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# Is There Gender Disparity in Vascular Access for Hemodialysis with New Percutaneous Systems? A Systematic Review

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**Abstract:** Background: Historically, a large gender-related disparity in vascular access (VA) has been demonstrated, with there being a lower prevalence of women with arteriovenous fistula (AVF) compared to men, and women have worse maturity rates. The cause of this difference is not entirely clear, although several reasons that could contribute to it have been hypothesized. The emergence of new percutaneous FAV (pFAV) systems could be an alternative for reducing these differences. Objective: This study aims to determine whether there is a gender difference in the creation of AVFs using new percutaneous systems. Material and Methods: A systematic review of the literature was conducted by searching PubMed and Google Scholar using the following terms: "percutaneous arteriovenous fistula", "endovascular arteriovenous fistula", and "hemodialysis". All clinical trials, comparative studies, and descriptive studies involving patients who underwent a pAVF were included. Results: Finally, the review includes 19 studies, comprising 14 retrospective studies and 5 prospective studies. Of these, six studies are comparative, five of which compare pAVFs with surgically created AVFs (sAVFs), and one compares pAVFs performed using different systems with each other. A total of 1269 patients were included in the review. Of the total number of patients, only 414 were women, representing 32.62% of patients. Conclusions: The number of women included in the various studies analyzing pAVF remains very low, representing less than one-third of all patients. Although the causes of this difference are not entirely clear, several reasons have been hypothesized, such as socioeconomic factors, anatomical factors, or even patients' preferences. Given these results, further studies are needed to try to clarify the reasons for this gender disparity and to establish different strategies to mitigate the barriers faced by women in accessing AVFs.

**Keywords:** percutaneous arteriovenous fistula; endovascular arteriovenous fistula; hemodialysis; Ellipsys; WavelinQ; EverlinQ



**Citation:** Vergara-Pérez, H.; Pérez Alba, A.; Baliño, P.; Rius Peris, A.; Reque, J. Is There Gender Disparity in Vascular Access for Hemodialysis with New Percutaneous Systems? A Systematic Review. *Kidney Dial.* **2024**, *4*, 163–171. https://doi.org/10.3390/kidneydial4030014

Academic Editor: Francesco Locatelli

Received: 21 July 2024
Revised: 6 September 2024
Accepted: 18 September 2024
Published: 23 September 2024



## 1. Introduction

According to the United States Renal Data System (USRDS) and the European Renal Association (ERA) registry, in 2021, 135,972 people in the United States and 76,240 in Europe started renal replacement therapy (RRT) [1,2]. Of these, 84.2% and 83% began their treatment with hemodialysis (HD). According to the 2023 Spanish Registry of Renal Patients (REER), in Spain, 7119 patients started RRT, of whom 78.4% started on HD [3]. Vascular access (VA), through which HD sessions are performed, is crucial for these patients. It affects both the quality of treatment and associated morbidity and mortality [4,5]. Following the recommendations of clinical guidelines, native AVFs remain the first option to consider to ensure VA when a patient needs to start HD, ahead of central venous catheters (CVCs) and prosthetic AVFs [6,7]. This is due to their lower complication rate, lower associated morbidity and mortality, and higher long-term patency rate [8–12]. Despite these recommendations, the number of incident and prevalent patients with CVCs for VA remains very high. According to the USRDS, in 2021, 85.4% of patients initiated HD through a CVC, while this percentage was reduced to 23% in prevalent patients [2].

Similarly, the latest data from the DOPPS 5 study show that 29% of patients use a CVC [13]. This issue is even more pronounced in certain minority groups, such as women, the elderly, or vulnerable populations. Thus, there is abundant evidence showing that women are less likely to receive an AVF than men and that they also have a higher probability of AV maturation failure [14–16]. However, there is limited evidence explaining the reason for this disparity, making it difficult to study different methods to address it.

In 2018, the United States Food and Drug Administration (FDA) approved two new endovascular systems for creating native AVFs using minimally invasive techniques [17,18]. These systems are the WavelinQ®™ EndoAVF System (Becton, Dickinson, and Company, Borough, NJ, USA) and the Ellipsys®™ EndoAVF System (Avenu Medical, San Juan Capistrano, CA, USA).

