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REVIEW

The electrocardiographic method for positioning the tip of central venous catheters

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ABSTRACT:
Tip position of a central venous access is of paramount importance and should be verified before starting infusion. Intra-procedural methods for verifying the location of the tip are to be preferred, since they avoid the risks, delays and costs of repositioning the tip. Among the intra-procedural methods, the electrocardiography (EKG) method has many advantages since it is as accurate as fluoroscopy, but simpler, more readily available, less expensive, safer and more cost-effective. The only contraindication to utilizing the EKG method is the difficulty in identifying the standard P-wave on a surface EKG (this happens - usually because of severe arrhythmias, such as atrial fibrillation - in only approximately 7% of cases: although such patients are easily identified before the procedure, and are referred to other methods for tip positioning). When dealing with the insertion of peripherally inserted central catheters (PICC), the EKG method (using the column of saline technique) virtually has no risk of false positives. The EKG method removes the need for the post-procedural chest x-ray, as long as there is no expected risk of pleuropulmonary damage to be ruled out (example: ultrasound guided central venipuncture for central venous catheter insertion or any kind of PICC insertion). In conclusion, evidence is mounting that the EKG method may be a valid and cost-effective alternative to the standard radiological control of the location of the tip of any central venous access device (VAD), and that will rapidly become the preferential method for confirming the tip position during PICC insertion.

Key words: Intracavitary EKG, Malposition, Tip position, Central venous catheters, Peripherally inserted central catheters

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Accurate control of tip position: a major concern for central venous access

There is no widespread agreement in the literature regarding the correct position for the tip of a central venous catheter (CVC) (1). Traditionally, most recommendations from the USA such as those from the AVA (formerly NAVAN) and from the FDA (2-4) state that the tip should be positioned in the lower third of the superior vena cava, while European guidelines (5, 6) often consider the position of the tip in the upper part of the atrium as acceptable.

Although when approaching the veins in the region of the superior vena cava, regardless of the type of technique used (venesection or percutaneous puncture) and of the choice of access vein (brachial, basilic, internal jugular, subclavian, external jugular, etc), most US and European experts agree that the most suitable position for the tip of a CVC is anywhere between the lower third of the superior vena cava and the upper region of the right atrium. In particular, the optimal site might be close to the junction between the superior vena cava and the right atrium. However, it should be emphasized that the evaluation of the optimal site may vary significantly, depending on the type and function of the central venous access (for example, the tip of a long-term access for parenteral feeding or chemotherapy should be positioned preferably in the lower third of the superior vena cava, whereas the distal end of a dialysis catheter should be positioned in the atrium, etc).

If the tip of the catheter is placed too "high" (in the middle third or the upper third of the superior vena cava, or in the brachiocephalic or in the internal jugular or in the subclavian vein), there is an increased risk of malfunction (7) and/or venous thrombosis (8). If the tip is positioned too "low" (right atrium, right ventricle or inferior vena cava), there is a risk of arrhythmias, heart cavity lesions, tricuspid valve dysfunction or lesions, or thrombosis (9-11).

In detail, "primary" malpositions that occur during implantation (the "secondary" ones are when the catheter tip migrates spontaneously in the weeks or months follow-

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ing implantation) can be classified as follows:

1. tip in the ipsilateral internal jugular/subclavian vein: so called <u>"high" malposition</u>, typically after the insertion of the catheter in the subclavian or internal jugular, due to the catheter failing to enter the brachiocephalic vein;
2. tip in the contralateral brachiocephalic/jugular/subclavian: <u>"low" malposition</u>, due to the catheter failing to enter the superior vena cava;
3. tip in the middle third or upper third of the superior vena cava: <u>"short" catheter</u>; note that a short catheter is also frequently associated with the occurrence of "secondary malposition" or "tip migration" (12);
4. tip in middle third or lower third of the right atrium, or in the right ventricle, or in the suprarenal or inferior vena cava: <u>"long" catheter</u>;
5. catheter tip in secondary or anomalous vessels (azygos, hemiazygos, internal mammary vein, etc): quite rare.

The overall incidence of these "primary" malpositions varies from 2-30% with a wide range due to the different implantation techniques used and the variability of the criteria for defining and verifying any possible malposition. Clinical experience suggests that peripherally inserted central catheters (PICCs) are associated with the higher risk of malposition than standard CVCs (13), and that insertion in veins on the left side is more frequently associated with malposition if compared to insertion on the right side.

