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ENGINEERING SCIENCES

Influence of hemodialysis blood flow rate on the thrombogenic potential in patients with central venous catheters

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Abstract: In this study we apply methods to determine the tendency for thrombus formation in different central venous catheters (CVC) models associated with flow rate variation. To calculate the thrombogenic potential, we proposed a new numerical model of the platelet lysis index (PLI) equation. To compare the results of PLI and flow rate in different models of catheters, numerical calculations were performed on three different tips of CVC. The results showed that the PLI increases as a power function of the flow rate independent of the type of CVC. This study evidenced that the higher the blood flow rate used in the catheter, the greater the potential for thrombus formation. The PLI computed at the catheter outlet presented higher values when compared to the values computed at the vein outlet indicating that the blood flow through the CVC arterial lumen presents a proportionally larger thrombogenic potential when compared to the blood flow that leaves the vein towards the atrium. This finding may have consequences for clinical practice, since there is no specific flow value recommended in the catheter when the hemodialysis machine is turned on, and with this equation it was possible to demonstrate the thrombogenic potential that the flow rate can possibly offer.

Key words: blood flow rate, central venous catheters, computational fluid dynamics, thrombogenic potential.

INTRODUCTION

Although native arteriovenous fistula (AVF) placement is the preferred form of permanent access, central venous catheters (CVC) remains the initial access for the majority of hemodialysis patients (Kennard et al. 2017, Fulker et al. 2017, Marques et al. 2017). CVC are discouraged due to high rates of infectious, thrombotic complications and malfunction (Kennard et al. 2017). However, nowadays there is a greater dependence on CVC and 10% to 40% continue to use a catheter up to 90 days after dialysis initiation as CVC are utilized as a bridge until AVF maturation (Kennard et al. 2017).

To achieve adequate effectiveness during an average dialysis treatment of 4 hours, a CVC blood pump velocity of a minimum of 100 to 300 mL/min has to be set (Petridis et al. 2017, Clark et al. 2015b). The variation in the minimum flow values, however, depends on the type of CVC, place of insertion and degree of chronic renal disease.

Thus, several authors have suggested various CVC designs to ensure an optimal high blood flow rate and a long-lasting catheter (Marques et al. 2017, Sutherland et al. 2018).

These improvements contributed greatly to the successful use of the CVC during hemodialysis and for the construction of new projects about these devices.

Computational fluid dynamics (CFD) has shown vascular research exploring the effects of the wall shear stress and the catheter angle on the endothelial surface (Peng et al. 2017, Wu et al. 2016, Piper et al. 2018). However, these research efforts do not take into account the different geometries of the catheters that could cause distinct flow rate patterns that may have important implications for thrombogenesis in the endothelial wall of the vessel.

There is a significant knowledge gap in the current literature concerning the impact of the blood flow rate passing through the CVC during hemodialysis associated with platelet activation. Thrombus formation plays a central role in establishing CVC dysfunction and its prevention may preserve the venous access site and avoid expenses with pharmacological and interventional treatments (Marques et al. 2017, Petridis et al. 2017, Clark et al. 2015b).CVC dysfunction, which is mainly associated with inadequate blood flow is a major cause of thrombus formation, in addition the falling of the thrombus may result in pulmonary embolism where the majority of associated deaths occurs within hours(Marques et al. 2017, Petridis et al. 2017, Clark et al. 2015b).

Previous studies on CFD in cardiovascular medical devices have predicted a specific flow rate value by means of a mathematical model with the objective of reducing their thrombotic effects (Sutherland et al. 2018, Peng et al. 2017, Wu et al. 2016). These studies elucidated an increased risk of thrombosis, by means of a flow pattern and the kinetics of platelet activation but cannot provide definitive insight to the flow rate and risk of thrombus development.

Studies have been developed to relate shear stress to thrombogenesis (Clark et al. 2012, 2015a, Tal 2005, Mareels et al. 2007) but to date there has been no study correlating flow rate with its potential for thrombus formation. Therefore, there is a need to provide new insights into these fundamental questions with the purpose of evaluating the influence of the flow rate on the downstream of the CVC associated with the new model to predict thrombogenesis. Finally, in this study we apply methods to determine the tendency for thrombus formation in different CVC models associated with flow rate variation. This model could contribute to the design of new models of catheters and for the creation of new health indicators in clinical practice.

