

# A GAVeCeLT-IVAS bundle for the Safe Insertion of Midline Catheters: The SIMiC protocol

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## Abstract

Midline catheters (MCs) are widely used in clinical practice, and the insertion procedure may be associated with minor or major complications. Correct technique and adherence to specific strategies during placement are key factors that significantly affect complication rates and device longevity. This paper describes an insertion bundle—developed by the Italian Group of Long-Term Venous Access Devices (GAVeCeLT) and by the Italian Vascular Access Society (IVAS), and named “SIMiC” (Safe Insertion of Midline Catheters)—consisting of a few evidence-based strategies aimed at reducing all immediate, early, or late complications potentially associated with the insertion of MCs. The SIMiC bundle includes seven steps: (1) systematic ultrasound evaluation of the veins of the arms and the supra/intra-clavicular area; (2) choice of the most appropriate vein of the upper arm; (3) appropriate hand hygiene, proper skin antisepsis, and maximal barrier precautions; (4) ultrasound-guided venipuncture; (5) intra-procedural tip location, using infra/supraclavicular ultrasound scan; (6) sutureless securement, preferably using subcutaneous anchorage; (7) protection of the exit site with cyanoacrylate glue and semipermeable transparent membrane.

## Keywords

Catheters, vascular access devices, interventional ultrasonography, midline catheters, patient safety

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## Introduction

Midline catheters (MC) are peripheral venous access devices commonly inserted by cannulation of a deep vein of the upper arm. Typical indications for the use of MCs include (a) infusion of peripherally compatible solutions in non-hospitalized patients, (b) prolonged need for a peripheral venous access (for more than 3–4 weeks) in hospitalized patients, (c) frequent blood sampling in hospitalized or non-hospitalized patients with unavailability of superficial veins of the upper limbs.<sup>1,2</sup> In hospitalized patients with difficult intravenous access who require peripherally compatible infusions for less than 3 weeks, long peripheral catheters (LPCs) are more cost-effective, though they may be less reliable for repeated blood sampling.<sup>1</sup> Obviously, if the prescribed infusions are not compatible with the

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**Table 1.** Main differences between long peripheral catheters (LPC) and midline catheters (MC).

	LPC	MC
<b>Characteristics</b>		
Length	6–15 cm	> 15 cm
Caliber	1–4 Fr	3–4–5 Fr
Number of lumens	1	1 or 2
Material	PUR, PEBA, PE	PUR, SIL
<b>Insertion technique</b>		
Vein	Veins of forearm or upper arm	Deep veins of the upper arm
Venipuncture	Direct or US-guided	US-guided
Venous cannulation	Simple Seldinger	Modified Seldinger
Tunneling	Impossible	Possible, if required
Position of the tip	Inside a vein of the arm	Inside the axillary or subclavian vein
Subcutaneous anchorage	Not recommended	Recommended
<b>Performance</b>		
Blood sampling	Difficult	Easy
Expected duration	1–3 weeks	Months
<b>Complications</b>		
Risk of dislodgment	High	Low
Risk of thrombophlebitis	High	Low
Risk of malfunction	High	Low

PE: polyethylene; PEBA: poly-ether-block-amide; PUR: polyurethane; US: ultrasound.  
Table modified from van Rens et al.<sup>2</sup>

peripheral route (e.g. irritant or vesicant solutions), or if hemodynamic monitoring is required, or if multiple simultaneous infusions are planned, a central venous access device is more appropriate than an MC.<sup>1</sup>

MCs are made of silicone or polyurethane and have been used in clinical practice for more than 30 years. They are so named because their length fell between “short” catheters (Short Peripheral Cannulas—SPC) and “long” catheters (Peripherally Inserted Central Catheters—PICC). Most MCs are 16–25 cm long; originally, they were intended to be inserted into the superficial veins of the antecubital fossa so that the tip of the device was expected to be in a deep vein of the upper arm, or in the brachial portion of the axillary vein.<sup>1,2</sup>

