Clinical use of Sherlock-3CG® for positioning peripherally inserted central catheters

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Abstract
Introduction: Intracavitary electrocardiogram technique is recognized as a safe, accurate, and inexpensive method for verifying the tip location of central venous access devices. While the technique can be carried out with any standard electrocardiogram monitor, dedicated electrocardiogram monitors specifically designed for the intracavitary electrocardiogram are also available. One of these dedicated monitors is Sherlock-3CG®, characterized by the integration of a magnetic-based tip navigation method with an electrocardiogram-based tip location method.

Methods: In this prospective study, we inserted 130 peripherally inserted central catheters using Sherlock-3CG, evaluating the safety, feasibility, and accuracy of both tip navigation and tip location. Magnetic-based tip navigation was compared with ultrasound-based navigation; electrocardiogram-based tip location was compared with electrocardiogram-based tip location performed by another dedicated monitor (Nautilus⁵) and with post-procedural tip location by chest X-ray.

Results: All insertions were successful and the overall safety of the device was 100%. In terms of tip navigation, the maneuver was feasible only in 81%; the accuracy was 100%. In terms of tip location, feasibility was 94% and accuracy was 100%, while Nautilus showed a 100% feasibility and 100% accuracy.

Conclusion: Our study could not demonstrate any specific advantage of Sherlock-3CG either as a magnetic-based tip navigation method or as an electrocardiogram-based tip location method.

Keywords
Tip location, intracavitary-ECG method, tip navigation, peripherally inserted central catheters, Nautilus, Sherlock-3CG

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Introduction
The intracavitary electrocardiography method (IC-ECG) is now widely accepted worldwide as a simple and accurate technique for verifying the proper location of the tip of any central venous access device.¹⁻³ The main advantages of IC-ECG are its safety, the extremely low cost of the maneuver (particularly if performed with a standard ECG monitor), the possibility of a real-time, intra-procedural verification of the position of the tip, and—last but not least—its superior accuracy compared to tip location by chest X-ray.⁴⁻⁵

The IC-ECG has been developed in 1949 in Germany and it has been used for decades in Europe using standard ECG monitors and low-cost sterile cables.³ Ten years ago, the first “dedicated” ECG monitor (i.e. specifically designed for IC-ECG) was introduced into the market by Romedex International: the Nautilus⁵. In the following years, many other companies have designed dedicated ECG monitors for the same purpose. One of the most popular dedicated monitors is currently “Sherlock-3CG®” (C. R. Bard/BD), which has two peculiar features: first, it

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couples an IC-ECG-based tip location technology with a magnetic-based tip navigation; second, it has a limited applicability since it cannot be used with any central venous access device but exclusively with peripherally inserted central catheters (PICCs), and more specifically only with special PICCs, equipped with a special stylet, marketed by a specific company (C. R. Bard/BD).

Many clinical studies have been conducted in the past 4 years, consistently suggesting the efficacy, accuracy, and cost-effectiveness of Sherlock-3CG. Although all of these studies share the same biases, (a) they offer no evidence that IC-ECG tip location, as performed by such device, is any better than IC-ECG tip location performed using any other dedicated ECG monitor or a standard ECG monitor; (b) they offer no evidence that IC-ECG-based tip location coupled with magnetic-based tip navigation is any better than IC-ECG based tip location alone, in terms of clinical outcome.

Both these biases originated from two misconceptions: first, some confusion (or at least a margin of ambiguity) between the clinical efficacy and cost-effectiveness of the IC-ECG per se versus the clinical efficacy and cost-effectiveness of a specific device adopting the IC-ECG technology; second, a failure to discriminate between “tip navigation” (the process of verifying the correct direction of the catheter and/or of the guidewire) and “tip location” (the process of verifying that the tip of the catheter is actually located in the desired final position).

In this article, we evaluated the clinical benefits of Sherlock-3CG adopting a plain and rational approach, that is, evaluating separately (a) the safety, feasibility, and accuracy of tip location by Sherlock-3CG and (b) the safety, feasibility, and accuracy of tip navigation by Sherlock-3CG.

**Methods**

**Design of the study**

We designed a prospective study on outpatient candidates to PICC insertion in our Day Hospital of Infectious Disease or in our Day Hospital of Oncology. Selection criteria were age >18 years, outpatient candidate to prolonged intravenous treatments (antibiotics, or home parenteral nutrition, or chemotherapy), written informed consent, and availability of post-procedural chest X-ray. Patients with overt local or systemic contraindications to PICC were obviously excluded.