MATERIALS AND METHODS

To calculate the thrombogenic potential related to the presence of catheters, we proposed a new numerical model of the platelet lysis index (PLI) equation, adapted from the original model (Goubergrits & Affeld 2004) (Equation 1). The calculation of PLI takes into account the combination between the magnitude of the shear stress and the exposure time to this stress, which are correlated with experimentally defined constants (Mareels et al. 2007, Goubergrits & Affeld 2004). Although originally developed for the calculation of platelet lysis, Equation 1 can be used to evaluate platelet activation, since they are determined by the same phenomenon (Clark et al. 2012, 2015a, Mareels et al. 2007). Thus, we use the PLI to calculate the thrombogenic potential of the computational domain.

$$PLI = 3.66*10^{-6} t^{0.77} \tau^{3.075} \tag{1}$$

where τ is the magnitude of shear stress and t is the exposure time. To facilitate the computational fluid dynamics calculation, Equation 1 was transformed into a partial differential equation. Initially, it was linearized as a function of time, and then it was derived along a current line by applying the Reynolds transport theorem (Haniel et al. 2019). After some algebraic manipulation, we obtained a transport equation (Equation 2) of PLI along the domain.

$$\frac{\partial}{\partial t}\left(PLI_l\right)+\left(\mathbf{u}\,.\,\nabla\right)PLI_l=\left(3.66{*}10^{-6}\right)^{\frac{1}{0.77}}\tau^{\frac{3.075}{0.77}} \qquad (2)$$

where $PLI_l = PLI^{\frac{1}{0.77}}$ and the total numerical value of PLI was calculated by the mass-weighted average computed at the domain outlets. To solve Equation 2, the boundary conditions entered were null inlets (PLI_l =0) and no PLI flux on the walls and outlets ($\partial PLI_l/\partial n$=0). The PLI value generated in the geometry was then calculated at the outputs of the computational domain, to compute the total mean value of PLI created by the shear stresses.

To evaluate the association of the possibility of thrombus formation with flow rate within the catheter, 10 values ranging from 140 to 340 mL/min were used. This range of flow values encompassed those normally used in clinical practice during hemodialysis (Marques et al. 2017, Petridis et al. 2017, Clark et al. 2015b).

Three-dimensional CVC

Three-dimensional catheter models were designed in the Spaceclaim® CAD software (ANSYS, Massachusetts, USA) (Figure 1). The first CVC consisted of a simplified, non-commercial catheter model with two cylindrical and separate lumens called “Cut Angle Hole”, developed by Mareels et al. (2007), with a design similar to Mahurkar™, PermCath (Tyco Health Care, Mansfield, MA).

The second catheter was a realistic model of short-stay CVC similar to the “Hemo-cath” catheter (MedCOMP, Harleysville, PA, USA) (Lucas et al. 2014). The third catheter consists of a long-stay model called “Palindrome” (Tyco Healthcare Group, Mansfield, MA, USA) (Clark et al. 2015a, Tal 2005). Both with external diameter of 3.67 mm (11 Fr) and cross-sectional area of 2.93 mm² in both arterial and venous lumens.

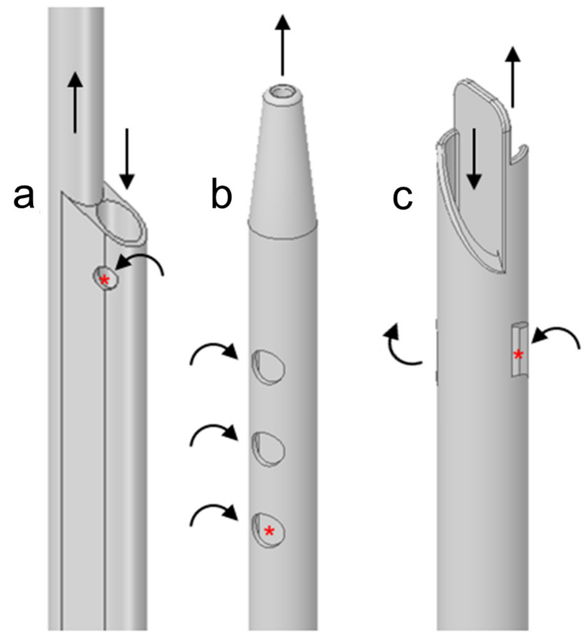

Figure 1. Representation of the catheter tips used. a) Cut Angle Hole, b) Hemo-cath and c) Palindrome. *Regions near holes, for shear stress computations.

