REFERENCES

1. Piccoli GB, Minelli F, Versino E, Cabiddu G, Attini R, Vigotti FN, et al. Pregnancy in dialysis patients in the new millennium: a systematic review and meta-regression analysis correlating dialysis schedules and pregnancy outcomes. Nephrol Dial Transplant. 2016;31:1915–34, http://dx.doi.org/10.1093/ndt/gfv395.
2. Holley JL, Reddy SS. Pregnancy in dialysis patients: a review of outcomes complications, and management. Semin Dial. 2003;16:384–8, http://dx.doi.org/10.1046/j.1525-139X.2003.16085.x.
3. Manisco G, Potì M, Maggiulli G, Di Tullio M, Losappio V, Vernaglione L. Pregnancy in end-stage renal disease patients on dialysis: how to achieve a successful delivery. Clin Kidney J. 2015;8:293–9, http://dx.doi.org/10.1093/ckj/sfv016.
4. Yang LY, Thia EWH, Tan LK. Obstetric outcomes in women with end-stage renal disease on chronic dialysis: a review. Obstet Med. 2010;3:48–53, http://dx.doi.org/10.1258/om.2010.100001.
5. Giatras I, Levy DP, Malone FD, Carlson JA, Jungers P. Pregnancy during dialysis: case report and management guidelines. Nephrol Dial Transplant. 1998;13:3266–72, http://dx.doi.org/10.1093/ndt/13.12.3266.
6. Hou SH. Pregnancy in women on haemodialysis and peritoneal dialysis. Baillieres Clin Obstet Gynaecol. 1994;8:481–500, http://dx.doi.org/10.1016/S0950-3552(05)80332-3.

João Carvão [a,*], Ana Calhau [b], Luís Resende [a], Carlota Vida [a], Francisca Silva [a], Pedro Vieira [a], Gil Silva [a]

[a] *Nephrology Department, Hospital Central do Funchal, Funchal, Portugal*
[b] *Obstetrics and Gynaecology Department, Hospital Central do Funchal, Funchal, Portugal*

[*] *Corresponding author.*
E-mail address: jnjcarvao@campus.ul.pt (J. Carvão).

https://doi.org/10.1016/j.nefroe.2022.01.012

Is the VasQ™ device useful in the maturation of native arteriovenous fistulas? A single-center experience

¿Es útil el dispositivo VasQ™ en la maduración de las fístulas arteriovenosas nativas? Experiencia de nuestro centro

Dear Editor,

Native arteriovenous fistulas (nAVF) are the vascular access of choice in patients with stage 5 chronic kidney disease on dialysis (CKD 5D). However, some studies report maturation failure rates ranging from 20% to 50%.[1] According to the latest data from the Registre de Malalts Renals de Catalunya (RMRC) [Catalan Registry of Renal Patients],[2] the rate of use of nAVF has reduced (55.8%) and only 36.1% of incidents in 2020 involved this type of vascular access.

From a pathophysiological point of view, low shear stress has been associated with increased stress in the walls of the efferent vein, turbulent flow and the generation of accelerated venous neointimal hyperplasia as the main cause of juxta-anastomotic stenosis. These mechanisms are related to the release of a host of inflammatory factors that induce platelet aggregation, migration of myofibroblasts from the media to the intima layer and, ultimately, thrombosis and loss of vascular access.[3]

The VasQ™ external device (Laminate Ltd., Tel Aviv, Israel) was developed with these problems in mind. It consists of two parts, a neck and arm, made of nitinol, and is implanted by the vascular surgeon at the surgical anastomosis and outside the first portion of the efferent vein (Fig. 1). This device enables the angle at the surgical anastomosis to be increased to 40–50°, resulting in a more uniform or laminar vascular flow and less stress at the juxta-anastomotic area of the vein (conical arrangement), as well as having a possible protective effect

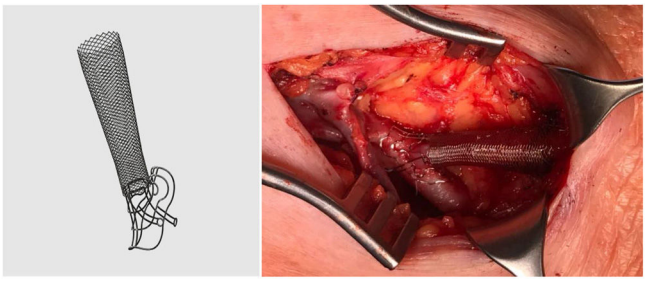

Figure 1 – VasQ™ external device (Laminate Ltd., Tel Aviv, Israel).

DOI of original article:
https://doi.org/10.1016/j.nefro.2023.01.011.

Table 1 – Changing ultrasound parameters after VasQ™ device (Laminate Ltd., Tel Aviv, Israel) implantation.