The WavelinQ®™ EndoAVF System, used to perform a pAVF, consists of two 4-French magnetic catheters. The venous catheter contains a radiofrequency (RF) electrode, connected via an electrocautery pencil to an electrocautery unit that delivers RF energy. Conversely, the arterial catheter contains a ceramic stop that receives the electrode once both catheters are attracted. Both catheters have rotational indicators to ensure they are in the correct position The arterial catheter is introduced through the artery (US approval was given for the brachial artery only; brachial, radial, or ulnar artery insertion has been approved in Europe), and a venous catheter (with an electrode) is placed through the brachial, radial, or ulnar vein. Fluoroscopic guidance with contrast imaging is used to position and align the catheters. At the same time, magnets hold the artery and vein together as a radiofrequency electrode incises a channel between proximal forearm vessels, resulting in AVF flow. Coil embolization of the brachial vein increases superficial pAVF flow through the DCV and completes the procedure [19].

The Ellipsys device is inserted over a single superficial venous guidewire, advanced through the deep communicating vein, and introduced through the vein wall into the proximal radial artery. The entire procedure is performed with duplex ultrasonographic guidance; no fluoroscopy or contrast is used. The device is advanced over the wire, capturing both arterial and venous walls, and when closed and activated, it generates a secure anastomosis through thermal resistance and pressure. A balloon dilation of the anastomosis completes the procedure, removing spasms and establishing outflow through the deep communicating vein to the superficial venous system [20].

Multiple publications have demonstrated the benefits of using these minimally invasive systems, which could increase the number of both incident and prevalent women with an AVF to ensure VA by providing a solution to some problems, such as cases with a smaller vessel caliber or lower maturation rate [19–23].

The main objective of this study is to analyze whether there is a gender disparity in access to the performance of an AVF using these minimally invasive systems to determine whether AVFs are alternatives to classic surgical methods and could contribute to reducing these differences.

## 2. Materials and Methods

### *2.1. Research Question*

At the beginning of the study, the following research question was formulated, and addressing this question is the main objective of this review: Is there a sex disparity in VA for hemodialysis with the new percutaneous systems?

### *2.2. Search Strategy*

To answer the above question, information was searched in two databases (PUBMED and GOOGLE SCHOLAR) using the following key terms: “percutaneous arteriovenous fistula”, “endovascular arteriovenous fistula”, and “hemodialysis”. The date when the last search was conducted in both databases was in April 2024. Additionally, a manual review of the bibliographic references of the selected articles was conducted to find any articles that could potentially be included in the review.

### *2.3. Selection Criteria and Information Analysis*

For this review, randomized clinical trials, comparative studies, and observational studies, both retrospective and prospective, were considered for inclusion if they involved patients who underwent pAVF creation. There were no limitations regarding the year of publication or language. Articles that did not differentiate gender in the results were excluded.

The present work follows the PRISMA guidelines for conducting and reporting systematic reviews and meta-analyses. These guidelines were followed during all steps of our process, from the literature search to data synthesis [24].

The PROSPERO platform has registered this systematic review with the ID CRD42024586593.

A flow diagram regarding the selection of articles is shown in Figure 1.