Over the past two decades, with the increasing use of ultrasound for venous access procedures, clinicians have been inserting MC into the deep veins of the upper arm. Therefore, the tip of these catheters is now positioned in the thoracic part of the axillary or subclavian vein (hence the name “midclavicular” catheters).<sup>1</sup> This tip position is not considered “central,” so administering solutions incompatible with the peripheral route, such as vasopressors, irritant or vesicant medications, may often cause thrombotic complications of the axillary or subclavian veins, which are often more serious than catheter-related venous thrombosis of an arm vein.<sup>3–7</sup>

To perform effectively and reduce complications, MC should ideally be pressure-injectable, made of polyurethane, open-ended, and non-valved.<sup>1</sup>

MCs are commonly used in hospitalized patients, outpatients, and palliative care,<sup>8–11</sup> especially in Europe. They should not be confused with long peripheral catheters (LPCs; also known as “mini-midline,” “short midline,” etc.), which are 6–15 cm long peripheral venous access devices inserted into superficial or deep veins of the forearm or arm, with the distal tip positioned in veins of the arm before the axillary fold. MCs and LPCs differ regarding their indications, insertion techniques, clinical performance, and risk of complications (Table 1).<sup>1,2</sup>

Many strategies have recently improved the safety of MC placement and management, among which the use of ultrasound (US) at multiple stages of the procedure is particularly important. Ultrasound is now routinely employed for pre-procedural venous assessment, enabling identification of suitable veins and exclusion of abnormalities prior to insertion. During the procedure, ultrasound guidance facilitates real-time venipuncture, increasing first-attempt success and reducing mechanical complications. Ultrasound can also be used immediately after venipuncture to detect procedure-related complications, such as soft-tissue hematoma or intramural venous hematoma. In addition, ultrasound supports intra-procedural catheter guidance, allowing visualization of the direction of the guidewire and/or catheter within the vascular system (“tip navigation”), and can assist with tip location to confirm the final position of the catheter tip. For optimal function, the tip of the MC should preferably be positioned in the thoracic segment of the axillary vein or within the proximal subclavian vein. Recent evidence suggests that

**Table 2.** The SIMiC protocol (Safe Insertion of Midline Catheters).

1. Preparation and ultrasound assessment: this includes ultrasound evaluation of the veins in both arms, according to the RaPeVA protocol, from the antecubital area to the supraclavicular area, without a tourniquet.
2. Choice of the most appropriate vein of the upper arm in the green zone according to Dawson's Zone Insertion Method; tunneling must be considered if the most appropriate vein is in the yellow zone.
3. Appropriate asepsis: hand hygiene, 2% chlorhexidine in alcohol for skin antisepsis, and maximal barrier precautions.
4. Ultrasound-guided venipuncture with micro-introducer kits, using the modified Seldinger technique (catheter-through-introducer).
5. Ultrasound-based tip location, i.e., intra-procedural assessment of the location of the tip in the thoracic tract of the axillary vein or in the subclavian vein, performing an ultrasound scan of the infra/supraclavicular area, adopting the "bubble test" for enhanced tip visualization.
6. Sutureless securement, preferably by subcutaneous anchorage.
7. Protection of the exit site with cyanoacrylate glue and semipermeable transparent membrane with high permeability.

placement at the axillary–subclavian junction (just above the first rib) may be associated with a higher risk of catheter malfunction.<sup>6,7</sup> Lastly, US is also essential for the diagnosis of most late non-infectious complications (fibroblastic sleeve, catheter-related venous thrombosis, tip migration, etc.).

