The appropriateness of cannulation devices in the management AVF

In Depth Review

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ABSTRACT
Hemodialysis cannulation is often done with a notoriously harmful device that also exposes operators to a high risk of accidental puncture. It is very interesting to look at the Japanese experience, that has introduced, with an excellent success rate, a new device for the cannulation of FAV: a plastic cannula.
The aim of this review is to verify if the literature describes any advantages in the use of the plastic cannula in hemodialysis compared to the traditional metal needle, in relation to mechanical and hemodynamic vascular trauma, treatment adequacy, patient comfort and operator safety. The study has been conducted by researching, reviewing and selecting scientific articles through search engines and specialized journals.
The peculiarities of the device's design allow to expand the current possibilities in the practice of cannulation, producing positive outcomes for the patient and the operator. There is a need, however, for further studies and an update of device's features.

KEYWORDS: hemodialysis plastic cannula, vascular access cannulation, arteriovenous fistula

Introduction

The autologous arteriovenous fistula (AVF) is still considered the gold standard among vascular accesses for hemodialysis treatment by the most recent guidelines [1, 2], in relation to the lower rate of complications and longer survival time. Nevertheless, its fragility is underlined by possible complications that may emerge during the maturation process, or post-maturation, often related to the insertion of metal needles [3].

An appropriate cannulation technique should go hand in hand with the careful choice of the device: the right needle for the right patient. In this sense, individual needs and risks should be assessed considering also the patient's own preferences, thus providing a personalized care and increasing the possibility of better outcomes in terms of AVF survival and comfort of the patient. The decision-making process should be discussed with the patient through a holistic assessment of their needs. The British Renal Society's 2018 Guidelines on the principles for a good cannulation procedure [2] recommend that this should be geared towards minimising the damage to vascular access, complications, but also pain and anxiety related to cannulation.

The traditional metal needle is associated with a high risk of vessel infiltration and mechanical and hemodynamic endothelial damage during both cannulation and treatment [3]. Complications related to the use of metal needles are not rare and may have a severe impact on the dialysis treatment and on the patient's health: they may result in the postponement or the abortion of the dialysis session, or in the need to consider alternative solutions, less recommended by scientific evidence, such as central venous catheterization (CVC) or arteriovenous prosthesis (AVG) [1, 2]. These latter solutions are in fact associated, compared to autologous AVF, with a higher incidence of postoperative complications and/or need for surgical and endovascular revisions; central venous catheterization, in particular, is associated with a "significant increase in morbidity and mortality rates" [1].

Hemodialysis patients are considered a population at high risk of developing aneurysms and iatrogenic pseudoaneurysms, both for the repeated cannulation of vascular accesses and for concomitant heparinization and/or use of anticoagulant drugs for associated pathologies [11]. Although metal needles have been considered dangerous to vessels since 1950 [4], with the identification of an "imperative need to invent a safer device", metal needle cannulation continues to be considered a lifeline for hemodialysis patients. However, this must be contextualized in today's healthcare scenario, in a clinical setting where chronic kidney disease is increasingly a global health concern, due to increasing incidence rates, mortality and disability [5]; the standard population of hemodialysis patients is increasingly represented by geriatric subjects with multiple comorbidities [6, 7] such as diabetes mellitus, hypertensive nephropathy, dyslipidemia, obesity and smoking, all factors that can seriously affect the function and survival of the arteriovenous fistula. The fistula puncture procedure is in fact also a recurrent trauma in this patient population, which are subject to this procedure twice per treatment, three sessions per week, with a total of about 312 punctures per year in an already stressful environment and in full awareness of the risks connected with losing a vascular access.

It should also be stressed that the use of large calibre cutting devices without safety features increases the risk of accidental puncture in healthcare professionals. Dialysis departments are considered "high risk" professional environments due to the presence of infectious diseases with parenteral transmission, to the use of extracorporeal circulation (connection, control and disconnection from the blood circuit), to the repeated execution of invasive traumatic manoeuvres (puncture of large calibre vessels with high blood flow), to the use of material detrimental to skin and tissue integrity (large calibre fistula needles). A haemodialysis operating unit presents peculiarities that require continuous attention from healthcare professionals in order to avoid events potentially risky for patients and for their health. The most frequent injuries are cases of cutaneous lesions, contamination of the oral and conjunctival mucous membranes, exposure of the skin to blood attachment and detachment from the extracorporeal blood circuit [9].