**Materials**

In total, 150 non-valved, open-ended, power injectable PICCs (Power PICC®, C. R. Bard/BD)—specifically designed to be used with Sherlock-3CG—were provided by C. R. Bard; 100 catheters were 4Fr, single lumen, while 50 were 5Fr, double lumen. We used two different ECG monitors specifically designed for IC-ECG, Sherlock-3CG and Nautilus. All ultrasound maneuvers (ultrasound scan of the vein before the puncture, ultrasound-guided puncture and cannulation of the vein, and ultrasound-guided tip navigation by supraclavicular scan of the central veins) were performed using NanoMaxx® (FujiFilm/Sonosite Inc.) equipped with a 38-mm, 7.5–10 MHz linear probe.

**Staff**

All procedures were performed by four clinicians with more than 10 years of experience in ultrasound-guided insertion of PICCs and more than 15 years of experience with IC-ECG. This was possible considering that IC-ECG was introduced in our hospital in 1997 and that ultrasound-guided insertion of PICCs was introduced in 2005. Before starting the project, all clinicians participating in the study were trained in the clinical use of Sherlock-3CG by a tutor provided by C. R. Bard; 20 PICCs were used for this training purpose, while 130 were used for the actual study.

**Patients**

We enrolled 130 consecutive adult patient candidates to PICC insertion in our Day Hospital of Infectious Disease or in our Day Hospital of Oncology. Selection criteria were age >18 years, outpatient candidate to prolonged intravenous treatments (antibiotics, or home parenteral nutrition, or chemotherapy), written informed consent, and availability of post-procedural chest X-ray. Patients with overt local or systemic contraindications to PICC were obviously excluded.

**Procedure**

All 130 PICCs were inserted according to the so-called “SIP” protocol (“Safe Insertion of PICCs”) developed by GAVeCeLT (the Italian Group of Long Term Venous Access Devices) and adopted by our hospital policies. The SIP protocol includes (a) pre-procedural scan of the vein of the arm; (b) maximal barrier precautions and skin antisepsis with 2% chlorhexidine in alcohol; (c) choice of a vein of caliber appropriate for the catheter caliber, with a 1:3 ratio (i.e. for a 4Fr catheter, the inner diameter of the vein must be 4 mm or larger); in case such a vein is not available in the middle third of the upper arm (Dawson’s green zone), a vein should be cannulated in the proximal third (Dawson’s yellow zone) and the catheter should be tunneled so as to have an exit site in the green zone; (d) real-time ultrasound identification of the brachial artery and the median nerve before the puncture; (e) ultrasound-guided puncture and...
cannulation of the vein; (f) ultrasound-guided tip navigation for checking the progression of the catheter, if needed; (g) tip location by IC-ECG; and (h) sutureless securement + application of glue on the exit site (and also on the puncture site, in case of tunneling) + coverage with transparent membrane.

In all patients, we assumed that the desired location of the tip of the PICC had to be the cavoatrial junction (as recommended by our hospital policies when inserting PICCs in patients who do not require hemodynamic monitoring). IC-ECG tip location was performed by Sherlock-3CG (study device) and then by Nautilus (control device). Before the procedure, the magnetic sensor “shield” of the study device was placed on the superior part of the sternal region of the patient. All connections were established according to the instructions for use of the device. In addition, a double set of pads for electrodes was applied to the patient, one for the study device and one for the control device. The control device was shut off and disconnected from the beginning of the procedure up to the moment of the completed tip location by the study device at this time; it was turned on and the tip location was verified a second time, using the control device. If the tip navigation by Sherlock-3CG suggested a wrong direction of the catheter or if the magnetic styllet was not properly working, we verified the direction of the catheter by a supraclavicular ultrasound scan of the subclavian vein, the internal jugular vein, and the brachiocephalic vein (ultrasound-guided tip navigation).

At the end of the procedure, a post-procedural chest X-ray was performed for a further assessment of the position of the tip. According to the “carina” criteria, we assumed that the cavoatrial junction would be approximately 3 cm below the carina; location ± 2 cm was considered correct; location ± 4 cm was considered acceptable. All chest X-rays were also evaluated according to the “sweet spot” criteria described by Symington.