Beyond the US, other strategies and technologies—such as selecting the appropriate vein and exit site, skin antisepsis with 2% chlorhexidine in alcohol, maximum sterile barrier precautions, sutureless securement, and cyanoacrylate glue—have improved the safety and cost-effectiveness of procedures to insert central and peripheral vascular access devices.<sup>10,12–19</sup>

A panel of experts from the Italian Group of Long-Term Venous Access Devices (GAVeCeLT) and the Italian Vascular Access Society (IVAS) has created this bundle for MC insertion, intended to minimize complications directly or indirectly related to the insertion process (such as accidental arterial injury, tip malposition, catheter-related venous thrombosis, and catheter-related infection). An insertion bundle includes a few clear, evidence-based recommendations that, when used together, can ensure maximum safety, positive outcomes, and the best cost-effectiveness for any procedure. Similar insertion bundles have been suggested for peripherally inserted central venous catheters (PICCs),<sup>20,21</sup> centrally inserted central catheters (CICCs),<sup>22</sup> femorally inserted central catheters (FICCs),<sup>23</sup> and totally implantable venous access devices (TIVADs).<sup>24,25</sup>

The bundle proposed by GAVeCeLT and IVAS for MC insertion—named "SIMiC" (Safe Insertion of Midline Catheters)—includes seven key, evidence-based recommendations (Table 2): (1) pre-procedural ultrasound evaluation of the veins of the arms and of the supra/infra-clavicular area according to the Rapid Peripheral Vein Assessment (RaPeVA) protocol; (2) choice of the most appropriate vein of the upper arm (vein diameter in mm = equal or superior to the catheter caliber in Fr); (3) appropriate hand hygiene, proper skin antisepsis, and maximal barrier precautions; (4) ultrasound-guided venipuncture with micro-introducer kits; (5) intra-procedural tip location, using infra/supraclavicular

ultrasound; (6) sutureless securement, preferably using subcutaneous anchorage; (7) protection of the exit site with cyanoacrylate glue and semipermeable transparent membrane dressing.

### Preparation and ultrasound assessment

The maneuver should be performed only after confirming an appropriate indication for midline catheter (MC) placement, such as the need for infusion of peripherally compatible solutions expected to continue for more than 3–4 weeks and/or the requirement for blood sampling in patients with limited or inaccessible superficial veins.<sup>1,2</sup>

Pre-procedural evaluation begins with a thorough patient assessment (history of previous venous access devices, difficult venipuncture, or venous thrombosis). Specific contraindications to MC insertion—such as presence of advanced chronic renal disease (stage 3b–4–5) or evidence of obstruction/compression of the superior vena cava—must be excluded.<sup>1,10,14</sup> In selected patients with chronic renal failure with poor prognosis and low probability of future arteriovenous fistula, MC may still be an option.<sup>26</sup>

Local conditions affecting the upper extremity should be carefully assessed prior to insertion. Midline catheter placement should generally be avoided in arms with paresis, prior axillary lymph node dissection, significant lymphatic compromise, major orthopedic abnormalities, or other conditions that may impair venous return or increase the risk of complications. These considerations are consistent with precautions commonly applied to upper arm vascular access device placement.<sup>21,24</sup>

The most appropriate vein for cannulation should be chosen after a systematic ultrasound evaluation of the deep veins of the arm.<sup>1,10,14,21–25</sup> For MC insertion, the same protocol adopted before PICC insertion, the Rapid Peripheral Vein Assessment (RaPeVA), can be used: this is a systematic bilateral ultrasound evaluation of the veins of the arms and cervico-thoracic area.<sup>20,21</sup> This assessment is performed using a 7–12 MHz linear probe positioned transversely to the main axis of the arm to obtain a panoramic

**Table 3.** Rapid Peripheral Vein Assessment (RaPeVA).

Step 1	Visualization of the cephalic vein at the antecubital fossa
Step 2	Identification of the artery and brachial veins and of the confluence between the antecubital vein and basilic vein
Step 3	Identification of the basilic vein in the bicipital-humeral groove
Step 4	Examination of the nerve-vascular bundle of the arm (brachial artery, brachial veins, median nerve)
Step 5	Visualization of the cephalic vein over the biceps muscle
Step 6	Examination of the axillary vein in the infraclavicular area
Step 7	Examination of the internal jugular, the subclavian, and the brachiocephalic vein in the supraclavicular area

view of veins and other relevant structures, such as arteries and nerves.<sup>21–25,27</sup>