In order to analyze the influence of the catheter dimensions on the thrombogenic potential, in addition to the standard geometry described above, simulations were performed with scale-modified geometries, being 20% smaller and 20% larger than the standard geometry of each type of CVC. The choice of variation of the geometry in scale, instead of using commercial models with larger and smaller sizes, was made to eliminate the possible design variations between catheters of different sizes. Thus, in all catheter models, the internal diameter, the external diameter and the size of the lateral holes, varied in size in the same proportion.

A simplified model of the superior vena cava was designed, which consisted of a cylinder 20 mm in diameter and 130 mm in length. Each catheter was positioned centrally within this superior vena cava model.

In each of the three CVC models, the PLI calculation was added to the simulation equations as a scalar variable, and its mass-weighted average value was computed at the catheter outlet and the vein outlet. To solve the PLI transport equation, it is necessary to know the flow velocity field, which is done by the *Fluent* by solving the fluid dynamics equations.

Numerical simulation

Numerical simulation was performed using ANSYS Fluent® software (ANSYS, Inc., USA). We used steady-state and turbulent flow models using k-ω SST model. This turbulent model was used because turbulent behavior is expected at the catheter outlets and inlets (holes). The k-ω SST model offers similar benefits to the standard k-ω in the treatment of stresses near to the wall, combined with the advantages of the k - ε model for regions away from the wall. The blood density was 1,060 kg/m^3, and the viscosity was considered non-Newtonian using the Carreau-Yasuda model (Shibeshi & Collins 2009), with the following parameters: = 0.056 Pa s; = 0.0035 Pa s; =3.313 s; = 0.3568; = 2, where = viscosity for null;= viscosity for infinite; = time constant; = Power-Law Index.

The meshes were refined until the velocity, pressure and PLI results were mesh-independent considering a maximum variation of 5%. The mesh resolution was maximized near the walls of the catheter and the vein and the catheter holes. On average, each geometry has approximately 8 × 10^5 nodes, 3 × 10^6 tetrahedral elements, and 4 × 10^5 wedges elements, with the average characteristic length of 0.15 mm.

The boundary conditions were constant at the inlet and outlet of the vein ($v_{vein\ inlet}$ = 0.18 m/s; $P_{vein\ outlet}$ = 0 Pa). For the catheter inlet and outlet, it was used ten mass flow values between 140 and 340 mL/min. The inlet and outlet mass flow in the catheter were always same with each other. Besides that, a no-slip and no-flux condition was applied at the walls. The CVC and venous wall were assumed to be a rigid body.

In addition to the PLI calculations, the shear stress variation was evaluated with the increase in flow rate for the different CVC models. For this, the volumetric mean of shear stress was calculated in regions close to the artery holes of each tip of the different CVC types (Figure 1). These regions present a high concentration of shear stresses and can better predict the behavior of variation of these stresses associated with the PLI values.

Data analysis

A power regression model was used to estimate the curve between PLI and flow rate. After curve fitting, a non-parametric analysis was performed using the Friedman test to compare the difference between the exponents of each regression of each different type of catheter. The significance level considered was p <0.05.

Ethical statement

According to the policy of the Ethics Committee in Research, numerical simulation studies do not require approval from the Ethics Committee.

RESULTS

PLI values as a function of the catheter flow rate calculated on the catheter and vena cava outlet, for the Cut Angle Hole, are shown in Figure 2. The same curve patterns were found in all other CVCs analyzed.

It can be observed that the PLI computed at the catheter outlet presented higher values when compared to the values computed at the vein outlet (Figure 2), indicating that the blood flow through the CVC arterial lumen presents a proportionally larger thrombogenic potential when compared to the blood flow that leaves the vein towards the atrium. Thus, the values of PLI calculated at the catheter outlets have greater quantitative importance in the analyzed CVCs than those calculated at the vein outlets. Therefore, the values calculated at vena cava outlet were not taken into account in the other analyses of the present study.

It is not trivial to predict the relationship between stresses and exposure time based on the velocity and pressure fields. Consequently, knowledge of velocity and pressure fields may not be sufficient to understand their relationship with PLI (Haniel et al. 2019). It is a fact that regions of higher shear rate are consistent with regions of high PLI, but it is simpler to predict thrombogenic potential based on PLI, since it incorporates the time of exposure with each shear stress (Haniel et al. 2019).