Endpoints

Our endpoints were separate for tip location and tip navigation. As regards tip location by Sherlock-3CG, we evaluated its safety (evidence of any adverse effect potentially related to the use of the device), its feasibility (percentage of cases in which the device identified the peak of the P wave), and its accuracy (correspondence between the tip location according to the control device vs tip location according to the study device). As regards tip navigation by Sherlock-3CG, we evaluated its safety (evidence of any adverse effect potentially related to the use of the device), its feasibility (percentage of cases in which the device actually indicated the direction of the catheter), and its accuracy (correspondence between the direction indicated by the device vs the direction detected by ultrasound).

Collected data

Clinical data concerning the patients were collected. Also, for each procedure, all technical aspects of some relevance were carefully noted, concerning both the materials and the performance of the maneuver.

Results

Insertion results

We enrolled 130 adult patients: 123 had neoplastic disease and PICC was required for chemotherapy; 7 patients had non-neoplastic disease and PICC was required for parenteral nutrition or prolonged home treatment with antibiotics. The female/male ratio was 76:54; the age ranged between 24 and 84 years; the body mass index (BMI) ranged between 17 and 42. Two patients were not eligible for the standard IC-ECG (one because of transient atrial fibrillation; one because of pacemaker-induced rhythm with P wave not identifiable): these patients were included in the study for tip navigation, but not for IC-ECG-based tip location (the position of the tip was verified by ultrasound: trans-thoracic echocardiography).

We inserted 130 power injectable PICCs: 94 were 4Fr, single lumen, and 36 were 5Fr, double lumen. The choice between the single and double lumen was based on the individual therapeutic plan, according to our hospital policies. Ninety-two catheters were inserted in the basilic vein and 38 in the brachial vein; 104 insertions were on the right arm and 26 on the left arm.

All insertions were successful, though in one case—after failure on the right side—the catheter had to be inserted on the left arm. In nine cases (7%), the veins were too small in the green zone so that we punctured a vein in the yellow zone and we tunneled the PICC, as recommended by our hospital policies. We had no puncture-related complications (no nerve injury, no arterial puncture). In 15 cases, the puncture and cannulation of the vein were difficult, apparently because of technical features of the guidewire and due to the micro-introducer/dilator provided with the Power PICC® kit; in all of these cases, the maneuver was successfully completed using an additional micro-introducer kit provided by another company (Galt Medical).

Technical issues before the procedure

Calibration of Sherlock-3CG was not always easy. Many factors were negatively affecting the process of calibration: the spatial relationship between the cable and the shield, the presence of small metallic objects on the patients (typically in the clothes of female patients), and the presence of various possible sources of electrical/magnetic interference (cell phones and any electrical device in the room, unless unplugged).
**Technical issues during the procedure**

The connection between the shield and the cable was sometimes difficult (and this was a serious issue in four cases: see below). The shield was well tolerated by the patients, but the overall draping system was quite rigid and implied limited movements of the neck by the patient: this was associated (a) with a potentially higher risk of wrong direction of the catheter into the internal jugular vein and (b) with some difficulties in redirecting the tip if needed; also, (c) the estimate of landmark measurements (which are needed before trimming the catheter) was more difficult.

**Tip navigation**

Tip navigation was successfully performed with Sherlock-3CG in 105 out of 130 (81%) cases. In 25 of 130 (19%) cases, tip navigation was not successful, for different reasons: in 10 cases, poor visualization (transient or unstable) of the indicator designed to confirm the progression of the catheter; in 15 cases, wrong information provided by the indicator (i.e. the tip was in the proper location according to IC-ECG, although the catheter was wrongly directed according to the magnetic sensor). In the 25 cases where the magnetic tip navigation was unsuccessful, ultrasound scan of the supraclavicular area confirmed that the catheter was in the correct direction. Considering only the cases of successful magnetic-based navigation, in 20 of 105 cases the study device detected that the tip was directed in the wrong direction, into the ipsilateral internal jugular vein; in all 20 cases, the malposition was also confirmed by ultrasound scan and the catheter was retracted and successfully redirected. Redirection was somehow difficult because of the limited movements of the neck of the patients (due to the shield and the drapes) and because of the difficulty in compressing the internal jugular vein with the ultrasound probe (maneuver that the SIP protocol suggests for facilitating the proper direction of the catheter).