Methods that may reduce the risk of malpositions

In order to minimize the incidence of primary malpositions, it is important to choose the appropriate implantation technique, and particularly the venous access route. Generally, insertions made via brachial venipunctures (brachial, cephalic, basilic, or axillary veins at the arm) or via infraclavicular venipunctures (axillary, subclavian veins) carry a higher risk of malposition if compared to insertions performed via supraclavicular venipunctures (subclavian, brachiocephalic, internal jugular veins). However, supraclavicular venipuncture protects, to a certain degree, from the risk of the catheter following an "abnormal" direction (for example, towards the contralateral brachiocephalic vein), but does not protect from the risk of a catheter being too short or too long.

As a matter of fact, during insertion, some methods may significantly reduce the risk of a catheter being too short or too long; although none of these methods protects against the risk of the catheter taking an "abnormal" direction (ie outside the brachiocephalic-cava axis). Examples of such methods are:

– estimation of the expected length of the catheter using topographical anatomy landmarks;
– use of algorithms based on some anthropometric data of the patient (height in adult patients; weight in infants) (14).

On the other hand, some other methods may help the operator to direct the catheter along the correct route (ie towards the superior vena cava), although they do not have any value in determining the correct length of the catheter: at the end of the procedure, the final position of the tip might be too high (upper third of the superior vena cava) or too low (atrium, inferior vena cava, ventricle). Examples of such methods are:

– use of specific tracking devices, mainly adopting electromagnetic technology (Navigator, Viasys; Sherlock, Bard, Cath-Finder, Pharmacia Deltec), sometimes used during PICC insertion (14, 15);
– routine adoption of CVC insertion techniques with low risk of malposition (for example, ultrasound guided venipuncture of supraclavicular veins, preferably on the right side);
– intra-procedural use of ultrasound for ruling out misdirection of the catheter (for example, ultrasound scanning of the internal jugular vein during PICC insertion to rule out an abnormal "upward" direction of the catheter);
– threading the catheter deeper than the expected length, until arrhythmias occur (obviously, such a method is significantly dangerous for the patient and should be abandoned; nonetheless, it has been described and in use for years).

Available methods for an accurate control of tip position

All the above methods may reduce the risk of malposition but cannot accurately verify the location of the tip. On the other hand, many intravenous infusions (vesicant drugs, drugs with pH >9 or <5, hyperosmolar solutions, etc) can be safely delivered through a central catheter only after the position of the tip has been accurately verified and documented. Therefore, it is necessary to adopt a methodology that simultaneously allows us to check the *correct direction* and *the correct length,* with reasonable accuracy.

This may be achieved <u>at the end of the procedure</u> using various imaging techniques, such as MR, CT scan, standard trans-thoracic echocardiography, or TEE (trans-esophageal echocardiography). The most commonly used "post-procedural" method (and one of the most cost-effective) is the standard post-procedural chest x-ray. A standard P-A film is appropriate to ascertain the exact position of the tip, with few false negatives (mainly due to technical problems and/or x-ray artifacts) and very few false positive results (for example, position of the tip in the internal mammary vein or in the hemiazygos). On the other hand, it is obvious that the post-procedural diagnosis of malposition requires the repositioning of the venous access (a further procedure which implies logistical problems and significant costs).

Historically, the suitability of radiographic control was also based on the need to exclude pleura-pulmonary complications. However, currently many CVCs are positioned using approaches that exclude the risk of this type of complication (brachial approach) or that minimize it (ultrasound guided central venipuncture).

It is interesting to note that three important guidelines dealing with the problem of central venous catheters in parenteral feeding - the *American Society of Parenteral and Enteral Nutrition* (ASPEN) (16); the *Società Italiana di Nutrizione Parenterale ed Enterale* (SINPE) guidelines (17); the *European Society of Parenteral and Enteral Nutrition* (ESPEN) guidelines (6) - state that radiological control after central venous catheterization should be considered essential only (a) if an implantation technique that involved a risk of pneumothorax was used and/or (b) if the position of the tip of the catheter was not verified via other methods during the procedure itself. This implies that the combination of a method that has zero risk of pleura-pulmonary complications (for example, positioning of a PICC or positioning a CVC via ultrasound guided puncture of the internal jugular vein) plus an intra-procedural method for checking the tip of the catheter would make post-procedural radiological controls superfluous.