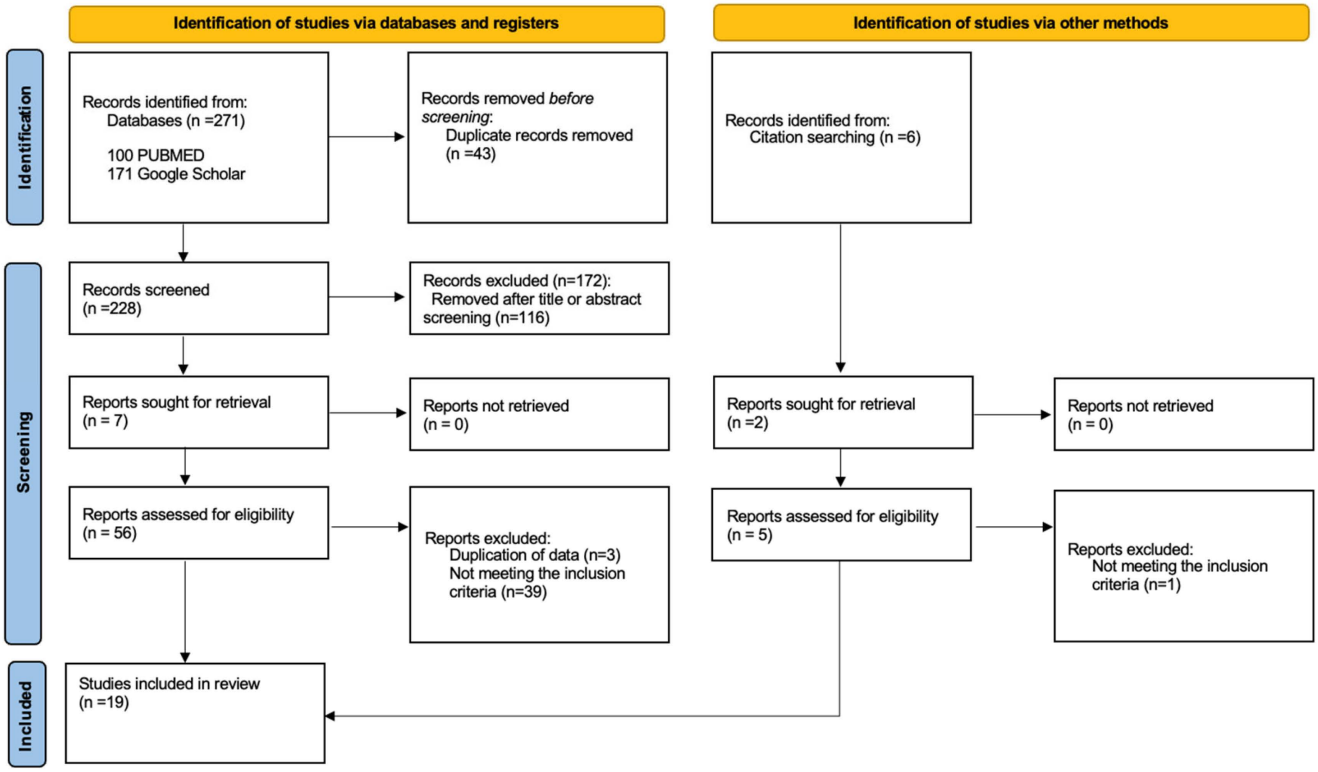


**Figure 1.** Flow diagram for study selection [25]. This PRISMA-recommended flow diagram has been used for systematic reviews that included searches in databases, registers, and other sources.

For the present work, the full text of the selected articles was read based on their publication date, starting from the oldest to the most recent. After completing the full-text reading stage, a table was created, including the main characteristics of the finally selected articles; information related to the authors, the year of publication, participant sex, participant age, and the type of study; and the systems used to perform pAVFs (Table 1). For articles comparing percutaneously or surgically created AVFs, only the data of patients with pAVFs were collected.

**Table 1.** Summary of studies included in the present systematic literature review. From each of the studies, data were extracted on the type of study, the mean age of the participants, the device(s) used for the creation of pAVFs, and the gender of the participants, both in absolute value and percentage.

| Author/Year | Study Type | Number of Participants | Mean Age | Sex, N (%) | Device |
|---|---|---|---|---|---|
| Beathard et al., 2020 [26] | Retrospective cohort study | 105 | 56.2 | Male: 77 (73.3) Female: 28 (26.3) | Ellipsys Vascular Access System |
| Berland et al., 2022 [27] | Retrospective cohort study | 120 | 55.6 ± 15.9 | Male: 97 (80.8) Female: 23 (19.2) | WavelinQ EndoAVF System |
| Harika et al., [28] | Retrospective comparative study | 107 | 63.6 ± 15.41 | Male: 66 (61.7) Female: 41 (38.3) | Ellipsys Vascular Access System/Surgical AVF |
| Habib et al., 2023 [29] | Retrospective comparative study | 51 | 58 ± 13.5 | Male 40 (78) Female: 11 (22) | Ellipsys Vascular Access System/WavelinQ EndoAVF System/Surgical AVF |
| Hebibi et al., 2019 [30] | Retrospective cohort study | 34 | 62 | Male: 20 (58) Female: 34 (42) | Ellipsys Vascular Access System |
| Hull et al., 2017 [31] | Prospective cohort study | 26 | 45.5 ± 13.6 | Male: 10 (38.46) Female: 16 (61.54) | Ellipsys Vascular Access System |
| Hull et al., 2018 [18] | Prospective cohort study | 107 | 56.7 ± 12 | Male: 78 (72.9) Female: 29 (27.1) | Ellipsys Vascular Access System |
| Inston et al., 2019 [23] | Prospective comparative study | 30 | 57 ± 15 | Male: 25 (75) Female: 5 (30) | WavelinQ EndoAVF System/Surgical AVF |
| Kitrou et al., 2022 [19] | Retrospective cohort study | 30 | 55.3 ± 13.6 | Male: 30 (100) Female: 0 (0). | WavelinQ EndoAVF System |
| Lok et al., 2017 [17] | Prospective cohort study | 60 | 59 ± 13.6 | Male: 39 (65) Female: 21 (35) | EverlinQ EndoAVF System |
| Mallios et al., 2020 [32] | Retrospective cohort study | 234 | 64 | Male: 148 (63.24) Female: 86 (36.76) | Ellipsys Vascular Access System |
| Mordhorst et al., 2022 [33] | Retrospective comparative study | 61 | 64 | Male: 46 (75.4) Female: 15 (24.6) | EverlinQ EndoAVF/Surgical AVF |
| Osofsky et al., 2021 [34] | Retrospective comparative study | 24 | 56.7 ± 22.6 | Male: 12 (50) Female: 12 (50) | Ellipsys Vascular Access System/Surgical AVF |
| Radosa et al., 2017 [35] | Retrospective cohort study | 8 | 57 | Male: 6 (75) Female: 2 (25) | EverlinQ EndoAVF System |
| Rajan et al., 2015 [36] | Prospective cohort study | 33 | 51 ± 11.4 | Male: 20 (61) Female: 13 (39) | EverlinQ EndoAVF System |
| Shahverdyan et al., 2020 [20] | Retrospective comparative study | 100 | 64.18 ± 14.18 | Male: 69 (69) Female: 31 (31) | Ellipsys Vascular Acces System/WavelinQ EndoAVF System |
| Shahverdyan et al., 2021 [37] | Restrospective comparative study | 89 | 67.9 | Male: 58 (65.2) Female: 31 (34.8) | Ellipsys Vascular Access System/Surgical AVF |
| Sultan et al., [38] | Retrospective cohort study | 18 | 63.8 | Male: 10 (55.6) Female: 8 (44.4) | EverlinQ EndoAVF System |
| Zemela et al., 2021 [21] | Retrospective cohort study | 32 | 60.2 | Male: 23 (71.9) Female: 8 (28.1) | WavelinQ EndoAVF System |