	US 1 m	US 3 m	US 6 m	*p*
Humeral artery[a] (cm)	0.57 ± 0.11	0.60 ± 0.08	0.61 ± 0.09	0.580
Vein[a] (cm)	0.61 ± 0.19	0.77 ± 0.18	0.99 ± 0.31*	0.013*
RI	0.52 ± 0.08	0.50 ± 0.08	0.50 ± 0.05	0.701
Qa (ml/min)	1306 ± 475	1595 ± 494	1288 ± 439	0.363

RI: estimated resistance index in the humeral artery; Qa: estimated vascular flow in the humeral artery.

[a] Transverse diameter (cm) in humeral artery and efferent vein.

* $p < 0.05$ efferent vein diameter 6 m follow-up versus 1 m.

in terms of cardiac haemodynamic factors (cardiac output).[4,5] *Theoretically,* this new device should reduce the development of stenosis in the first portion of the vein, improving patency rates in nAVF.

In the medical literature, there are few studies and all with small sample sizes.[6–8] To our knowledge, we are the first national centre in Spain to use this new vascular device and evaluate its results.

Our main objective was to evaluate our experience of implanting the VasQ™ device in the maturation of nAVF in a subgroup of patients (2018–2019). Sociodemographic, ultrasound and revascularisation procedure data were analysed. For the statistical analysis, descriptive techniques were used: Chi[2] test for proportions and *t*-test for continuous variables. Kaplan-Meier survival curves were used to calculate primary patency (PP) and secondary patency (SP), and Cox regression analysis for subgroup comparison, using the SPSS® v. 21 statistical package. Significance was considered if $p \leq 0.05$. For the study of clinical and ultrasound maturation, the standards of the current Spanish vascular access guidelines were used.[9]

A total of 21 patients with 5D CKD were included (six female and 15 male), with a mean age of 69.8 ± 13.2 years (26–85 years), nine with radiocephalic and 12 with humerocephalic nAVF over which the VasQ™ device was implanted. Adequate clinical and ultrasound maturation rates were achieved in 95.2% of patients. There were no surgical complications of note or significant differences in the location of the nAVF (distal vs proximal). Preoperative mapping showed a mean feeding artery of 0.31 ± 0.16 cm and vein of 0.31 ± 0.15 cm. Table 1 shows the different ultrasound parameters during the first six months of the follow-up period. As can be seen, there was a significant increase in the diameter of the efferent vein between months one and six (0.61 ± 0.19 vs 0.99 ± 0.31 cm; $p = 0.002$). The PP rates obtained at 1, 3, 6 and 12 months were 95.2%, 90.5%, 71.4% and 52.4%, respectively, and the SP rates at the same times points were 95.2%, 90.5%, 85.7% and 83%, respectively. A total of 20 balloon-catheter percutaneous transluminal angioplasties (PTA) were performed during the follow-up period, although 14 of these procedures were carried out on just three of the patients. We found no significant differences in patency when comparing these results with a similar small retrospective cohort with isometric exercises (30 patients). The six-month PP and SP rates reported by other VasQ™ device studies were similar to those obtained by our group (PP 79–87.5% and SP 79–100%).[6–8] The main limitation of these investigations lies in the inclusion of few patients (<35), as well as the lack of randomisation with a control group based on conventional surgery, which makes interpretation of the results difficult.

Based on our preliminary data, we conclude that the VasQ™ device is useful and safe, providing adequate maturation and good patency rates in nAVF. However, we are designing a prospective, randomised study in patients with radiocephalic (distal) nAVF in order to assess whether or not this new device represents a cost-effective advance in the field of vascular access.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.nefroe.2024.02.010.

REFERENCES

1. Ferring M, Henderson J, Wilmink T. Accuracy of early postoperative clinical and ultrasound examination of arteriovenous fistulae to predict dialysis use. J Vasc Access. 2014;15:291–7.
2. Registre de Malalts Renals de Catalunya. Informe estadístic 2020. OCATT. Generalitat de Catalunya. Departament de Salut. [Accessed 18 January 2023]. Available from: https://trasplantaments.gencat.cat/web/.content/minisite/trasplantament/registres_activitat/registre_de_malalts_renals/arxius/Informe-RMRC-2020.pdf.
3. Brahmbhatt A, Remuzzi A, Franzoni M, Misra S. The molecular mechanism of hemodialysis. Kidney Int. 2016;89:303–16.
4. Bozzeto M, Soliveri L, Polomi S, Brambilla P, Curtò D, Condemi G, et al. Arteriovenous fistula creation with VasQ™ device: A feasibility study to reveal hemodynamic implications. J Vasc Access. 2022 (Online ahead of print).
5. Palumbo R, Dominijanni S, Centi A, D'Urso G, Tatangelo P, Floccari F, et al. Hemodynamic impact of VASQ device in vascular access creation. J Vas Access. 2022;23:105–8.
6. Chemla E, Velazquez C, DÁbate F, Ramachandran V, Marytham G. Arteriovenous fistula construction with the VasQ™ external support device: a pilot study. J Vasc Access. 2016;17:243–8.
7. Leonardi G, Campagna M, Pellicanò V, Guarena C, Bergamo D, Lavacca A, et al. Implanted blood vessel external support device (VasQ™) for creation of hemodialysis arteriovenous fistula: A single-center experience. J Vasc Access. 2021;22:658–65.
8. Shahverdyan R, Meyer T, Matoussevitch V. Patency and functionality of radiocephalic arteriovenous fistulas with an external support device (VasQ™): Real-world single-center experience. J Vasc Access. 2021;22:166–72.
9. Ibeas J, Roca-Tey R, Vallespín J, Moreno T, Moñux G, Martí-Monros A. Spanish clinical guidelines on vascular access for hemodialysis. Nefrologia. 2017;37 Suppl 1:1–191.