However, checking the position of the tip of the catheter <u>during the procedure</u> is preferable to a post-procedural control (6). During catheter insertion, the correct position of the catheter tip can be checked by three different methods:
– intra-operative fluoroscopy and/or intra-operative control radiography;
– standard trans-thoracic echocardiography or trans-esophageal echocardiography;
– the electrocardiographic method (intracavitary EKG).

In this field, radiological methods have often been considered as the “gold standard” even though they have many disadvantages, such as:
– exposure of the patient and staff to radiation;
– high costs;
– logistical problems related to the availability/transportability of the equipment and the availability of a radiology technician and/or radiologist;
– possible errors in interpreting the radiological image;
– variability of the image of the catheter tip position depending on the position of the patient (orthostatic vs. supine vs. Trendelenburg position).

A potential advantage of the radiological methods lies in the theoretical possibility of simultaneously checking the position of the catheter and the possible presence of pneumothorax or acute pleura-pulmonary lesions. There are, however, some specific objections to this:
– the intra-procedural radiological control (or the control performed just after the procedure) does not totally exclude the presence of pneumothorax, considering the current increase, widely reported in the literature, in the incidence of delayed pneumothorax occurring 12-24 hr after implantation;
– the adoption of ultrasound guided venepuncture - now universally recommended - virtually eliminates the risk of acute pleura-pulmonary lesions;
– an ultrasound exam of the pleura - performed with the same probe used for ultrasound guided venepuncture - can rule out the presence of pneumothorax more accurately than a standard chest x-ray, by checking the presence of the so called “sliding sign”;
– some central venous approaches (ie PICC insertion) are not associated with any risk of pleura-pulmonary complications.

In addition, many authors have recently suggested that chest x-ray and chest fluoroscopy are not 100% accurate in detecting the actual position of the catheter tip: studies carried out using more accurate imaging methodologies such as MR and trans-esophageal echocardiography have shown that the “traditional” radiological landmarks of the cavo-atrial junction are not reliable (18-20).

Intra-procedural ultrasound monitoring of the position of the catheter tip is currently not a standardized method. Trans-thoracic echocardiographic control requires specific know-how on the part of the health operator and can often be difficult (for example, for an indirect visualization of catheters in the superior vena cava it may be necessary to adopt special techniques such as the use of some echogenic contrast media). On the other hand, the performance of trans-esophageal echocardiography - possibly the most accurate method of all (21, 22) - is associated with excessive invasiveness and high costs.

The other option for intra-procedural control of the catheter position is electrocardiography. The so called ‘EKG method’ was first described 60 yrs ago, in 1949 (23) and after the first experiences in the 1960s (24, 25), it was accepted in clinical practice in the 1980s (26-30).

At present, the EKG method is currently widely used in Europe (specifically in Germany and in Italy) for positioning the tip of different types of central venous access devices (22, 31-43); in a few cases, the method has also been tested in neonates (44-47), for positioning the tip of umbilical catheters and epicutaneo-caval catheters.

Description of the EKG method

The EKG method uses the catheter itself as an intracavitary (endovascular) electrode. This can occur with two different techniques:
a) the so called “<u>metal guidewire technique</u>”; intracavitary electrode = metal guidewire inserted inside the catheter;
b) the so called “<u>column of saline technique</u>”; intracavitary electrode = column of fluid (physiological saline