A retrospective study collecting data on health care workers' exposure to biological material reports that, out of a total of 704 accidents, 472 involved nurses and that a high percentage were percutaneous injuries from needles and sharps. As far as the operative units of Nephrology and Dialysis are concerned, the data collected between 1995 and 2001 show the presence of 8.8% of subjects exposed to biological risk, which is a "considerable percentage if compared to the other units in the medical area" [32]. To date, several authors conclude that there is a need for an upgrade in the design of hemodialysis needles to incorporate safety features and avoid the risk of accidental exposure and/or puncture [33, 34]. The Italian Legislative Decree 626 (art.5) already underlined in 1994 that "each operator must take care of their own safety and health". It is in fact important that health workers acquire a greater knowledge of the risks to which they are subject while at work; each activity always includes a share of risk, and safety cannot be an absolute value, but the risks can often be controlled through knowledge of the problem and the use of appropriate operational tools.

Research outside Europe reveals that a different device for cannulation has been an integral part of standard practice in hemodialysis for several decades. In Japan, where there are approximately 300,000 dialysis patients every week, most of them are cannulated with a plastic device rather than a traditional metal needle, with excellent success rate, minimal complications and no reported medical incidents [8]. Plastic *cannulae* have long been used in other areas of medicine, with good results. Developments in different fields of medicine have led to an optimization of the design, tip geometry and positioning in blood vessels in order to reduce the risk of complications; in contrast, the design of metal needles has remained relatively unchanged over the years. Plastic *cannulae* are the first choice in these fields due to their higher performance and to the reduced risk of complications [14]. The world of hemodialysis, however, seems to be still dominated by traditional metal needles and central venous catheters.

These data, together with the observation of a clear gap in traditional cannulation that could be filled with the *fistula cannula*, have stimulated research in recent years and encouraged the partial introduction of this device in the practice of Australian and Canadian hemodialysis units, with the implementation of dedicated operating protocols.

Materials and methods

We wanted to verify whether the literature described advantages in the use of the plastic cannula for arteriovenous fistula in hemodialysis compared to the traditional metal needle, in relation to the mechanical and hemodynamic vascular trauma, treatment adequacy, comfort of the patient, safety and feedback of the healthcare professionals. The research methodology began with the formulation of inclusion/exclusion criteria and a clinical question using the "P-I-C-O" method.

After the identification of keywords, the search for articles was initially restricted to studies carried out over the last five years. Subsequently, given the scarcity of articles in the literature, the search was conducted without time restriction and extended to specialist journals.

The study was done by carrying out a review of specific or related literature in August, September and October 2019. We searched published scientific articles through search engines such as PubMed, ResearchGate, Google Scholar, and specialized journals such as Renal Society of Australasia Journal, SAGEpub (Sage Journal, the journal of vascular access).

Results

In the literature, we found a general lack of studies on this subject, often limited to specialist Australian and Canadian journals. The studies are not long-term, are not randomized and controlled, are performed on relatively small samples and are not tested in Italian clinical settings.

After a review of the available literature, 23 scientific articles were selected and included in the study. In relation to the research question, we explored various aspects of the use of the plastic fistula cannula compared to the traditional metal needle:

- trauma: mechanical and hemodynamic damage to the vascular access;
- treatment adequacy: achievement of parameters useful to obtain optimal extracorporeal filtration;
- patient's safety and comfort: possibility of movement, pain perception, risk of adverse events during nocturnal home hemodialysis, potential complications and consequent interventions;
- operator safety and feedback: risk of occupational disease (accidental puncture, contact with blood) and technical or procedural difficulties;
- costs.

Discussion

Device structure and characteristics

Stainless steel compound needles can be equipped with a sharp or beveled tip, designed for the Buttonhole cannulation technique, or they can be equipped with an intermediate sharpening. They are also often fitted with a silicone coating, which makes them easier to insert and gives them less resistance to friction. The traditional needle is equipped with plastic wings to secure the device to the skin and part of the tip (*bevel*) can be equipped with one or two back holes (oval or ellipsoidal *back eyes*), which should be smooth and flat so that the edges do not damage the vessel during insertion or removal of the needle; the arterial needle should always be equipped with these in order to maximize flow from the vascular access and reduce the need for needle rotation, or the possibility of needle overturning [1]. Optimal flow can prevent the suction of the vessel inner wall by the needle and reduce the need for needle rotation, a potentially traumatic procedure for AVF [31].

Another option is the device known as "fistula cannula", "fistula catheter", "plastic cannula" or "plastic needle"; it is specifically designed for fistula cannulation in hemodialysis and is considered highly biocompatible [15]. The basic design is a sharp metal needle housed within a flexible and ductile plastic cannula, which will therefore have a larger internal diameter. The metal needle is essentially a mandrel which is intended to access the vascular lumen and guide the insertion of the cannula into the vessel, acting as an introducer.