Néstor Fontseré[a,*], Gaspar Mestres[b], Xavier Yugueros[b], Valentín Lozano[a], Lida María Rodas[a], Marta Burrel[c], Francisco Maduell[a]

[a] *Servicio de Nefrología, Unidad Funcional de Acceso Vascular, Hospital Clínico de Barcelona, Barcelona, Spain*
[b] *Servicio de Cirugía Vascular, Unidad Funcional de Acceso Vascular, Hospital Clínico de Barcelona, Barcelona, Spain*
[c] *Radiología Vascular Intervencionista, Unidad Funcional de Acceso Vascular, Hospital Clínico de Barcelona, Barcelona, Spain*

* *Corresponding author.*
E-mail address: fontsere@clinic.cat (N. Fontseré).

https://doi.org/10.1016/j.nefroe.2024.02.010

Experience with PCSK9 inhibitors from a Nephrology unit

Experiencia con inhibidores pcsk9 desde una consulta de nefrología

Dear Editor,

There is clear evidence about the role of low-density lipoproteins (LDL) in the process of atherosclerosis. Chronic kidney disease (CKD) entails high/very high cardiovascular risk (CVR) associated with multiple classic and non-classic CVR factors related to CKD. Despite the evidence for the benefit of lowering LDL cholesterol (LDL-C), the percentage of the population achieving guideline-recommended goals, including in CKD, remains low.[1] In recent years, proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) have been shown to reduce the risk of cardiovascular disease (CVD) when added to statin therapy by potently lowering LDL-C levels.[2]

The aim of this retrospective observational study was to evaluate the profile of patients who started treatment with PCSK9i (alirocumab or evolocumab), added to their usual lipid-lowering treatment, when they did not meet the recommended LDL-C goal according to their CVR, from a Nephrology unit, and the lab test changes achieved with this treatment.[3] The LDL-C goal in high CVR was <70 mg/dl and in very high CVR < 55 mg/dl. The Hospital Dr. Peset ethics committee approved the study.

We define high-intensity lipid-lowering therapy (HILLT)[4] as high-intensity statins alone (atorvastatin 40–80 mg, rosuvastatin 20 mg) or medium-intensity statins (atorvastatin 10–20 mg, rosuvastatin 5–10 mg, pitavastatin 2–4 mg) combined with ezetimibe. We define atherogenic dyslipidaemia (DL) as triglycerides (TG) >150 mg/dl, together with HDL cholesterol (HDL-C) <40 mg/dl in men or <45 mg/dl in women.

In total, 43 patients were analysed, with a median follow-up of 12 (7–19) months: mean age 65 ± 12 years, 58.1% of the series were male. 65.1% had CKD and there were five kidney transplant patients (11.6%). 79.1% had a history of CVD. There were 13 statin-intolerant patients (30.2%); 69.8% were on statins and 34.9% on ezetimibe (32.6% of the series on statin-ezetimibe combination); 58.1% of the series were taking HILLT. The baseline clinical characteristics of these patients are shown in Table 1. In 79.1% of cases the first PCSK9i prescribed was evolocumab. Only three patients (7.1%) had to discontinue the drug due to intolerance.

Table 2 shows the lab test results before and after starting PCSK9i. The LDL-C before starting PCSK9i was 120 mg/dl (102–154). Treatment with PCSK9i led to significant reductions in total cholesterol (TC), LDL-C and TG, with LDL-C being reduced by 61%. This allowed 59% of the patients to achieve their recommended LDL-C goal. A significant difference in LDL-C reduction achieved with PCSK9i was seen between patients that were previously with or without statins, with a greater reduction in those on statins (66% vs 48%). No signifi-

Table 1 – Baseline characteristics of the series.

	n (%)
CKD (GFR < 60 ml/min/1.73 m^2)	28 (65.1)
GFR <30 ml/min/1.73 m^2	10 (23.3)
Albuminuria (uACR >30 mg/g creatinine)	26 (60.5)
HT	40 (93)
DM	9 (20.9)
Pre-diabetes/abnormal basal glucose	18 (41.9)
Atherogenic DL	8 (18.6)
CVD	34 (79.1)
Peripheral arterial disease	18 (41.9)
Coronary heart disease	15 (34.9)
Stroke	11 (25.6)
Heart failure	8 (18.6)
Asymptomatic plaques	2 (4.7)

CKD: chronic kidney disease; CVD: cardiovascular disease; DL: dyslipidaemia; DM: diabetes mellitus; GFR: glomerular filtration rate; HT: hypertension; uACR: urine albumin-creatinine ratio.

DOI of original article:
https://doi.org/10.1016/j.nefro.2022.04.006.