHETER
Image 8: Real Blood Flowl

In table 5 complications related data were collected, both for conventional needles and Supercath AZ. We observed that with Supercath AZ the time of haemostasis is lower, and also the post-session bleeding. Also, it is important to report the absence of extravasation with the fistula catheter.

	NEEDLE	SUPERCATH AZ	p
Post session re-bleeding (1)	10,68	9,160	NS
Extravasations (1)	0,76	0	NS
Time of Arterial Haemostasis	4,76±1,87	4,71±1,9	NS
Time of Venous Haemostasis	4,89±2,29	4,6±1,9	NS

(1) Nr. of occurrences for every 100 dialysis sessions
Table 5. Differences between complications

As far as tolerability is concerned, conventional needles is usually performing better, even though tolerance was very good with both devices: “no pain” and “slight pain” Table 6.

	NEEDLE	SUPERCATH AZ	p
Puncture pain	0,74±0,51	0,99±0,52	**0,036**
Comfort during session	3,81±0,36	3,79±0,23	NS

Table 6. Comparing tolerability

DISCUSSION

The results of this trial show that after replacing conventional needles with Supercath AZ fistula catheters AP and VP decreased without affecting dialysis effectiveness. The puncture caliber of Supercath AZ was smaller (16G) than the conventional needle gauge (15G), but the internal caliber of the fistula catheter is bigger (14G) and this allow higher real blood flows. It has already been published in literature that a bigger gauge allows for a higher blood flow[4 5 6]. The Supercath AZ can optimize real blood flow for each patient.

Although the small patient sample makes it difficult to reach statistically significant results for some variables, it is evident that with fistula catheters there are fewer vascular complications, because a lower dose of heparin is necessary and the mechanical trauma produced while creating vascular access is also lower. The evaluation of pain for HD patients is uncertain, because there are no tools that can detect these patients' needs[7]. In our trial we observed a slight increase of pain with the fistula catheter, and the reason we found for this is the lack of experience in the handling of the Supercath AZ, as the data unquestionably show.

CONCLUSIONS

1) Dialysis with Supercath AZ shows a better hemodynamic profile than treatment with conventional needles.
2) The lower mechanical trauma in the vascular access achieved with Supercath AZ fistula catheter allows for a lower dose of heparin without interfering with dialyzer coagulation and the condition of arterial and venous chambers.
3) The Supercath AZ catheter is as effective as conventional needles for adequate dialysis, while we observed that the quantity of dialyzed liters, the episodes of flow collapse, and the value of Kt increase, without reflecting this improvement in Kt/V
4) The fistula catheter shows a decrease in vascular complications: extravasation and bleeding, and also a lower time of haemostasis if compared to conventional needles.
5) The fistula catheter is well tolerated, even though the pain sensation during puncture is slightly higher. The use of fistula catheters requires appropriate training by personnel.
6) Further trials with a higher number of enrolled patients and sessions are required, to follow the evaluation of our results.
7) The improvement observed in the dynamic parameters opens new possibilities to reach higher dialysis effectiveness, because the catheter provides higher flows and more adequate pressures in the system.
8) The ideal candidates to gain from the use of this fistula catheter are patients with vascular accesses and a high blood flow, usually with high venous pressures, and patients more likely to suffer from vascular complications or haemostasis problems and patients whose treatment could benefit from the use of higher blood flow rates.

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