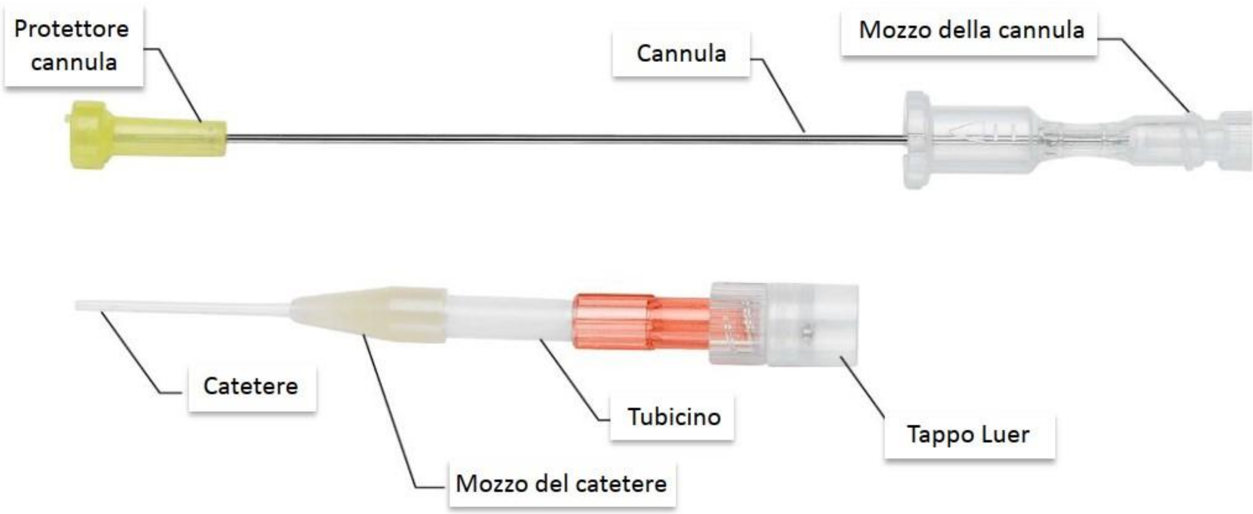

Fig. 1: Components of a plastic cannula (courtesy of Nipro Medical Europe)

As soon as the mandrel has accessed the vessel – the feedback to the operator will be a blood flashback in the HUB of the garrison – it needs to be retracted, while the cannula is pushed and placed in the vascular lumen, leaving only the flexible plastic portion of the device inside the vessel (see Figs. 1, 2, 3, 4, 5).

The plastic cannula (but not its introducer) can be equipped with side holes, specifically designed for the management and optimization of blood flow, but may not be equipped with plastic wings to secure the skin. The safety systems to make the connection and disconnection from the extracorporeal circuit safer and to reduce the risk of contamination and accidental puncture of the operator are for example: the isolation system of the mandrel tip at the retraction, the anti-reflux blood valve, the connections with Luer-Lock system.

The high biocompatibility of the plastic cannula extends its use to patients with hypersensitivity to metal alloys, an uncommon but still possible occurrence. In this case, the use of a metal needle represents an absolute contraindication that requires the evaluation of alternative options, with their related costs and risks [15,16].

Fig. 2: Fistula puncture with plastic cannula (courtesy of Nipro Medical Europe)