The RaPeVA is performed according to a systematic approach consisting in seven steps: (1) visualization of the cephalic vein at the antecubital fossa; (2) sliding of the probe from the radial side to the ulnar side, identification of the brachial artery and brachial veins, and of the confluence between antecubital vein and basilic vein; (3) sliding the probe upwards, identification of the basilic vein in the bicipital-humeral groove; (4) examination of the nerve-vascular bundle of the arm; (5) moving laterally over the biceps muscle, visualization of the cephalic vein at midarm; (6) visualization of the axillary vein in the infraclavicular area; (7) visualization of the internal jugular, subclavian, and brachiocephalic vein in the supraclavicular area.<sup>20,21</sup>

The RaPeVA protocol (Table 3) allows the systematic real-time evaluation of all possible venous options, choosing the best vessel and venipuncture site.

### *Choice of the most appropriate vein of the upper arm*

Pre-procedural ultrasound assessment is essential to identify venous abnormalities—such as thrombosis, stenosis, external compression, or anatomical variations in vein size and course—and to guide optimal vein selection. Ultrasound evaluation also allows clinicians to select a vein with an adequate diameter to minimize the risk of catheter-related thrombosis while providing a comprehensive anatomical assessment to determine the most appropriate puncture and exit sites.<sup>10,14,20,21,24,26</sup>

The internal diameter of the vein should be assessed using ultrasound to ensure the most favorable catheter-to-vein ratio (CVR), whenever possible. Sonographic evaluation must be performed without a tourniquet to avoid artificial vein distension and ensure an accurate baseline measurement. According to the suggestions of Nifong and McDevitt<sup>28</sup> and to the GAVeCeLT recommendations,<sup>29</sup> a CVR equal to or less than 1:3 is considered appropriate to maintain adequate blood flow around the device and reduce the risk of catheter-related venous thrombosis. In short, 4 and 5 Fr MCs should be preferably inserted by cannulating veins with an inner diameter not exceeding 4 and 5 mm, respectively.

Careful selection of the insertion site is also critical to reduce the risk of infection and catheter dislodgement. The SIMiC bundle recommends applying the same approach used for peripherally inserted central catheters (PICCs), specifically the Zone Insertion Method (ZIM) developed by Dawson.<sup>30</sup> In this framework, the red zone, corresponding to the antecubital region, should be avoided for both venipuncture and catheter exit due to the increased risk of catheter instability and dislodgement associated with elbow movement. The yellow zone, located near the axilla, may present a higher risk of bacterial skin colonization and contamination.

For these reasons, cannulation of an appropriately sized vein within the green zone of the upper arm is preferred. Ideally, the vein diameter (in mm) should be equal to or greater than the catheter size expressed in French, ensuring an acceptable catheter-to-vein ratio. When a vein of adequate diameter is available only within the yellow zone, subcutaneous tunneling may be performed to achieve a catheter exit site within the green zone, according to the RAVESTO protocol.<sup>31</sup>

When tunneling is required, it should be performed using hydrodissection with local anesthetic infiltration to facilitate tissue separation and reduce patient discomfort. The use of blunt tunneling instruments is recommended, particularly in patients with coagulopathy or thrombocytopenia, as this technique minimizes tissue trauma and reduces the risk of localized bleeding.<sup>21–25,32</sup>

