Tunneled catheters for hemodialysis of the type «twin Tesio catheters system» by ultrasound-guided technique. Retrospective analysis of 210 catheters

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SUMMARY

Placement, Performance and complications of The Tesio Twin Tunnelled Catheter System for hemodialysis ***Purpose:*** *Review a large experience in the placement of tunnelled catheters to assess the outcomes with Twin catheter System as hemodialysis access.* ***Material and Methods:*** *We retrospectively reviewed clinical and hemodialysis data regarding of ESRD patients who were referred from 2 dialysis facilities for placement of tunnelled catheter as hemodialysis access between 1996 march and 2005 july. For catheter insertion it was used a real-time sonography technique (Site Rite II Dymax corporation) in performing vascular access procedure. The twin catheter system available during the study period consisted of 2x10-F12. Patients suspected to present bacteraemia related to catheter were followed with established protocols. Catheter suspected malfunction or thrombosis was treated with low dose Urokinase. To evaluated dialysis dose and adequacy, blood flow rates were recorded and Kt/v calculated by Daugirdas 2nd generation formula.* ***Results:*** *Over all study period of 112 months, 210 catheters were inserted in 148 patients (93 males and 55 females, mean age 68,6 ± 4,95 years). 101 catheters were inserted in internal jugular vein, 84 in femoral and 25 in subclavian. The successful insertion rate with only single needle pass was 87,8%, immediate procedural complications rate was 4.7%. The catheters were in place a total of 18,324 days during the study period (mean 87,2 days; range 4-1,280 days). The mean flow blood rate was 252,4 DS ± 42.4 mL/min, Mean Kt/v was 1,21 DS ± 0,07. Seventy —seven Catheters malfunctioned during study period, in 55 cases urokinase was effective in recovering blood flow rate over 250 mL/min and 25 were necessitated removal for ineffective urokinase. Infection incidence was 11.9% with bacteraemia related catheter rate of 2.8 episodes per 1,000 catheter-days, Gram positive bacteria was found in (84%), Gram negative in (12%) and others (4%).* ***Conclusion:*** *Placement of Tunnelled twin catheters system using real-time sonografy technique can be performed with excellent technical success, safety and acceptable catheter performance and outcomes for effective hemodialysis.*

Key words: ***Vascular Access. Tunnelled Catheter. Hemodialysis. Real-time sonography technique.***

CATÉTERES TUNELIZADOS PARA HEMODIÁLISIS TIPO «SISTEMA TESIO DE CATÉTERES GEMELOS» MEDIANTE TÉCNICA ECODIRIGIDA. ANÁLISIS RETROSPECTIVO DE 210 CATÉTERES

RESUMEN

Objetivo: *Revisar nuestra experiencia en la colocación del «Sistema Tesio de catéteres gemelos» tunelizados con cuff y evaluar sus resultados como acceso vascular para hemodiálisis.*

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Material y métodos: *Hemos revisado retrospectivamente nuestra base de datos clínicos de pacientes con IRC que han sido remitidos desde dos unidades de hemodiálisis para la colocación de catéter tunelizado como acceso vascular para hemodiálisis, entre marzo de 1996 y julio del 2005. Se ha utilizado la técnica ecodirigida para la localización, punción y canalización del vaso. El catéter utilizado durante todo el estudio fue el conocido sistema Tesio de catéteres gemelos de 10-F. Los pacientes con sospecha de bacteriemia relacionada con el catéter y/o disfunción del mismo siguieron protocolos establecidos. Para la disfunción y trombosis del catéter se utilizaron dosis bajas de uroquinasa. Para evaluar dosis de hemodiálisis se registraron los flujos de bomba de sangre (Qb) y el Kt/v, calculado por la formula de 2ª generación de Daugirdas.*