The variation profile of PLI in relation to the flow rate in the catheter presented values close to a power function (Figure 3). The increase in flow rate in the catheter caused an approximately cubic increase in the PLI. This means that, for example, a 10% increase in flow rate generated an increase of more than 30% in the thrombogenic potential.

The PLI also showed sensitivity to the variation in CVC dimensions, as illustrated in Figure 4. However, observing the power regression equation, it was verified that the exponent value presented very small variations, which is an indication that the exponent has a small sensitivity to the change in the size of the catheter.

Table I lists the calculated regressions, with the equations of the power curve adjustments, as well as their R-squared values.

The Friedman test (Montgomery 2012) for the values of the exponents found indicated that the exponent values are independent of the scale and type of CVC (p> 0.05), when considering

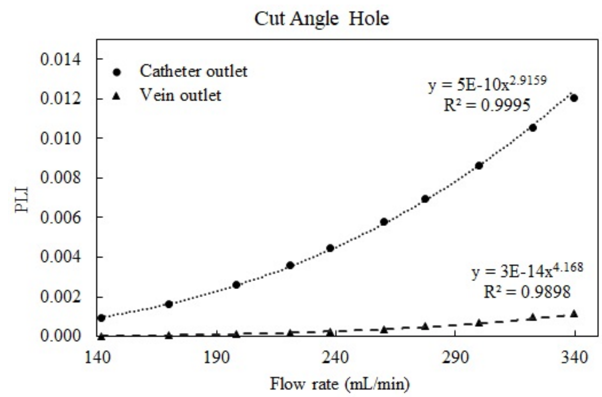

Figure 2. **PLI variation at the catheter outlet and vein outlet as a function of the flow rate in the CVC (Cut Angle Hole-standard geometry). The arrows indicate the flow direction.**

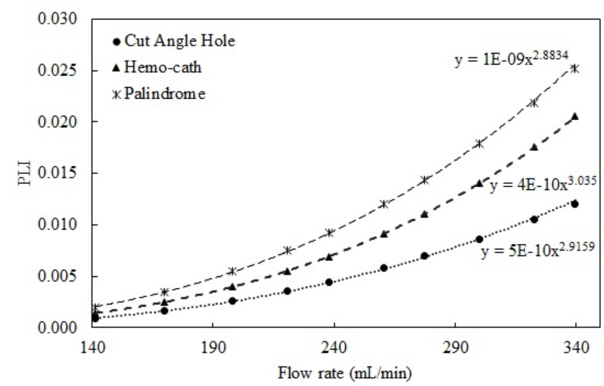

Figure 3. **Comparison between the PLI values computed at the catheter outlet as a function of catheter flow rate, for each of the CVC analyzed with standard geometry.**

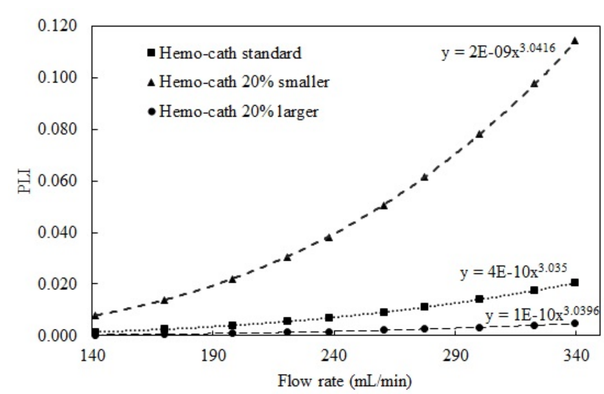

Figure 4. **Comparison between PLI values computed at the catheter outlet as a function of catheter flow rate, for Hemo-cath with standard geometry, 20% larger and 20% smaller at scale.**

Table I. Constants obtained in the power regressions, given by the form, of PLI values computed at the catheter and vein outlets for each CVC (Hemo-cath, Cut angle hole, Palindrome), and in each case of size; the R-squared values calculated for each regression are also presented.