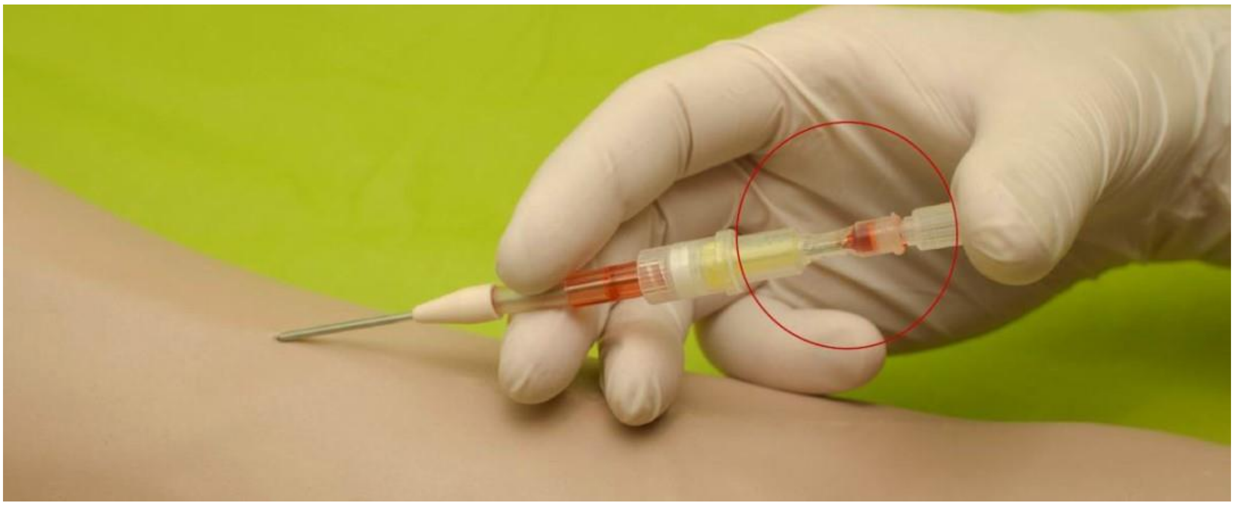

Fig. 3: Blood flashback in the catheter HUB (courtesy of Nipro Medical Europe)

Fig. 4: Spindle retraction (courtesy of Nipro Medical Europe)

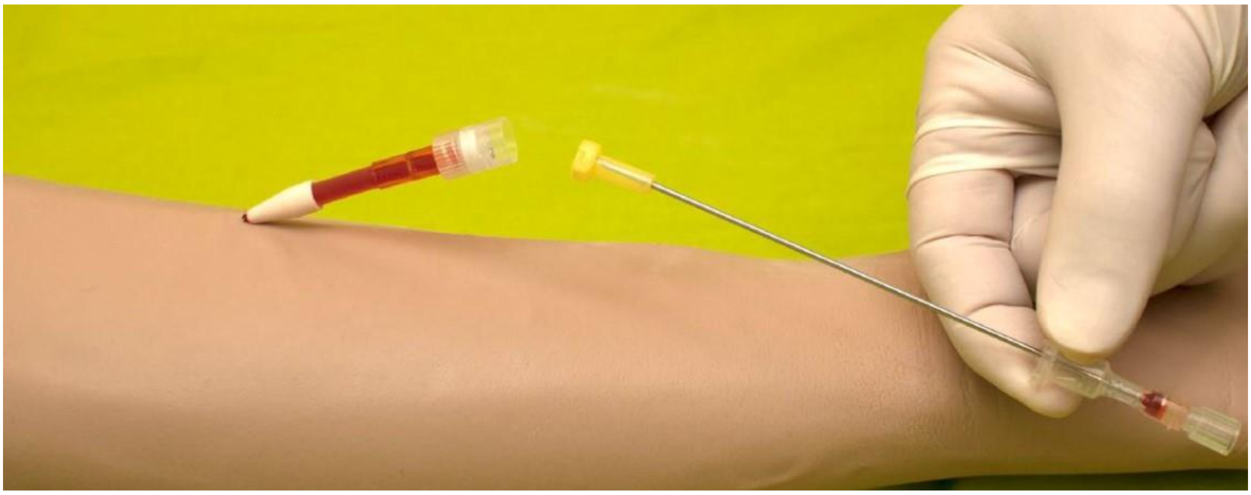

Fig. 5: Tip isolation system at full spindle retraction (courtesy of Nipro Medical Europe)

The size of the needle influences the actual blood flow and the quality of the treatment itself. An appropriate choice of gauge should be made in relation to the pump speed and flow available from the vascular access, in order to optimize the efficiency of the hemodialysis treatment; changes in gauge should require a prescription, due to the potential impact on blood flow and treatment itself.

It is recommended to use smaller gauge needles (17G) during the first 3-6 weeks of cannulation and then progress, after two weeks of cannulation without complications, to a larger gauge (16G), so as to increase the blood flow useful for blood filtration [2]. Regarding the plastic cannula, it is important to specify that the metal introducer has a smaller diameter than the cannula that houses it. Some cannulae are described with two different Gauge values (inner and outer diameter), or only the size of the introducer or the inner diameter of the cannula are sometimes reported. The catheter of a cannula with a diameter useful for treatment will then be introduced with a smaller needle size, as a smaller puncture is less detrimental to tissue integrity [15] (Table I).