There was no case of wrong direction to the contralateral brachiocephalic vein.

**Tip location**

Successful tip location with the study device was recorded in most cases, that is, in 120 out of 128 (94%) cases. There was always a perfect match between IC-ECG with the study device and IC-ECG with the control device. In four cases out of 120, tip location by Sherlock-3CG was difficult because of technical problems (loose/defective connection between the shield and the cable); despite the inconstant ECG reading, the peak of the P wave was nonetheless identified. Tip location by the study device was not feasible at all in eight cases (6%) due to difficult/impossible interpretation of the IC-ECG (abnormal or severely disturbed ECG traces, artifacts, low wave voltage, and no modifications of the P wave); in these eight patients, IC-ECG was performed with the control device only (Nautilus). Tip location by the control device was successful in all 128 cases (100% feasibility).

The performance of Sherlock-3CG has been explored in different papers in the past 5 years. In a 2014 observational study on 239 patients, the use of the device was associated with a very high incidence of malpositions (20.5%), although apparently this result was an improvement over the authors’ previous experience. Apart from some papers published on non-peer-reviewed journals, a few other studies have confirmed the effectiveness and cost-effectiveness of Sherlock-3CG tip location, when compared to intra-procedural landmark estimation with post-procedural radiologic tip location by chest X-ray, although all these papers share the bias of ascribing the clinical advantages to a specific device that adopts IC-ECG (i.e. Sherlock-3CG) rather than to the IC-ECG method itself. It is noteworthy that the IC-ECG technique has been used for many decades before the appearance of any monitor ECG specifically dedicated to IC-ECG. Also, long before the development of Sherlock-3CG, several clinical studies had already shown that IC-ECG was more accurate than chest X-ray in terms of tip location. Furthermore, intra-procedural methods of tip location such as IC-ECG are considered to be more convenient and more cost-effective than post-procedural methods. Finally, comparing IC-ECG with fluoroscopy (both

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<thead>
<tr>
<th>Method</th>
<th>Feasibility</th>
<th>Accuracy</th>
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<tr>
<td>Sherlock-3CG®</td>
<td>120/128 (94%)</td>
<td>120/120 (100%)</td>
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<tr>
<td>Ultrasound</td>
<td>130/130 (100%)</td>
<td>130/130 (100%)</td>
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<tr>
<td>Nautilus®</td>
<td>128/128 (100%)</td>
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*Compared to chest X-ray.*

**Discussion**

The performance of Sherlock-3CG has been explored in different papers in the past 5 years. In a 2014 observational study on 239 patients, the use of the device was associated with a very high incidence of malpositions (20.5%), although apparently this result was an improvement over the authors’ previous experience. Apart from some papers published on non-peer-reviewed journals, a few other studies have confirmed the effectiveness and cost-effectiveness of Sherlock-3CG tip location, when compared to intra-procedural landmark estimation with post-procedural radiologic tip location by chest X-ray, although all these papers share the bias of ascribing the clinical advantages to a specific device that adopts IC-ECG (i.e. Sherlock-3CG) rather than to the IC-ECG method itself. It is noteworthy that the IC-ECG technique has been used for many decades before the appearance of any monitor ECG specifically dedicated to IC-ECG. Also, long before the development of Sherlock-3CG, several clinical studies had already shown that IC-ECG was more accurate than chest X-ray in terms of tip location. Furthermore, intra-procedural methods of tip location such as IC-ECG are considered to be more convenient and more cost-effective than post-procedural methods. Finally, comparing IC-ECG with fluoroscopy (both
intra-procedural methods for tip location), IC-ECG is recommended as safer and less expensive. In other words, there is robust evidence that IC-ECG should be the first option as the tip location method, regardless of the choice of performing it with a standard ECG monitor or with a dedicated ECG monitor.

Therefore, the really unsolved issue is whether any dedicated ECG monitor might have advantages over standard ECG monitors. This contention is still to be solved. In a multicenter study on IC-ECG in pediatric patients, the use of a dedicated ECG monitor (Nautilus) was associated with a better clinical performance when compared to standard ECG monitors, although this observation was not based on a randomized controlled comparison.

As far as we know, no study has ever compared the performance of Sherlock-3CG with another standard or dedicated ECG monitor.