Resultados: *Durante un periodo de seguimiento de 112 meses se han insertado 210 catéteres en 148 pacientes (93 ♂ y 55 ♀, edad media de 68,6 ± 4,95 años), 101 catéteres en vena yugular interna, 84 en femoral y 25 en subclavia. El índice de éxito con un solo pase de aguja fue del 87,8%, la tasa de complicaciones inmediatas del procedimiento fue del 4,7%. El tiempo total de permanencia de todos los catéteres fue de 18.324 días con una media de 87,2 días y rango de (4-1.280 días), la tasa media de Qb fue 252 ± 42,4 mL/min. El Kt/v medio fue de 1,21 ± 0,07. Setenta y siete catéteres presentaron trombosis durante el periodo de seguimiento, en 55 casos la uroquinasa fue efectiva en recuperar Qb ≥ 250 mL/min. En 25 casos no fue efectiva siendo necesaria la retirada del catéter y la reinserción de otro. La incidencia de infección ha sido del 11,9% con una tasa de bacteriemia relacionada con el catéter de 2,8 por 1.000 catéteres-día, los gérmenes Gram positivos fueron responsables de la infección en el 84% de los casos, los Gram negativos en 12% y otros en el 4%.*

Conclusión: *La inserción de catéteres tunelizados del sistema Tesio de catéteres gemelos como accesos vasculares para hemodiálisis utilizando la técnica ecodirigida constituye un procedimiento con un alto grado de éxito, seguridad y eficacia. Además ofrece aceptables resultados de efectividad y desarrollo de la hemodiálisis.*

Palabras clave: ***Acceso vascular. Catéter tunelizado. Hemodiálisis. Técnica ecodirigida.***

INTRODUCTION

The number of patients suffering from chronic renal failure (CRF) requiring renal replacement therapy (RRT) has been increasing linearly in our country in recent years, the current prevalence being 1,000 patients per one million population. according to the data recently published from the registry of the Spanish Society of Nephrology[1,2,3], 89% of these patients start on RRT by hemodialysis (HD).

Internal arterial-venous fistula (iAVF), with its different modalities, currently is the best vascular access to start on hemodialysis; however, 15-50% of these patients start on HD by a central venous catheter (CVC)[4,5]. Today, both the American and European recommendations suggest drastically limiting the use of CVCs in order to prevent the increase in morbimortality of CRF patients. It is also recommended that in the case of needing a catheter as a vascular access (VA) for longer than 3-4 weeks funneled catheters should be used[6-9]. The placement of funneled catheters (fCVC) has shown to reduce the incidence of infections and dysfunction, achieving higher HD doses in terms of blood flows within the dialysis circuit pump (Qb) and higher urea clearance (Kt/v) as compared to non-funneled catheters[10-12].

The aim of the present study was to retrospectively assess survival, functioning, and complications of fCVC placed by means ultrasound-guided technique.

MATERIAL AND METHODS

All catheters of the type «twin Tesio catheters system» placed between March of 1996 and July of 2005 in patients from two hemodialysis units were assessed. The two hemodialysis units were the HD Unit of the Hospital of Mollet (the reference center) is included in the Nephrology Department of a regional hospital from Catalonia that has not available an angio-radiology department and with limited availability of vascular surgery, taking care of 200 patients on outpatient HD program and covering a population of 300,000 inhabitants, and the Nephrologic Institute of Granollers (satellite center).

Procedure of the ultrasound-guided technique

For catheter placement, the ultrasound-guided (UG) technique has been used to locate, puncturing, and further channeling the vessel. A portable ultrasound device has been used with a 7.5 Hz transducer and two-dimensional imaging *(Site Rite II-Dymax corporation)* with sterile coverage, and placed on the corresponding area of each anatomical site. This technique allows identifying the artery, which pulses, and the corresponding vein, which is distinguished from the artery by the lack of pulsing activity and the characteristic collapse when compressed with the transducer and further expansion when decompressed. The ul-