### *Appropriate asepsis*

The third important recommendation concerns aseptic technique. Hand hygiene should preferably be performed using an alcohol-based gel. In special cases or when hands are visibly dirty, the hydroalcoholic gel should be preceded by washing with soap and water, according to current international infection-prevention guidelines.<sup>10,29</sup> Before inserting the device, skin antisepsis with 2% chlorhexidine in 70% isopropyl alcohol is recommended. Povidone-iodine in alcohol can be considered an alternative in cases of known chlorhexidine allergy. Regarding the antiseptic application technique, there is no significant difference in microorganism reduction between the concentric and back-and-forth methods, as long as the antiseptic is applied on clean, healthy skin.<sup>33</sup>

As recommended by all current guidelines for central venous catheterization,<sup>10,29,33,34</sup> also for MC insertion maximal barrier precautions should be adopted, such as wearing a non-sterile cap, non-sterile mask, sterile gown and gloves, using a full-size sterile drape over the patient, and employing a sterile ultrasound probe cover that is long enough to protect the probe and cable, along with sterile gel.

### *Ultrasound-guided venipuncture*

Ultrasound-guided venipuncture is now the “gold standard” for cannulation of any deep vein.<sup>10,13–15</sup> The technique using a short-axis view of the vein and an out-of-plane venipuncture is often preferred for cannulation in the arm, due to the panoramic view of the surrounding structures.<sup>35</sup>

The maneuver should preferably be performed without a tourniquet and always using the modified Seldinger technique (“catheter through introducer”). The use of a micro-introduction kit, which includes a 21G echogenic needle, a 0.018” nitinol guidewire with a straight soft tip, and a micro-introducer/dilator of appropriate size and length, is strongly recommended. This allows for a minimally invasive or less traumatic approach during the puncture and dilation procedures.<sup>20–25</sup> Immediately after venipuncture, ultrasound visualization of the guidewire within the vein is advised.

### *Ultrasound-based tip location*

This important step of the MC insertion protocol includes intraprocedural assessment of the correct tip position. Post-procedural control of the catheter tip is openly discouraged by current guidelines for all venous catheters: tip location must be performed during the maneuver, and not after.<sup>10,13–15,29</sup>

Regarding MCs, though hard evidence is missing, recent studies suggest that the tip should preferably be positioned in the thoracic portion of the axillary vein or in the subclavian vein. Placement of the tip at the junction of the two veins appears to be associated with a higher risk of thrombosis and malfunction.<sup>6,7</sup> In fact, the axillary/subclavian transition corresponds to a curvature of the venous trajectory, and there is a risk of impingement of the tip against the vein wall; furthermore, in this tract, the vein may be easily compressed between the first rib and the clavicle.

The simplest, safest, and most accurate method for MC tip placement is to scan the axillary vein in the infraclavicular area using a linear ultrasound probe, in both short- and long-axis views; the subclavian vein can be scanned in long-axis view using a supraclavicular approach. If there is doubt about the precise location of the tip, the “bubble test” (rapid infusion of 5 ml of agitated saline) may ensure proper visualization of the distal end of the MC.<sup>7,29</sup> After confirmation of tip location, the proper function of the

device must be verified by easy blood aspiration and easy infusion.

### *Sutureless securement*

Securing the catheter to the skin with sutures is now an outdated practice, widely discouraged by most current guidelines. Sutures are linked to a higher risk of exit-site infection, catheter dislodgement, tissue damage, and accidental needlestick injuries.<sup>10,14,29,33,34</sup>

The currently preferred options for catheter securement are (a) skin-adhesive sutureless devices, (b) transparent dressings with integrated securement, and (c) subcutaneous anchorage.

Subcutaneous anchorage is more effective than skin-adhesive devices at preventing dislodgment; it also enables more thorough 360° skin antisepsis around the exit site, potentially reducing the risk of infection.<sup>36–39</sup> In patient populations at high risk for catheter dislodgment (non-collaborative patients, skin abnormalities, diaphoresis, etc.), subcutaneous anchorage should be preferred over other securement strategies.<sup>36–39</sup>

### *Protection of the exit site*

Protection against bacterial contamination via the extraluminal route is primarily based on the appropriate selection of the exit site location, but optimal management and dressing of the exit site itself are also important.