Size (gauge)	***Lengths available in Europe for metal needle***	***Lengths available in Europe for plastic cannula***
14G	20, 25 mm	25, 32, 38 mm
15G	15, 20, 25, 32 mm	25, 32, 38 mm
16G	15, 20, 25 mm	25, 32, 33, 38 mm
17G	15, 20, 25 mm	25, 32, 33, 38 mm
18G	20 mm	25 mm

Table I: Measures available in Europe according to size-length ratio [15]

In order to prevent the penetration of the needle into the vessel back wall (infiltration), the shortest possible device should be adopted; however, to reach deep AVF, as in the case of obese patients, it may be necessary to adopt a longer device [31]. It is worth noting, in this respect, that the longest plastic cannula commercially available is longer than the traditional needle. Due to the different cannulation technique, which does not involve fully inserting the cutting mandrel into the vessel, the risk of infiltration during the cannulation procedure is in any case lower. However, the length of the device may make it more difficult for the operator to handle it further away from the distal end, which amplifies any movement made at the insertion point [15].

Outcomes related to cannulation

Because of the high prevalence of certain diseases and of the progressive ageing of the general population [6], there is often a need to set up or revise AVF using vessels that are not always appropriate in terms of trajectory, cannulation outcomes and access site. In this regard, plastic cannula potentially increases the number of sites that can be used for fistula cannulation, including immature, deep, tortuous and traumatized AVF; it also makes viable areas difficult to access, such as the cubital fossa and the elbow area [3,8,18,23,28,29], where cannulation with a metal needle is not recommended as it would expose the patient to a high risk of infiltration. Some authors claim that it may also allow a more efficient rotation at the insertion sites by the staff, a procedure associated with the Rope Ladder cannulation technique, rather than the Area technique [10], and that is not recommended because of a high risk of develop aneurysms and related complications.

In a study focused exclusively on the cannulation of difficult AVFs [29], 226 plastic cannulae were used by 7 haemodialysis nurses on 23 patients during 107 haemodialysis sessions; the main indications for the use of the plastic device were: the presence of a deep fistula, known cannulation difficulties and previous hematoma formation limiting accessible puncture sites. The results of the study show that an actual blood flow 300 ml/min was reached in 87% of cases (72 of 83 sessions); a flow between 230 and 280 ml/min was achieved in the other cases. The mean arterial and venous pressure were 140 (40-200) and 130 (100-200) mmHg respectively. In most cases, a 15G (218/226) cannula was used. There were 24 failed cannulation attempts that caused infiltration. The authors concluded that plastic hemodialysis cannulae have a satisfactory performance and allow to achieve the desired blood flow parameters, especially in patients with difficult vascular access.

Metal needle cannulation is made difficult by multiple factors, such as the presence of poorly cooperating patients: oligophrenics, children, or patients in nocturnal hemodialysis, whose movements could cause significant damage to the vascular wall due to the sharp portion of the needle impacting on the vascular walls. In this regard, according to recent guidelines [1,2], the plastic cannula can greatly improve the comfort and the safety of patients, giving them the possibility to safely move the limb. This is confirmed in the conclusions to the National Kidney Foundation's KDOQI 2018 Guidelines, where the authors argue that plastic fistula cannulae allow patients greater mobility, with a lower risk of infiltration due to the flexible, blunt lumen inside the vessel; this is particularly important in the case of agitated, elderly and frail patients who cannot tolerate the immobilization often required during dialysis, as well as for nocturnal hemodialysis and other modalities requiring a higher weekly frequency of cannulation. It is also specified how the flexible catheter can make it safer to access the cubital fossa and tortuous vessels, thus increasing the number of potential sites for cannulation [23].

Fig. 6: Plastic cannulas with anti-reflux valve stabilized to the patient's arm (courtesy of V.Smith, from "Plastic Cannula use in Haemodialysis Access"[10])

Mechanical trauma

In the management of end-stage chronic renal disease (CKD stage V) patients in extracorporeal purification treatment, the functionality and preservation of AV is crucial. Any acute complications, associated with cannulation or needle repositioning procedures, expose the patient to damage that could lead to dysfunction, failure and the need for central venous catheterization or surgical revision of the vascular access.

The mechanical trauma of autologous or prosthetic arteriovenous fistulae by a metal needle is well investigated in literature. Such events are not uncommon and can have a severe impact on the dialysis treatment, resulting in the postponement or abortion of the dialysis session, the inability to use the fistula for a number of sessions and/or the need to insert a CVC, which all increase the risk of liquids and toxic products accumulation in the body of a patient that is already in a precarious condition. The diagnostic or therapeutic interventions that may result not only increase the disease burden in this patient population, but also add an economic burden on the health care system, due to the costs associated with such services [3]. According to the KDOQI 2018 guidelines, given the dependence on catheters for hemodialysis and the increased risk of infection and complications due to early AVF failure, the introduction of a new cannulation device that can potentially reduce these risks is highly desirable. In this regard, the Buttonhole technique using a blunt tip needle has been associated with a significant reduction in the rate of hematoma and an improved survival of AVF; long-term results, however, show conflicting evidence and an increased risk of infection. These KDOQI guidelines stress the need for randomized controlled trials to investigate the possible reduction in the rate of hematoma formation and in the risk of infection, and the improved survival of AVF, associated with plastic cannulae [23].