trasound-guided technique allows puncturing and channeling the vessel, and introducing the metallic guide, the remaining steps of the procedure being exactly the same as with the classical Seldinger technique. It has been shown that this procedure is successful with just a single puncture and single needle introduction achieving the vessel channeling and introduction of the guide with no difficulty. The catheter kit includes both 50-cm long silicone catheters with six lateral wholes spirally located and within 4 cm far from the tip, with two separated cuffs (fig 1). This peculiarity of having the catheter free from the cuff before its placement allows for an important maneuvering margin to carry out the appropriate measurements with a rule between the reference anatomical sites and introduce the appropriate length placing the tip at the target level within the vessel. Then the cuff is positioned at the appropriate distance within the tunnel, the exceeding section of the catheter is discarded, and finally external connections are placed. Then a plane control X-ray film is done to check for the correct placement of the catheter tip and rule out the presence of procedure-related complications. We have not used fluoroscopy to assess the placement of the catheter tip because it was not a suggested technique, as reflected in today's NKF-K/DOQI guidelines, when se started using fCVC 9 years ago. The patient was kept under supervision for the two following hours for potential complications from the procedure.

Managing the catheter

Catheter management and dressing during hemodialysis sessions was done by the nursing staff of both units following the same standardized protocol for managing fCVC. It essentially consisted in thorough arms and hands washing with antiseptic solution, followed by the use of cap and facemask, gown, gloves, and sterile operating field. Disinfection and cures of the catheter outlet and external connections were done with 1% sodium hypochlorite. During the final disconnection maneuver, the catheter is primed with 1% sodium heparin at a dose equivalent to the total priming volume corresponding to the whole length of the inserted catheter. Finally, the covering of the catheter was an occlusive sterile dressing that was removed and changed at each HD session.

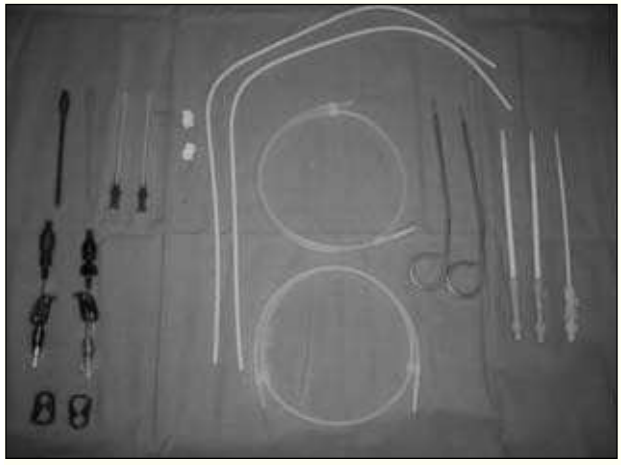

Fig. 1.—Kit of catheter.

Assessment and management of catheter infection

In all cases, when there was fever suspected to be a catheter-related bacteriemia (CRB) episode, the patient was referred to the nephrology department where several peripheral blood cultures and cultures from the catheter inner side and outlet orifices were taken. A screening protocol for other infection causes was started with careful clinical assessment, urine culture, and chest X-ray. In the case of positive CRB (positive peripheral blood cultures and inner side of the catheter, with the same microorganism and same antibiogram), the catheter was taken out within the following 12-24 hours and empirical antibiotic therapy was started with vancomycin and tobramycin, until antibiogram results were available.

Assessment and management of catheter malfunctioning

Catheter malfunctioning was defined as the impossibility of achieving a Qb ≥ 200 mL/min. Under these circumstances, the patient was referred to the nephrology department where fibrinolytic therapy with urokinase (UK) was started. It was first injected as a bolus of 1 mL of UK (5,000 U) and normal saline until completing the total priming volume of the catheter. When the procedure failed, it was considered that the cause of catheter malfunctioning was different (fibrin film, tip dislodgement, etc.) and the catheter was taken out with replacement by a new one within 24-48 hours.

Flows and Kt/v analysis

Hourly Qbs during the HD session were registered, and to analyze the Kt/v we used the urea kinetic model according to the second generation Daurgidas formula[14]. The pre-dialysis urea sample was obtained immediately before the session, thus avoiding blood dilution with normal saline or heparin, that is before connecting the arterial line. The post-dialysis urea sample was obtained following the low flow technique (50-100 mL/min) or by stopping the pump to avoid sample contamination by recirculation and minimizing the urea rebound effect.