During MC insertion, the best way to prevent local bleeding and bacterial contamination outside the lumen is to seal the exit site with cyanoacrylate glue. Glue also provides the benefit of decreasing “micro-movements” of the catheter in and out of the exit site, which could cause damage to the endothelium and increase the chance of forming a thrombus inside the vein.<sup>40</sup> In tunneled MCs, glue is used not only to seal the exit site but also to close the skin at the venipuncture site. Glue is currently recommended only during insertion; at the first dressing change, consider using antibacterial protection for the exit site with a chlorhexidine-impregnated sponge dressing in non-tunneled MC.<sup>29,41</sup> Glue has been shown to be beneficial across various patient populations, including neonates,<sup>42,43</sup> due to its hemostatic and antimicrobial effects.<sup>44–48</sup> Though, repeated weekly application of glue on the exit site may theoretically be associated with skin damage.<sup>49</sup>

The exit site should be covered with a semi-permeable, transparent membrane dressing, preferably with a high Moisture Vapor Transfer Rate (MVTR), to ensure adequate antimicrobial protection, provide additional stabilization of the catheter, and reduce the risk of skin injury. In fact, membranes with high permeability (MVTR >1500 g/m<sup>2</sup>/day)<sup>50</sup> may effectively prevent fluid accumulation and associated skin maceration, a potential risk in diaphoretic patients.

Proper catheter securement and skin and exit site protection are essential for reducing dislodgment, infection, venous thrombosis, and catheter-related skin injuries.<sup>10,14,21–25</sup>

## Special considerations

Placement of MC in a lower limb has recently been described by some authors in patients in whom the arm vein approach is contraindicated.<sup>51,52</sup> In these instances, the SIMiC protocol would need some adjustments in specific steps.

Step 1 will involve adopting the Rapid Femoral Vein Assessment (RaFeVA) protocol, a systematic ultrasound evaluation of the veins at different levels of the lower limb, from the groin to the middle of the thigh.<sup>53</sup>

Step 2 will include selecting the superficial femoral vein as the first option, with the exit site at mid-thigh.<sup>54,55</sup> As a second option, we may consider puncture/cannulation of the common femoral vein, tunneling the catheter so as to achieve an exit site far from the groin.

Step 5: The tip location will be performed by ultrasound visualization of the catheter tip in the external iliac vein—both in short and long axis—according to the ECHOTIP protocol.<sup>56</sup>

## Conclusions

The technique of catheter insertion is crucial, having the most relevant impact on early and late complications. The choice of an inadequate vein or the failure to assess the correct tip position increases the risk of catheter-related thrombosis.<sup>7,29</sup> The choice of a suboptimal exit site can increase bacterial contamination, and thus the risk of infection.<sup>1,10,14,20–25,29</sup>

Implementing a well-designed bundle for MC insertion which includes all recommended practices can reduce immediate complications (such as puncture failure, arterial injury, hematoma, nerve injury), early issues (dislodgement, tip malposition), and late complications (infection, venous thrombosis). This approach enhances patient safety, saves time and resources, and improves cost-effectiveness.

Lastly, a standardized bundle of insertion may facilitate comparisons of clinical outcomes across studies and serve as a structured educational tool for training.

## Author contributions

FB: Conceptualization, Investigation, Visualization, Writing-original draft, Writing-review and editing; MGA: Conceptualization, Investigation, Visualization, Writing-original draft, Writing-review and editing; MP: Conceptualization, Project administration, Supervision, Writing-review and editing; GS: Conceptualization, Project administration, Supervision, Writing-review and editing; VF: Conceptualization, Project administration, Supervision, Writing-review and editing; FP: Writing-review and editing; DG: Writing-review and editing; RB: Writing-review and editing; AG: Writing-review and

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