Regarding mechanical damages produced by plastic cannulae, the analysis of the studies shows that, thanks to the plastic and ductile nature of the catheter and the different cannulation technique, its use can decrease the rate of infiltration/extravasation and of aborted sessions during cannulation and/or treatment [2,3,8,11,14,16,17,18,19,20,21,22,23]. We report, among others, data from a Canadian pilot randomized trial [11] whose objective was to evaluate the feasibility of a randomized trial aimed at comparing the two devices in the development of complications requiring diagnostic or surgical intervention (aneurysms, stenosis). 33 subjects were enrolled from a cohort of 420 without any significant differences in terms of sex, age, year of treatment, causes of renal disease, position or age of the vascular access. The subjects were then randomized into two groups, depending on the device used: metal n=17, plastic n=16. The cannulation was performed exclusively with the Rope Ladder technique; the length of the device was chosen in relation to the depth of the cannulation segment; the gauge used was 15G for metal needles and 17G for plastic cannulae (both available in 25mm and 33mm lengths); the evaluation was performed before and during the cannulation procedure, as well as during the treatment, with the aid of ultrasound. Complications were identified by clinicians (nephrologists and vascular surgeons) who were not informed of the participation in the study. The results show 17 adverse events, 9 of which in the metal group (53%) and 8 in the plastic group (50%). One patient in the metal group developed infiltration with a large hematoma during the first months of the study and needed to continue cannulation with the plastic cannula. The procedures to treat complications along the cannulation segment increased from 0.41 to 1.29 per patient in the metal group and decreased from 1.25 to 0.69 per patient in the plastic group ($p=0.004$). The relative risk of undergoing surgery was higher in the metal group. The first intervention time evolved in favour of the plastic cannula ($p=0.069$). In conclusion, the authors point at a decreased disease burden, in relation to the cannulation procedure, and fewer infiltrations during treatment within the plastic group. The follow-up of this study was 13 months.

Hemodynamic trauma

The laminar flow of systemic circulation is disturbed at the insertion site throughout the duration of the dialysis treatment and, consequently, the intima of the vessel wall may respond by activating biochemical cascades contributing to the proliferation of neoinitima and the development of neointimal hyperplasia (NIH); these factors contribute to the genesis of stenotic lesions and consequential thrombosis.

In a study aimed at examining the effectiveness of the plastic cannula with anti-reflux valve [14] by means of a computational model, emphasis was placed on the comparison of the hemodynamic conditions produced by a metal needle under similar conditions. A 15G-gauge device was inserted in an idealized 10mm-diameter cephalic vein, assuming the non-compliance of the vessel walls due to arterialization after the creation of the AVF, stabilized at a 10° angle (common in clinical practice) and tested with Newtonian fluid with similar density and viscosity to blood, with BFRs of 200 ml/min, 300 ml/min and 400 ml/min and with three different positions of the tip in the vessel (upper third, middle and lower third of the vein).

The plastic cannula and the venous needle create similar blood flow structures, as both devices produce high speed jets that result in disturbed flows downstream of the impact zone. The hemodynamic differences between the plastic cannula and the needle are small; the metal needle seems to do slightly worse due to the presence of smaller regions with high shear stress and residence time on the vascular wall. The abundant blood flow through the side holes of the cannula, however, shows a design advantage of the plastic device over the metal needle. Where the "back eye" of the metal needle is highly ineffective, the presence of four side holes in the cannula produces a reasonable flow distribution that helps to reduce the speed of the main jet, as shown also in peripheral catheters. Reducing the speed of the main jet can reduce the average time of shear stress on the vascular walls and impact zone, preventing the formation of secondary flows with high residence times. The design and geometry optimization of plastic cannulae allow for 50% of the blood flow to enter through the lateral holes during extraction from the body, helping to increase the exhaustion of the jet. The authors also argue that the use of plastic cannulae in hemodialysis could reduce the risk of infiltration due to the design of the tip. The technique of needle rotation, performed with metal needles in order to relieve pressure, is not necessary with the cannula because of the symmetrical design and the great influence of these side holes.