Also, no study has ever compared magnetic-based tip navigation with ultrasound-based tip navigation or with ECG-based navigation, currently available with some dedicated ECG monitors. In a 2013 study, Sherlock-based tip navigation was more effective than no intervention—although the study had several biases, the main one being confusion between the concept of “tip location” and “tip navigation.”

In our study, we tested the safety, feasibility, and accuracy of Sherlock-3CG, both in terms of tip navigation and tip location. The use of the device was absolutely safe, as it was not associated with any kind of direct or indirect adverse effects.

As regards tip navigation, feasibility was 81% (105 cases out of 130). This limited feasibility was probably due to the high sensitivity of the system to many different disturbing environmental factors and the need for calibration (which may not be easy to set up). In our study, the magnetic sensor shield was also associated with some potential practical problems: the forced position of the neck of the patient may explain the high rate of malposition in the internal jugular vein found in this study (19%; much higher than in our previous experience without Sherlock-3CG). Also, the presence of the shield may be an obstacle to the maneuvers for redirecting the catheter. On the contrary, the accuracy of tip navigation—checked by a comparison with ultrasound—was 100%, since there were no false-positive and false-negative results.

The IC-ECG tip location with Sherlock-3CG was feasible in 94% (120 out of 128 cases); its accuracy for tip location was 100%, both when compared to Nautilus and when compared to post-procedural chest X-ray. Similar results were obtained either considering the carina criteria or the sweet spot criteria. Interestingly, although there was a perfect match between the study device and the control device in terms of IC-ECG, Nautilus had a 100% feasibility; it was easier to use than Sherlock-3CG and—in most cases—it offered an ECG trace which was more stable, less prone to artifacts, and of easier interpretation. The main practical problem experienced during our study with Sherlock-3CG was the complex calibration of the device and its high sensitivity to many possible sources of electromagnetic interference. This apparently affected the performance of the device, reducing the feasibility of tip navigation and tip location.

As limitations of our study, we mention the fact that the choice of Nautilus as a control device might be regarded as arbitrary; this is obviously true, but we thought it is appropriate to choose a dedicated ECG monitor rather than a non-dedicated ECG monitor, and we decided to select the dedicated ECG monitor characterized—in our experience—by the best performance in terms of feasibility and accuracy.

Conclusion

Our study has not identified specific advantages in the clinical use of Sherlock-3CG. While our data report a 100% safety and a 100% accuracy of both tip navigation and tip location, the feasibility of tip navigation was only 81% (compared to the 100% feasibility of ultrasound-based tip navigation) and the feasibility of tip location was 94% (while tip location with Nautilus was feasible in 100% of cases).

Also, a major problem is the limited applicability of the device. While the IC-ECG technique per se (both using non-dedicated ECG monitors and dedicated ECG monitors such as Nautilus) is applicable to all types of central venous access devices, of any brand, and to any population of patients, as long as there is a visible P wave on the surface ECG, the IC-ECG technique performed with Sherlock-3CG is applicable only to adult patients, only to PICCs, and—more specifically—only to specific types of PICCs marketed by a specific company.

Finally, although the evaluation of cost-effectiveness was not among the endpoints of our study, some generic comments are required: (a) the overall cost-effectiveness of Sherlock-3CG for tip navigation—when compared to current methods for detecting a wrong direction (ultrasound (US) scan, ECG navigation, etc.)—is probably very poor, considering the higher cost of the PICCs specifically needed, the higher complexity of the device, and its poor performance; (b) the overall cost-effectiveness of Sherlock-3CG for tip location with IC-ECG—when compared to Nautilus or to other dedicated or non-dedicated ECG monitors—might also be questioned, considering the higher cost and the higher complexity in setting and operating the system, while the results are similar or slightly worse. Further controlled studies should be directed to evaluate the cost-effectiveness of Sherlock-3CG for tip navigation compared with ultrasound-based tip navigation and/or ECG-based tip navigation, currently available with some dedicated ECG monitors (Nautilus Delta®, C. R. Bard/BD; Pilot®, Vygon); also, it would be interesting to compare the cost-effectiveness of Sherlock-3CG for tip location compared with IC-ECG tip location using standard ECG monitors or other dedicated ECG monitors.
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M.P. and G.C. conceived the study, and participated in its design. All the authors performed the insertions and collected the data. M.P. and G.S. were in charge of the analysis and interpretation of data, and prepared the manuscript. All authors read and approved the final manuscript.

Declaration of conflicting interests

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