RESULTS

During the 112-month period analyzed, 210 fCVC were inserted into 148 patients (93 men and 55 women), with a mean age of 68.6 ± 4.95 years. CRF etiology was diabetic nephropathy in 37 cases, nephroangiosclerosis in 23 cases, primary glomerulopathy in 12 cases, interstitial nephropathy in 9 cases, adult polycystic renal disease in 8 cases, systemic disease-associated glomerulopathy in 8 cases, and

Table I. Criteria for catheter placement

Reason for catheter placement	Num. of cases (%)
First vascular access	94 (44.76)
VA dysfunction	74 (35.23)
VA worm out	27 (12.85)
End-stage disease	15 (7.14)

unknown origin in 23 cases. The catheters were placed in the following vascular territories: 101 catheters in the internal jugular vein (IJV) (91 right IJV, 10 left IJV), 84 in the femoral vein (FV) (56 right FV and 28 left FV), 25 in the subclavian vein (SCV) (16 right SCV and 9 left SCV). Table I shows the criteria for catheter placement.

The success rate for vessel channeling with the first and single puncture was 87.8% and with two or more punctures was 12.8%. The rate of procedure-related immediate complications was 4.7% (10 cases). Eight of these cases had local and superficial bruising of little clinical significance. In the remaining two cases, there was hemo-pneumothorax. One of these cases was a female patient requiring for the third time placement of a funneled catheter with just one vessel suitable for channeling by ultrasound, and who had a favorable course with surgical drainage and aspiration. The other case was a female patient in whom the catheter was placed for the first time in the left internal jugular vein, with vessel perforation during the dilation and insertion procedure. She required admission into the ICU, with surgical drainage of the hemothorax with adequate clinical course later on. The imaging studies done afterwards showed the presence of a «loop» malformation of the venous vessels.

Mean time of catheter insertion has been 87.2 ± 15.5 days, the longest time being 1280 days in a patient with worn out vascular accesses that died with functioning catheter. The shortest period has been 4 days in a patient dying from acute myocardial infarction 4 days after catheter placement. The catheter functional study has shown an average Qb of 252.41 ± 42.43 mL/min., and mean Kt/v of 1.21 ± 0.07. Table II shows the efficacy of urokinase as fibrinolytic therapy for catheter permeability. Table III shows the reasons for catheter withdrawal or loss at the end of the study.

The incidence of CRB was 2.8/1.000 catheters/exposure day, gram-positive microorganisms being implicated in 21 cases (84%),and of these, Staphylococcus was involved in 17 occasions (80.9%), and gram-negative microorganisms were implicated in 3 cases (12%), and other microorganisms in 1 case (4%).

Table II. Intervention with Urokinase

Cases	% of total	num. of interventions	Result
34	44.15%	1	success
13	16.88%	2	success
5	6.49%	≥ 3	success
25	32.46%	≥ 3	Failure

Table III. Reasons for catheter withdrawal and loss to follow-up

Reason for catheter withdrawal and loss to follow-up	Num. of cases (%)
Vascular access developed and functioning	83 (39)
Exitus	46 (21.9)
Thrombosis/malfunctioning	25 (11.9)
Catheter-related bacteriemia	25 (11.9)
Accidental loss	6 (2.8)
Active catheters	25 (11.9)

DISCUSSION

Since their introduction in 1998, fCVC for hemodialysis represent an alternative as a temporary or permanent vascular access becoming more important nowadays. Although many patients start on a HD program with an iAVF or a prosthetic graft as their vascular access, which is desirable, an important number of them start their program with an fCVC. According to the *US renal data system annual report*, in 1996 18.9% of the patients started on HD with an fCVC and within 60 days, 12.9% still carried the catheter.[5,6,8] In our country, 44% of the patients do not have a permanent vascular access at the time of starting on HD, CVCs being their first vascular access, and 11% of the population on HD carry a CVC[4]. Most of the CVCs implanted in our country are percutaneous whereas 10% are fCVC. The internal jugular vein is the first option, the femoral vein accounts for the third part, and almost 10% are placed within the subclavian vein[10]. The data from the present study regarding the anatomical site distribution and the catheter modality evenly compare to those reported in those studies.