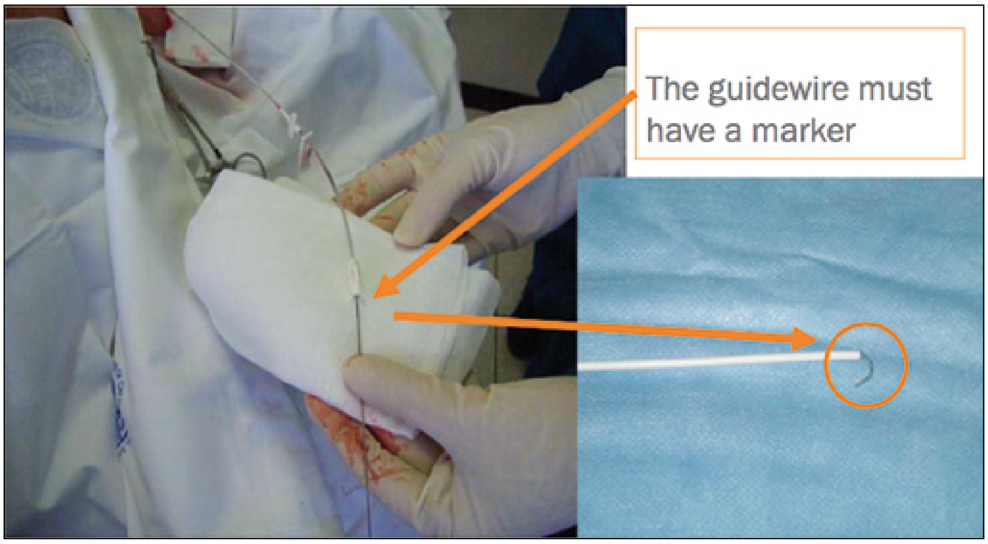

Fig. 1 - *Metal guidewire technique: the guidewire must be pre-marked so that it is possible to know exactly when the J of the guidewire protrudes from the tip of the catheter.*

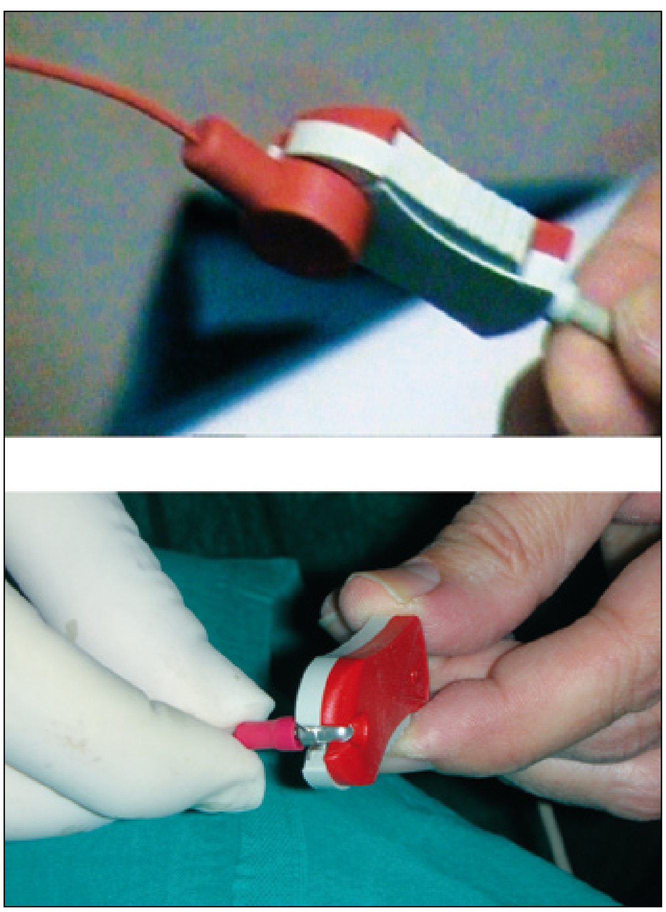

Fig. 2 - *Direct connection between the red electrode ("right shoulder" electrode) and the cable (upper box: Vygocard cable, Vygon; lower box: cable from Romedex).*

solution) contained in the catheter (48-52).

For centrally inserted catheters, it is usually possible to use both methods, according to choice. For PICCs, only the saline column option is commonly available.

Metal guidewire technique

The metal guidewire technique is easily feasible only with CVCs specifically designed for this purpose: the catheter and its guidewire must be pre-marked so that it is possible to know exactly when the J of the guidewire protrudes from the tip of the catheter.

Once the chosen vein has been punctured and the guidewire threaded through the needle (according to the standard Seldinger technique), the needle is removed and the catheter is inserted over the metal guidewire, until the marking on the latter is level with the proximal end of the catheter. This corresponds to the protrusion of the "J" from the tip, which will allow the intracavitary electric potential to be recorded (Fig. 1).

The signal differences recorded as the catheter advances through the superior vena cava towards the right atrium will show up as variations in the height of the P-wave.

The metal guidewire is connected via the connector cable to the "red" electrode of the EKG monitor, which is the electrode usually placed on the right shoulder of the patient. This can be done either directly (via an appropriate cable) (Fig. 2) or indirectly (by connecting both the electrode and the cable to a commuter In the latter case, the red electrode is connected to the commuter and this is in turn connected to an electrode placed on the right shoulder (Fig. 3); the signal can thereby be recorded on the monitor and thanks to the commuter it is possible to shift from surface EKG to intracavitary EKG at any time.