Types of central venous catheter	20% Smaller		
	Base (a)	**Exponent (b)**	**R-squared**
Hemo-cath			
Catheter outlet	2.281×10^{-9}	3.042	1.000
Vein outlet	2.566×10^{-12}	3.922	0.962
Cut Angle Hole			
Catheter outlet	8.629×10^{-10}	3.159	1.000
Vein outlet	1.053×10^{-14}	4.798	0.964
Palindrome			
Catheter outlet	7.266×10^{-9}	2.952	0.997
Vein outlet	6.634×10^{-13}	4.169	0.995
	Standard Size		
	Base (a)	**Exponent (b)**	**R-squared**
Hemo-cath			
Catheter outlet	4.260×10^{-10}	3.035	1.000
Vein outlet	2.762×10^{-12}	3.587	1.000
Cut Angle Hole			
Catheter outlet	5.172×10^{-10}	2.916	1.000
Vein outlet	3.129×10^{-14}	4.168	0.990
Palindrome			
Catheter outlet	1.292×10^{-9}	2.883	0.998
Vein outlet	9.538×10^{-12}	3.301	1.000
	20% Larger		
	Base (a)	**Exponent (b)**	**R-squared**
Hemo-cath			
Catheter outlet	9.514×10^{-11}	3.040	1.000
Vein outlet	8.960×10^{-13}	3.552	0.996
Cut Angle Hole			
Catheter outlet	1.312×10^{-10}	2.914	1.000
Vein outlet	5.729×10^{-13}	3.366	0.999
Palindrome			
Catheter outlet	8.878×10^{-11}	3.166	0.999
Vein outlet	2.387×10^{-12}	3.321	1.000

the values of PLI calculated at the catheter outlet. The median exponent value was 3.035 for the values calculated at the catheter outlet. However, for the values of base, the Friedman test indicated that these values depend on the variation of the scaled CVC size and the type of CVC used (p <0.05).

With these results, we can present a simplified relationship between the thrombogenic potential of a given CVC and the flow rate used in this CVC, given by Equation 3:

$$PLI = K*FlowRate^{3.035} \tag{3}$$

where K is a constant that must be defined experimentally for each specific CVC geometry.

Shear stresses tended to vary linearly as a function of flow rate in the catheter (Figure 5).

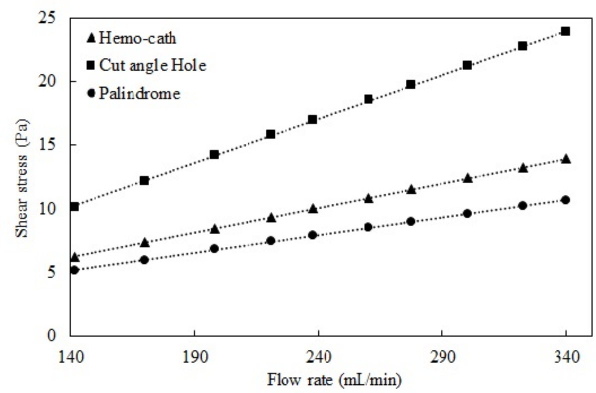

Figure 5. Variation in the mean value of shear stress as a function of flow rate, in regions near the lateral holes of Hemo-cath, Cut angle hole and Palindrome catheters with the standard size.

DISCUSSION

The results from the CFD analysis showed that the PLI increases as a power function of the blood flow rate independent of the type of CVC (Figure 3). This increase in the flow-dependent thrombogenic potential can lead to catheter dysfunction due to the formation of thrombi in the central and lateral holes of the catheter. These findings of the current study should be of great concern for health care professionals in the hemodialysis process and raises questions concerning the long-term implications of blood flow rate used on its relative thrombogenic potential during hemodialysis.

Most dialysis catheters can be capable of achieving flow rates exceeding 300 mL/min, with the intent of producing a more efficient dialysis session. However, recent studies showed that countries that had high success in hemodialysis had a much lower average blood flow rate (200mL/min) (Pisoni et al. 2018, Alyousef et al. 2016). In Europe and in Saudi Arabia, for example, a blood flow rate lower than 300 mL/min is frequently used in dialysis treatment, once the adequate hemodialysis depends on certain factors that include duration and frequency of dialysis sessions, dialyzer size, dialysate characteristics, blood flow rate, vascular access, protein intake, physical activity, and hematocrit (Alyousef et al. 2016).