Although placement of fCVC was almost always traditionally performed by vascular surgeons and radiologists[9], some interventional nephrologists undertake this task since they represent the first and immediate reference for patients needing hemodialysis without any delay. The introduction of ultrasound as a new tool for visualizing, channeling, and correct insertion of the catheter, in short, for a safer management, has greatly facilitated this task and, in the last decade, we have witnessed the publication of large series supporting the use of ultrasound for insertion of CVC for hemodialysis[13,15,16]. In the present study, the success rate at the first try has been 87.8%, a similar or even better figure than that reported by Densy et al.[13] of 78% in a series of 302 catheters, or that by Farell et al.[15], of 83.3% in a series of 99 catheters. Docktor et al.[16] report a success rate similar to ours of 87.4% in 880 catheters. The rate of complications presented by these authors ranges from 0% to 4%[13,15,17], ours being 4.7%.

The efficacy and safety of the ultrasound-guided technique for catheters placement in a population of patients on HD exposed to repeated punctures and insertions of catheters as vascular access have been shown in recent years. Besides allowing for correct puncturing and channeling of the vessel, this technique also facilitates an appreciated

previous assessment of the integrity, viability, and anatomical positioning of the artery being considered. Besides, it detects the presence of thrombosis, stenosis, and anatomical aberrations that may suppose severe immediate complications with the classical anatomical technique. Experiences such as the one by Hernandez et al.[18], in which they detect by venography subclavian stenosis in more than 50% of the patients, suggest that these complications are rather common, beyond of what reported by Wilkin et al.[19] in a group of 143 patients on HD having carried one or more catheters and in whom it has been found a thrombosis rate of 25.9%, with 62% of the cases presenting total vessel occlusion total. Forauer et al.[20] in a retrospective study on 100 catheters implanted in 79 patients verified that the ultrasound findings (total occlusion, partial stenosis, and anatomical aberrations) were present in 28 patients (35%), in 21 of them (75%) being necessary to change the vascular approach. Dynes et al.[21] detected a thrombosis incidence of 2.5%, and a diameter < 0.5 cm of the IJV in 3%, which renders it indistinguishable to be canalized. On the other hand, the anatomical positioning of the IJV varies in a considerable number of patients. Gordon et al.[16] in a prospective study on 659 patients submitted to IJV canalization by ultrasound-guided technique found that in 77% of the cases the vein lies in a position anterior and slightly medial and lateral from the common carotid artery, this position being considered as normal, and in 22% of the cases the vein was completely lateral, and in 1% directly medial to the artery; these two later positions are anatomical deviation completely impossible to foresee with the classical anatomical technique. In the present study, in 48% of the cases the IJV has been the first choice access, and the second one has been the FV. Only in those patients in whom some abnormality of the IJV was found and canalization of the FV was not possible, we chose to use the SCV as our third and last option.

Similar to other studies, we have obtained an average catheter survival for all patients of 87.2 days, which is in agreement with health care protocols of our Unit of inserting an fCVC in all patients with a predicted time of achieving a stable vascular access longer than 2 months. In 80% of the patients, this has been the criterion for insertion of the catheter, and the remaining 20% were patients with worn out venous network or with short expected survival without HD, thus the fCVC has been their last and definitive vascular access for HD. Wivell et al.[22], using the same fCVC system (twin Tesio catheters system) in a series of 184 catheters, obtained an average survival of 74.6 days, and Zaleski et al.[23] of 85 days.