## 3. Results

Finally, the review included 19 studies, 14 retrospective and 5 prospective. Of these, six studies are comparative. Five studies compare pAVFs with sAVFs, and one compares pAVFs performed using different systems. Five studies include data from pAVFs performed using the EverlinQ System (TVA Medical Inc., Austin, TX, USA), ten include data from pAVFs performed using the Ellipsys system (Avenu Medical, San Juan Capistrano, CA, USA) and six include data from pAVFs performed using the WavelinQ system (TVA Medical Inc., Austin, TX, USA).

A total of 1269 patients were included in the review. Of these, only 414 were women, representing 32.62% of the number of total patients (Figure 2).

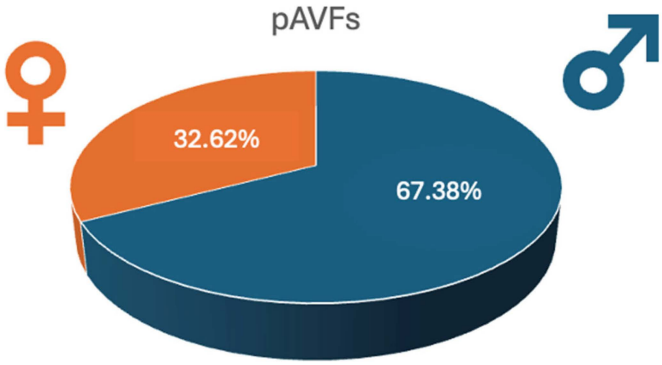


**Figure 2.** Percentage of women with pAVFs included in the review. Of the 1269 patients included in the 19 studies reviewed, only 414 were women, representing 32.62% of the total patients included.

None of the studies included differences by sex in the results regarding maturation, patency, or complication rate.

## 4. Discussion

The main finding of our study is that despite the overwhelming evidence supporting the use of AVFs as the preferred way of ensuring vascular access in hemodialysis patients due to its association with lower complication rates, reduced costs, and decreased mortality rates [6,7], only a third of the patients selected for this endovascular technique are women, revealing a gender disparity. Numerous other studies have corroborated the existence of this gender disparity in VA, consistently demonstrating a lower prevalence of AVFs in women compared to men [16,39–45]. The underlying cause of this disparity is not entirely clear, although several hypotheses have been proposed to explain it.

One possible explanation for this gender difference could be related to vessel diameter, as vein size is a critical predictor of AVF maturation failure [46]. Some authors have hypothesized that the lower maturation rates observed in women might be due to the smaller diameter of both veins and arteries [14,47–49]. These findings could contribute to a clinical bias, leading nephrologists and surgeons to consider women as less suitable candidates for AVF creation due to their anatomical characteristics and perceived higher likelihood of maturation failure. However, evidence suggests that these differences in vessel diameter may not be as clinically significant as previously thought, with variations in maturation rates being attributable to other factors [40,42,43,50,51]. This hypothesis regarding smaller vessel sizes in women might contribute to the significant gender disparity observed in percutaneous arteriovenous fistula (pAVF) studies, given that both currently available systems, Ellipsys and WavelinQ, require a vein and artery diameter greater than 2 mm for catheter insertion.