A numeric study investigated different blood flow rates (200, 300 and 400 mL/min) produced in a plastic cannula when returning the blood to the cephalic vein (Fulker et al. 2017). The results suggested using flow rates between 300 and 400 mL/min, where higher flow rates would cause high wall shear stresses leading to endothelial damage and intimal hyperplasia, and lower flow rates would significantly increase the blood residence time (Fulker et al. 2017). This shows that the flow control must also be taken into account for the thrombogenic potential caused by mechanisms other than the activation of platelets by high shear stresses.

There is no clear scientific definition of the ideal blood flow rate for optimal hemodialysis so that the catheter maintains patency and at the same time does not stimulate platelet activation. Frequently small thrombi form in the holes of the CVCs, and only when all of them are occluded the CVCs are replaced. However, occlusions of holes are visualized only by radiographs, and often when the thrombi are well developed, the removal of CVC is not indicated and increases the risk of pulmonary embolism. In other cases when only a few of the holes are pervious, the dialysis can occur normally, even with different flow rate values, without indication of catheter removal.

Therefore, flow rate values within the CVC may vary during the hemodialysis sessions and the professionals do not take into account the difference in flow rate values and the increased possibility of thrombus formation. Early identification of the presence of the thrombus by means of flow rate variation may contribute to reduce morbidity and to the maintenance of venous access, especially for End Stage Renal Disease (ESRD) patients with limited vascular access (Alyousef et al. 2016).

Figure 4 and Table I show that by the power regression model the exponent presented small variations when compared to the different catheter sizes. Therefore, the risks of thrombogenesis for the three catheters are proportionally dependent on higher flow rate.

Our research presented a simplified relationship (Equation 3) between the flow rate applied to the catheter and the potential for thrombus formation induced by shear stresses and changes in flow due to the presence of CVC in the vein. Although the PLI has a power function relation with shear stresses (Equation 1), this relationship is not trivial due to the exposure time that it is related. The great advantage of PLI calculation in relation to the direct measurement of shear stresses is precisely to simplify the analysis of this interaction between the shear stress and its exposure time.

In the simulations, a linear relationship between the shear stress and the flow rate was also observed (Figure 5), which were not predictable due to the geometric complexity of the CVC. Nevertheless, this linear relationship corroborates the other results obtained in this study, since in Equation 1 the shear stress is elevated to a power very close to those calculated by the regressions (respectively 3.075 and 3.035). This evidenced the existence of a simplified relationship between the flow rate in the catheter and its thrombogenic potential. The value of the exponent found for Equation 3 is probably associated with exponent of the shear stress used in Equation 1 (Goubergrits & Affeld 2004). Therefore, in future studies new experimental relationships between thrombogenic potential, shear stress and time of exposure could identify different values for the exponent.

The base constant (K) of Equation 3 varied for each type and size of CVC and, therefore, should be determined experimentally for each specific case of CVC. It is also worth noting that despite the lack of experimental studies in this work, the PLI value can be used to predict quantities of activated platelets due to the presence of CVCs and is therefore a good indicator of the thrombogenic potential caused by changes in flow and by exposure to high shear stresses.

The use of the proposed equation (Equation 3) may contribute both to clinical practice and to the development of new CVC models, because it makes clear and simplified an association between the thrombogenic potential and the flow values used for hemodialysis CVC.

This study evidenced that the higher the blood flow rate used in the catheter, the greater the potential for thrombus formation. On the other hand, excessive reduction in blood flow rate may cause other problems that can be equally harmful, such as increased hemodialysis time, and increased blood residence time, which may also increase thrombogenic potential. The authors suggest that an optimal hemodialysis blood flow rate should be set by an experimentally defined mean critical value of PLI for patients. And the time of hemodialysis should be sufficient to maintain the patient's health, which is most commonly assessed through measures of urea clearance during hemodialysis.The present study presented the limitation of not performing experiments or clinical studies that could compare the validity of the numerical model. However, the model used to calculate PLI presented constants based on experimental data (Mareels et al. 2007, Goubergrits & Affeld 2004) and therefore, makes the model effective for the qualitative prediction of platelet activation and thrombogenic potential.

The increase in the thrombogenic potential with the blood flow rate, allowed the creation of an equation associating these variables. This finding may have consequences for clinical practice, since there is no specific flow value recommended in the catheter when the hemodialysis machine is turned on, and with this equation it was possible to demonstrate the thrombogenic potential that the flow rate can possibly offer. Future studies could clinically evaluate the prevalence of results obtained from the relationship between blood flow and thrombogenic potential.

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