In order to prolong catheter survival and as a recovering procedure of the catheter functionality for an adequate HD, we have used UK as fibrinolytic therapy. In more than 66% of the times we were able to recover the functionality of the catheter, and 20% of these have required 2 or more administrations of UK to achieve this goal. This success rate favorably compares to that by Seddon et al.[12] of 71% and of 74% by Suhocki et al.[24]. These two latter studies used low UK doses, similar to those used in the present study, achieving to reestablish adequate Qb. Therefore, low-dose UK constitutes a quick, effective, and safe way for thrombolysis and reestablishments of adequate Qb.

The use of funneled central catheters as vascular accesses for hemodialysis has gained important reputation in recent years and has been accepted since they show better functionality and durability, and lower rate of infections as compared to non-funneled catheters, a fact that is supported by the dialysis doses expressed in terms of Qb and/or Kt/v, and infection rates in terms of catheter-related bacteriemia (CRB). In the present study we have obtained a mean Qb of 252.4 mL/min and mean Kt/v of 1.21. Table IV summarizes the figures for functionality parameter from other published series[22-29].

Accidental loss of the catheter occurred in 2.8% of the cases, and although we have not enough data to carry out a complete analysis of this complication, it is surprising that all were femoral catheters, so that we believe that anatomic and functional factors of this particular location, defects in cuff positioning (to close to the outlet), and likely manipulation by the patient all might have contributed to accidental loss of the catheter.

CRB constitutes, together with thrombosis and catheter dysfunction, the more relevant and common delayed complications of central catheters. One of the essential contributions of fCVC, as alternative and long-lived vascular accesses, is precisely their lower rate of infections, particularly due to their system including cuff insertion, which acts as a barrier for microorganism migration from the outside to the venous lumen, with a mean incidence of CRB with non-funneled catheters of 3.8-6.5 per 1000 catheters-day, and with funneled catheters of 1.6-5.5 per 1000 catheters-day[27-29]. In the present study, the incidence of CRB has been 2.8 per 1000 catheters-exposure day, an acceptable rate within the range reported by most authors. Thus, in the series by Wivel et al.[22] on 184 catheters, they report 2.3 episodes/1000 catheters-day, Zaleski et al.[23] on 41 catheters report 2.4 episodes/1000 catheters-day, Rocklin et al.[30] on 182 catheters report 5.8 episodes/100 catheters-day, and Perini et al.[27] on 79 catheters report 1.4 episodes/1000 catheters-day. The more frequent microorganisms in our series have been gram-positives (84%), Staphylococcus being responsible of bacteriemia in about 81% of the cases; these data are in agreement with other studies[31-33].

We may highlight that the mortality rate of 21.9% for this group of patients is an annual cumulative percentage rate for the 9-year period of the study; therefore, it may not be

Table IV. Dialysis dose

Author	Num. of catheters	Num. of patients	Qb (ml × min)	Kt/v
Wivell[22]	184	132	281,4	NC
Zaleski[23]	41	21	272	NC
Da Vanzo[25]	NC	38	369-404,8	1.5-1.6
Hernández-Jaras[26]	42	40	278.3 ± 34.1	1.48 ± 0.27
Perini[27]	79	71	301	≥ 1.2
Gallieni[28]	28	28	303 ± 20	1.51 ± 0.3
Di Dorio[29]	NC	NC	273 ± 39	1.32 ± 0.15
Present study	210	148	252.4 ± 42.4	1.21 ± 0.07

compared to the annual mortality rate of 13-13.8% of all patients on hemodialysis in our country[2].

CONCLUSION

Funneled catheters represent a valid alternative as vascular access in those patients requiring starting on hemodialysis and not having an arterial-venous fistula or a prosthetic access, especially in those patients in whom it is not presumed they will have a stable vascular access within 2 months and in those considered not suitable for an iAVF or a prosthesis for any reason or criterion. On the other hand, the use of the ultrasound-guided technique brings agility, safety, and efficacy for vein puncturing and insertion of the catheter, significantly reducing procedure-related immediate complications. Finally, the use of a «twin catheters system» with sufficient length, diameter and separated cuffs allows for a sufficient maneuver margin to adapt the positioning of the tip of the catheter and the cuff to each patient's anatomical and morphological characteristics, contributing notably to improve the catheter functionality and survival.

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