Fig. 7: Sharp end of the mandrel housed in the plastic catheter with side holes (courtesy of Nipro Medical Europe)

Dialysis suitability

When considering dialysis adequacy, several studies report achieving optimal hemodialysis parameters [14,20,21,24,25,28,29,30]. An effective blood flow (BF) of 300 ml/min with 15G (gauge) plastic cannula was achieved in 87% of 83 treatment sessions (the remaining between 230/280 ml/min), with average blood pressure of -140 mmHg and venous pressure of 130 mmHg [36]. BF of 200 ml/min with 15G and 250 ml/min with 17G, without exceeding blood or venous pressure of +/-140 mmHg, has also been reported [15]. The cannula has a smaller puncture gauge with a larger internal gauge and this allows to maximize the flow and the efficiency, with fewer vascular complications. It has been demonstrated that its use can reduce blood and venous pressure without reducing dialysis efficiency, resulting in a better hemodynamic profile: the actual blood flow, the number of dialyzed liters and Kt/V are significantly improved [24,25]. It was also possible to use smaller puncture gauges (16G cannula vs. 15G metal needle) with a larger internal gauge (14G) that allowed a higher effective blood flow [24].

Computational models indicate that a greater blood flow can be used with the plastic cannula, without increasing the risk of endothelial damage while at the same time increasing the efficiency of blood filtration and reducing the duration of treatment [14]. The high blood flow through the lateral holes of the cannula (27% vs. <1% through the *back eye of the* metal needle) also shows that the extraction of blood from a fistula is more efficient, compared to the metal arterial needle.

Finally, the author of a descriptive study on nocturnal hemodialysis [16] advises against the use of sharp metal needles because of the risk of infiltration during treatment and suggests using a cannula needle with Rope Ladder or Buttonhole technique, according to specific protocols. A case-control analytical study, with the aim of analysing data collected over a period of 5 years on 33 patients in home night-time hemodialysis, reports on the use of the plastic cannula (16 or 17G) using the Buttonhole technique during the last 10 months of treatment. Most of the patients were able to auto-cannulate and to start treatment independently [35]. However, in a descriptive observational study [27], the use of the cannula for nocturnal home hemodialysis was judged to be difficult and was instead replaced with blunt metal needles using Buttonhole technique.

Perception of pain

Some comparative studies aimed at assessing pain perception report on average positive outcomes in favour of the plastic cannula. A study that used “Numeric Rating Scale” to assess pain during the insertion/removal of the two devices (metal needle and plastic cannula), as well as during treatment, reports an average score in favour of the plastic cannula. Patients also reported an increase in comfort owning to the possibility to move the arm safely during treatment [19]. In a prospective non-randomized controlled trial using the “Visual Analogue Scale”, significantly less pain was recorded during cannulation and removal of the plastic cannula; however, this difference was not detected by another study, using the “Short-Form McGill Pain Questionnaire” [25]. One study reports that cannulation with a plastic cannula was perceived as more painful by patients, with the author attributing this to the operators’ lack of experience in manipulating the device [24].

In this regard, some studies [10,26,27] report that operators may initially found it difficult to use a plastic cannula because it requires a different technique to the traditional needle. Senior staff were reportedly more reluctant to learn this new technique. In addition, more practical difficulties were reported in other health settings, by staff with no experience of peripheral venous catheterization; however, staff with experience of using CVP generally perceived the technique as easy to perform.

Criticality of the plastic cannula

Some criticalities have been found in the design of the plastic cannula: compared to the traditional needle, the greater distance separating the HUB from the end of the mandrel leads to greater difficulties in handling the device. This underlines the need for cannulators to achieve good practical skills, as inexperience can increase the risk of failure of the procedure; this event, however, would have a much less catastrophic outcome when using a plastic device, compared to a metal needle.

Although needle repositioning is considered a high risk procedure for AVF injury, and therefore it is not recommended, the inability to perform this procedure with the cannula has been reported by staff as one of the conditions that increase difficulties. In this sense, the non-pulsating blood flashback in the HUB may mislead the operator, causing him to retract the mandrel prematurely and proceed with the cannula, and perhaps hesitate at the inability of the cannula to access the vascular lumen in case of suboptimal access. The failure of the procedure results in the need for a new attempt, due to the absence of a sharp end that would instead allow the (not recommended) practice of needle repositioning.

Given the intrinsic difficulties related to the design of the plastic cannula (longer length, absence of wings for stabilization, distant HUB) and given the need, in accordance with the most recent guidelines, for a “one shot” cannulation of the fistula, without subsequent repositioning, cannulation with a plastic cannula in hemodialysis is considered a “skill” to be acquired with adequate training and support from specialized staff, identified in the “Vascular Health Nurse” [10,17].