Similarly, obesity has been shown to have a detrimental impact on AVF outcomes, with lower maturation rates and a higher number of reinterventions being reported in obese patients. This may be due to a variety of factors, including lower intraoperative blood flow, higher leptin levels, and elevated inflammatory markers related to myointimal hyperplasia [52–54]. It has been hypothesized that these factors could be related to the lower maturation rate of AVFs in women, as women tend to have a greater accumulation of fatty tissue in the arms compared to men [55]. Nevertheless, pAVFs could offer a viable alternative for this population, as these minimally invasive systems reduce inflammatory markers and myointimal hyperplasia. Additionally, because pAVFs are performed in the deep venous system and increase the number of potential puncture sites, they could minimize cannulation problems associated with the greater depth of veins in obese individuals.

Beyond anatomical and physiological factors, psychological and social determinants could also play a role in the observed gender disparity in AVF utilization. Patient preferences, for instance, may contribute to the lower rates of AVF creation in women. Data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) indicated that 58% of

women preferred a fistula compared to 69% of men [13]. While the primary reason for this preference included avoiding needles and reducing bleeding, it has been hypothesized that aesthetic concerns could also influence women's decisions [16]. Given that pAVFs are minimally invasive and do not involve surgery, sutures, or surgical scars, it would be expected that aesthetic concerns would be less relevant, yet the underrepresentation of women in pAVF studies persists. This suggests that there may be other, less obvious factors influencing these choices. It has also been shown that there is a lower rate of aneurysms in the cannulation area [26,32].

Socioeconomic factors and access to healthcare may also contribute to the observed gender disparity. Evidence suggests that a smaller percentage of women start renal replacement therapy (RRT), opting for conservative treatment, and those who do start RRT tend to do so later than men [56,57]. While this might be partially explained by the slower progression of CKD in women, it is possible that limited access to specialized medical care in certain regions also plays a role [58,59]. Moreover, there may be a lack of awareness or recognition of gender-specific differences in the presentation and progression of CKF, potentially leading to delayed diagnosis and treatment in women [58,60].

Finally, it is essential to consider the limitations of our review when interpreting these findings. This review is purely descriptive and includes studies with a very limited number of patients, several of which are retrospective, raising the potential for selection biases. Another significant limitation is that none of the studies included in the review differentiate outcomes by sex, making it challenging to draw definitive conclusions about the gender disparity in AVF maturation and use. Additionally, this review only considers the percentage of women selected to undergo an AVF, rather than the total population from which the sample was drawn. This limitation stems from the fact that several articles did not provide this information, which restricts the generalizability of our findings.

Future research should aim to address these limitations by conducting prospective studies with larger sample sizes that stratify outcomes by sex. Additionally, exploring the role of social, psychological, and economic factors in influencing AVF utilization could provide valuable insights into the gender disparities observed in VA. Understanding these nuances is crucial for developing targeted interventions to ensure equitable access to optimal vascular access for all hemodialysis patients, regardless of gender.

## 5. Conclusions

Historically, there has been a significant gender disparity in the use of AVFs as way of ensuring VA, despite the substantial benefits demonstrated compared to the use of CVCs. Although the causes of this difference are not entirely clear, several reasons have been hypothesized, including socioeconomic factors, anatomical factors, and even patient preferences. The emergence of new percutaneous and minimally invasive systems for creating AVFs could provide a good opportunity to reduce these differences and increase the number of women undergoing dialysis through an AVF. However, in the various studies published in the literature, the low number of women included remains striking.

Given the gender disparity in the reviewed studies, further research is necessary to examine the differences in results between the sexes. Additionally, it is important to work on identifying and mitigating the barriers women face in accessing AVF creation, ensuring that medical decisions are based on individual needs, and avoiding assumptions or biases.

**Author Contributions:** H.V.-P. was involved in the study design, data collection, interpretation, and manuscript writing. J.R. participated in the study design, supervision, and final manuscript review. P.B. participated in the study design, data collection, and data synthesis. A.R.P. and A.P.A. were involved in the search and review of articles. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research received no external funding.

**Conflicts of Interest:** The authors have no conflicts of interest to declare.

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