

Review

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Review

Is There Gender Disparity in Vascular Access for Hemodialysis with New Percutaneous Systems?

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Abstract: Background: Historically, a large gender-related disparity in vascular access (AV) has been demonstrated, with a lower prevalence of women with arteriovenous fistula (AVF) compared to men and 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:** The study aims to determine if there is a gender difference in the creation of AVFs using the 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 and 5 prospective studies. Of these, 6 studies are comparative, 5 of which compare pAVF with surgically created AVFs (sAVF), and 1 comparing pAVFs performed using different systems with each other. A total of 1,269 patients were included in the review. Of the total number of patients, only 414 were women, representing 32.62%. **Conclusion:** 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 socio-economic 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 the creation of an AVF.

Keywords: percutaneous arteriovenous fistula; endovascular arteriovenous fistula; hemodialysis; Ellypsis; WavelinQ; EverlinQ

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 respectively started renal replacement therapy (RRT) [1,2]. Of these, 84.2% and 83% began with hemodialysis (HD). In Spain, according to the 2023 Spanish Registry of Renal Patients (REER), 7,119 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 as 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 incidents and prevalent patients using CVCs as vascular access remains very high. According to the USRDS, in 2021, 85.4% of patients initiated HD through a CVC, reducing this percentage to 23% in prevalent patients [2].

Similarly, the latest data from the DOPPS 5 study shows 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 multiple 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 reduce 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) and the Ellipsys®™ EndoAVF System (Avenu Medical).

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 brachial artery only; brachial, radial, or ulnar artery insertion was approved in Europe), and a venous catheter (with an electrode) 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 radio-frequency 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, 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 as their VA by providing a solution to some problems such as 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 if it is an alternative to classic surgical methods and could contribute to reducing these differences.

2. Material and Methods

2.1. Research Question

At the beginning of the study, the following research question was formulated as 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. Additionally, a manual review of the bibliographic references of the selected articles was conducted to find any potential articles that could 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.

This review followed the methodological guidelines recommended by the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [24]. The selection of articles is shown in Figure 1.

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, a table was created including the main characteristics of the finally selected articles, information related to the authors, year of publication, sex, age, type of studies, and system used to perform the pAVF (Table 1]. For those articles comparing percutaneously or surgically created AVFs, only the data of patients with pAVFs were collected.

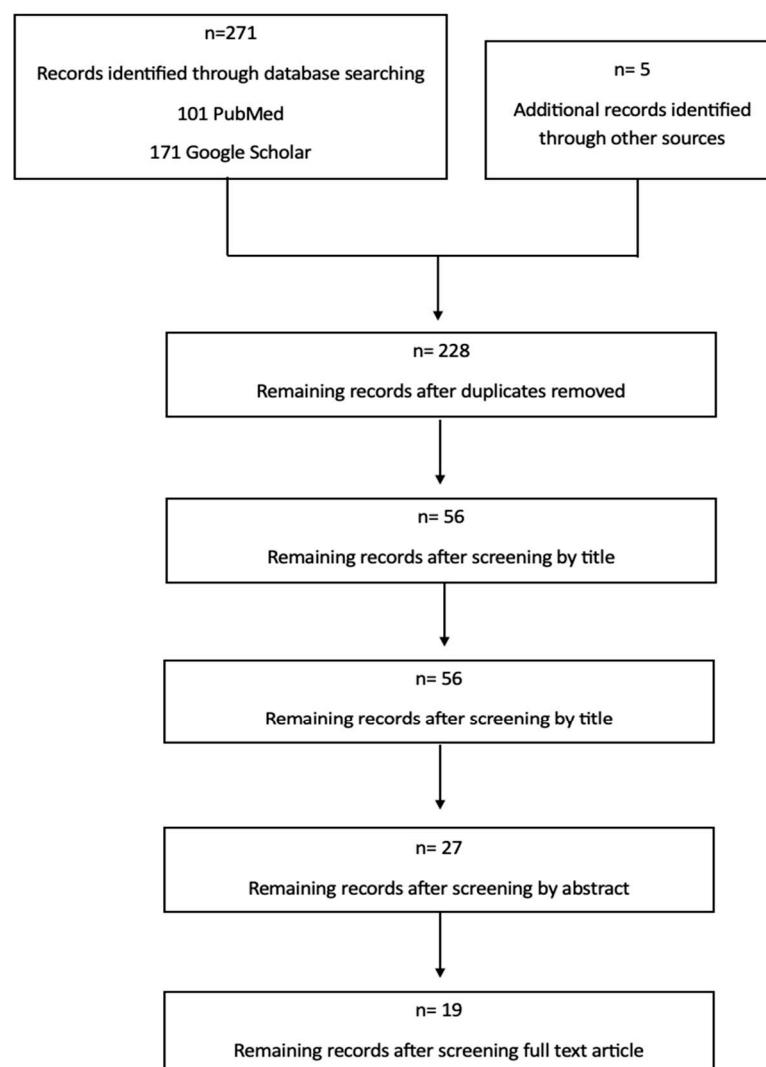


Figure 1. flow diagram for study selection.