Despite the possible benefits of the plastic cannula, the higher associated costs mean that its use has often been prioritised for subpopulations of patients. Although the use of plastic cannulae entails higher direct costs than the metal needle, its use could result in less damage to the vessels, reduce the rate of infiltration, the development of haematomas and aneurysms and, in the long term, lower the incidence of AVF thrombosis and stenosis. This in turn could increase the survival of AVFs, reducing hospitalization and treatment, all aspects that must be taken into account in a rational cost-benefit analysis [15].

Conclusions

The DOPPS 2018 study [5] shows that the success rate in the use of AVF and AVG is significantly higher in Japan, than in Europe and the United States. Given that almost the totality of Japanese patients is cannulated with a plastic cannula, this substantial difference in practice can be assumed to have been a contributing factor, as hypothesized by Smith et al. in their study [10]. This same study reports (using performance indicators) an increased success rate after the implementation of the plastic cannula, from 50% to 78%.

The unique design features and geometry of the plastic cannula (malleability, longer lengths available, presence and arrangement of side holes) have the potential to significantly expand the possibilities in the practice of cannulation, with positive outcomes for the patient and the operator and without compromising the dialysis efficiency.

Its use allows for the expansion of the number of cannulation sites (deep, tortuous, traumatized, fragile, not mature or located in areas of difficult access), increases comfort in a fragile population of patients, drastically reduces the risk of vascular infiltration during treatment as well as the development of related complications (aneurysms, pseudo-aneurysms and stenosis, the primary cause of AV failure), allows for a high blood flow, improves hemodialysis adequacy and, last but no less important, improves both individual and environmental safety. The presence of slightly favourable hemodynamic flows when using a metal needle do not justify their exclusive use. The hemodynamic damage generated by the geometry of the cannula seems to be comparable to traditional needles with the same internal gauge; there is the advantage, however, that the puncture diameter is smaller and yet it is possible to achieve higher flow rate and efficiency in blood extraction. The dialysis efficiency is therefore optimized: the possibility to access high flows, supported by optimal pressure parameters, allow to reduce treatment time.

The operator’s safety is enhanced by the absence of cutting edges and by the presence of additional options designed ad hoc, such as the isolation system of the cutting tip of the mandrel, the Luer-Lock connections and the anti-reflux valve, which make the connection and disconnection from the extracorporeal circuit safer and more efficient. The design of the cannula however should be further improved to solve some deficits that make it difficult to manipulate and increase the potential for procedure failures.

In home hemodialysis and night-time home hemodialysis positive outcomes are reported in relation to patient comfort (given the ability to move the arm safely) and safety (reduced possibility of infiltration and dislocation). Cannulation with a plastic cannula in home hemodialysis has often been associated with the Buttonhole technique. With regard to the risk of infection related to the blunt needle technique, recent guidelines stress the need for randomized trials that investigate the possibility that the plastic cannula reduces hematoma formation in the same way as blunt needles do, but with a lower risk of infection and an improved survival rate of the AVF [23].

In various settings, there is a need to conduct randomised controlled trials, whose feasibility has already been investigated [11], on large samples in order to generate in-depth, objective data. The aim should not be to confirm that a ductile plastic device with a blunt end is less harmful then a sharp metal needle, which is already suggested by common sense, but rather to investigate flow dynamics and long-term AV patency, combined with cost-benefit analyses that also consider potential later complications and interventions. The increase in costs following the implementation of the plastic cannula should be weighed against the potential long-term savings: the cannula allows for the successful use of difficult vascular access in patients who would otherwise be destined for future surgical vessel repositioning or CVC positioning, with the related risks and costs.

Introducing this device in the dialysis units, together with operational protocols and an adequate training of the staff to fill specific skill gaps, could bring better outcomes for the patient and the operator, which can be detected through continuous monitoring and through surveys built according to appropriate study drawings. Change can be a difficult but researching and analysing past experiences of other professionals can help with the implementation of new devices in the world of hemodialysis. More attention should be paid to the holistic evaluation of patients and their care needs, and to correctly informing them about the possibilities available to them, as to promote a personalised care. In the future, the question should be posed from a different perspective: it should be necessary to justify the use of a sharp metal fistula needle instead of a different device, and not vice versa. In accordance with Japanese health care professionals, the answer could be: “We do not find any plausible reason to use a device that is harmful to patients and caregivers” [8].

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