3. Results

Finally, the review included 19 studies, 14 retrospective and 5 prospective. Of these, 6 studies are comparative. 5 compares pAVFs with sAVFs, and 1 compares pAVFs performed using different systems. 5 studies include data from pAVFs performed using the EverlinQ system (TVA Medical Inc., Austin, TX, USA), 10 include data from pAVFs performed using the Ellipsys system (Medtronic), and 6 using the Wavelin Q 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 total patients (Figure 2).

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

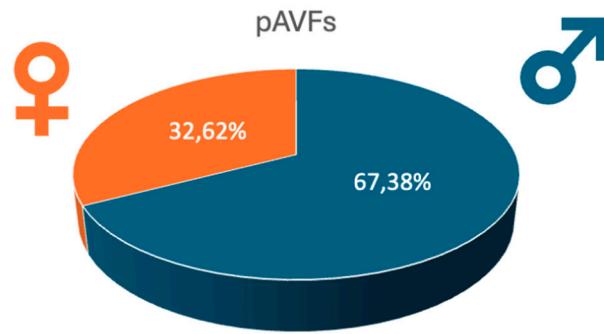


Figure 2. Percentage of women with pAVFs included in the review.

4. Discussion

The main finding of our study is that despite the overwhelming evidence supporting the use of the AVF as the preferred vascular access in hemodialysis patients due to lower complication rates, lower costs, and lower mortality rates [6,7], only a third of the patients selected for this endovascular technique are women, revealing a gender disparity. Many other studies have shown a significant gender disparity in VA, demonstrating a lower prevalence of AVFs in women compared to men. [16,25–31]. The cause of this disparity is not entirely clear, although several reasons have been hypothesized that could contribute to it.

One reason for this difference could be related to vessel diameter, as vein size is the main predictor of AVF maturation failure [32]. Some authors have hypothesized that the lower maturation rates observed in women might be related to the smaller diameter of both veins and arteries [14,33–35]. 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 anatomy and higher likelihood of maturation failure. However, evidence suggests that these differences are not significant in clinical practice and that variations in maturation rates are due to other factors [26,28,29,36,37]. This hypothesis regarding smaller vessel sizes in women might contribute to the significant gender disparity observed in percutaneous arteriovenous fistulas (pAVFs) studies, for both currently available systems, Ellipsys and WavelinQ, a vein and artery diameter greater than 2 mm is required to insert the catheters.

Similarly, numerous studies have shown the impact of obesity on AVFs, with lower maturation rates and a higher number of reinterventions. This could be due to various causes, such as lower intraoperative blood flow or higher leptin levels and inflammatory markers related to myointimal hyperplasia [38–40]. It has been hypothesized that these factors could be related to the lower maturation rate of AVFs in women, due to the greater accumulation of fatty tissue in the arms [41]. However, pAVFs could be a good option for this patient profile as they are minimally invasive systems that reduce inflammatory markers and myointimal hyperplasia. Being performed in the deep

venous system and increasing possible puncture sites, they could minimize cannulation problems due to the greater depth of veins in obese individuals.

Other potential causes for the women's lower AVF maturation rates have been studied, such as venous dilation capacity or different inflammation mechanisms [42]. In this regard, a study by Dember LM et al. analyzed different markers of vascular function before AVF creation. However, the lower maturation rates of AVF in women were not explained by preoperative vascular function tests [43].

At the hormonal level, certain factors could contribute to these differences in maturation rate. Sex hormones and their receptors play a significant role in the progression of chronic kidney disease (CKD) through various pathophysiological pathways. However, these hormones may play an unclear role in inflammation during AVF maturation [44]. To address these uncertainties, Satam K et al. studied the role of sex hormones in AVF maturation in mice, demonstrating that estrogens can lead to early failure due to increased recruitment of immune cells [45].

Another reason that could explain the lower rate of women with AVFs is the patients' preferences. In this regard, The Dialysis Outcomes and Practice Patterns Study data (DOPPS) showed that when patients were asked to indicate their preferences for VA, 58% of women preferred a fistula compared to 69% of men [13]. Although the two main reasons for this choice were to avoid needles and bleeding, it has been hypothesized that one of the reasons could be aesthetic [16]. In the case of pAVFs, the lower number of women included in the studies should not be justified by aesthetic reasons. One of the main advantages is that these minimally invasive techniques do not involve surgery, sutures, or surgical scars. It has also been shown that there is a lower rate of aneurysms in the cannulation area [46,47].

Another reason that could lead to a lower number of women using an AVF as a VA could be certain socioeconomic factors and access to healthcare. There is evidence showing that a smaller percentage of women start renal replacement therapy (RRT), opting for conservative treatment and that those who do start it, start it later than men [48,49]. This could be justified by the slower progression of CKD in women, although certain factors such as lower access to specialized medical care in certain regions could contribute [50,51]. Additionally, there may be a lack of awareness about the impact of gender on the presentation of certain diseases such as chronic kidney disease (CKD) [50,52].

One limitation of our review is that it is purely descriptive. It also includes studies with a very limited number of patients, and several of them are retrospective, which could lead to selection biases. Another important limitation to consider is that none of the studies included in the review distinguish by sex in terms of outcomes. The final important limitation to note is that this review only considers the percentage of selected women who underwent AVF, rather than the total population from which the sample was drawn. This is due to several articles not providing this information.

5. Conclusions

Historically, there has been a significant gender disparity in the use of AVFs as 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 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.

Table 1. Main Characteristics of the Studies.

Autor/year	Study Type	Number of participants	Mean Age	Gender N (%)	Device
Beathard et al [47], 2020	Retrospective Cohort Study	105	56,2	Male: 77 (73,3) Female: 28 (26,3)	Ellipsys Vascular Access System
Berland et al [53], 2022	Retrospective Cohort Study	120	55,6±15,9	Male: 97 (80,8) Female: 23 (19,2)	Wavelin Q EndoAVF System
Harika et al [54]	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 [55], 2023	Retrospective comparative study	51	58 ± 13,5	Male 40 (78) Female: 11 (22)	Ellipsys Vascular Access System/ Wavelin Q EndoAVF System / Surgical AVF
Hebibi et al [56], 2019	Retrospective Cohort Study	34	62	Male: 20 (58) Female: 34 (42)	Ellipsys Vascular Access System
Hull, et al [57], 2017	Prospective Cohort Study	26	45,5±13,6	Male: 10 (38,46) Female: 16 (61,54)	Ellipsys Vascular Access System
Hull et al [18], 2018	Prospective Cohort Study	107	56,7±12	Male: 78 (72,9) Female: 29 (27,1)	Ellipsys Vascular Access System
Inston et al[23], 2019	Prospective comparative study	30	57±15	Male: 25 (75) Female: 5 (30)	Wavelin Q EndoAVF System/Surgical AVF
Kitrou et al [19], 2022	Retrospective Cohort Study	30	55,3±13,6	Male: 30 (100) Female: 0 (0).	Wavelin Q EndoAVF System
Lok et al [17], 2017	Prospective Cohort Study	60	59 ±13,6	Male: 39 (65) Female: 21 (35)	Everlin Q EndoAVF System
Mallios et al[46] , 2020	Retrospective Cohort Study	234	64	Male: 148 (63,24) Female: 86 (36,76)	Ellipsys Vascular Access System
Mordhorst et al[58], 2022	Retrospective comparative study	61	64	Male: 46 (75,4) Female: 15 (24,6)	Everlin Q EndoAVF/Surgical AVF
Osofsky et al[59], 2021	Retrospective comparative study	24	56,7±22,6	Male: 12 (50) Female: 12 (50)	Ellipsys Vascular Access System/ Surgical AVF
Radosa et al [60], 2017	Retrospective Cohort Study	8	57	Male: 6 (75) Female: 2 (25)	Everlin Q EndoAVF System
Rajan et al [61], 2015	Prospective Cohort Study	33	51±11,4	Male: 20 (61) Female: 13 (39)	Everlin Q EndoAVF System
Shahverdyan et al [20], 2020	Retrospective comparative study	100	64,18 ± 14,18	Male: 69 (69) Female: 31 (31)	Ellipsys Vascular Acces System/ Wavelin Q EndoAVF System
Shahverdyan et al [62], 2021	Restrospective comparative study	89	67,9	Male: 58 (65,2) Female: 31 (34,8)	Ellipsys Vascular Access System/ Surgical AVF
Sultan et al [63]	Retrospective Cohort Study	18	63,8	Male: 10 (55,6) Female: 8 (44,4)	Everlin Q EndoAVF System
Zemela et al [21], 2021	Retrospective Cohort Study	32	60,2	Male: 23 (71,9) Female: 8 (28,1)	Wavelin Q EndoAVF System

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