The DII lead (right shoulder - left leg) should be used, since in this lead the variations of the P-wave are particularly evident (the electric axis of the right atrium is oriented similarly to the DII axis in Einthoven's triangle). The cables are inexpensive and available through several companies (BBraun, Teleflex, Romedex) and the commuter is easily available and offered by BBraun (Certo-

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Fig. 3 - *Indirect connection: the red electrode is connected to the commuter and this is in turn connected to an electrode placed on the right shoulder.*

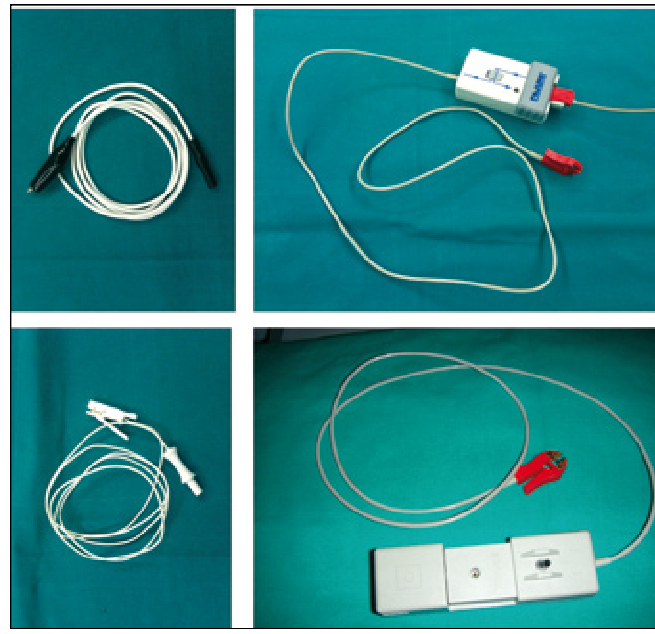

Fig. 4 - *Cables and commuters more commonly used: Teleflex cable (upper left), Pajunk-Teleflex commuter (upper right), BBraun cable (lower left) and BBraun commuter (Certodyn) (lower right).*

dyn) or by Teleflex (Pajunk) (Fig. 4).

The correct reading of the P-wave variations can be influenced by many technical factors, such as:

- the position of the electrodes (which must be standardized);
- the choice of the most appropriate voltage on the monitor display (one should choose the amplitude that best magnifies the P-wave variations);
- the choice of monitoring mode (the "diagnostic" mode should be preferred, if such option is available on the monitor);
- the presence of other electro-medical devices in the proximity of the patient (it is advisable to turn off any device that is not essential; if possible, it is better to unplug them rather than just switch them off, or switch them to battery power).

The catheter and the metal guidewire should be advanced together carefully until a maximum P-wave height is recorded: this indicates that the CVC tip is at the entrance of the atrium (ie close to the crista terminalis, at the cavo-atrial junction). If the guidewire and catheter are retracted, a gradual reduction of the P-wave height is obtained, until the height is approximately half of the maximum P-wave height (this means that the tip is in the lower third of the superior vena cava, just above the cavo-atrial junction). If the catheter and the guidewire are retracted further, the P-wave reaches "normal" dimensions, ie similar to those of the P-wave on the "surface" or trans-parietal EKG, which indicates that the tip is back again in the upper part of the superior vena cava. However, if the guidewire is accidentally inserted deeper (which is potentially dangerous since it may cause arrhythmias), the P-wave progressively decreases and/or becomes diphasic (negative/positive) and then becomes overtly negative; usually, the appearance of a small negative incision before the standard positive wave is the first sign that the catheter/guidewire has entered the right atrium (Fig. 5). Although the detection of a maximal P is a constant finding, and is constantly associated with the cavo-atrial junction, the patterns of variation of the P-wave as the catheter/guidewire is pushed deeper downward are less constant and depend on several factors (most notably, whether the catheter enters the atrium or the inferior vena cava, and whether the DII axis and the right atrium axis are similarly oriented or not). The catheter is secured so that the tip remains in the desired location.

With minor variations, the same technique can also be used for long-term central venous access devices which require a modified ("indirect") Seldinger technique, such as large bore tunneled catheters or catheters meant to be connected to a totally implanted reservoir (of course,

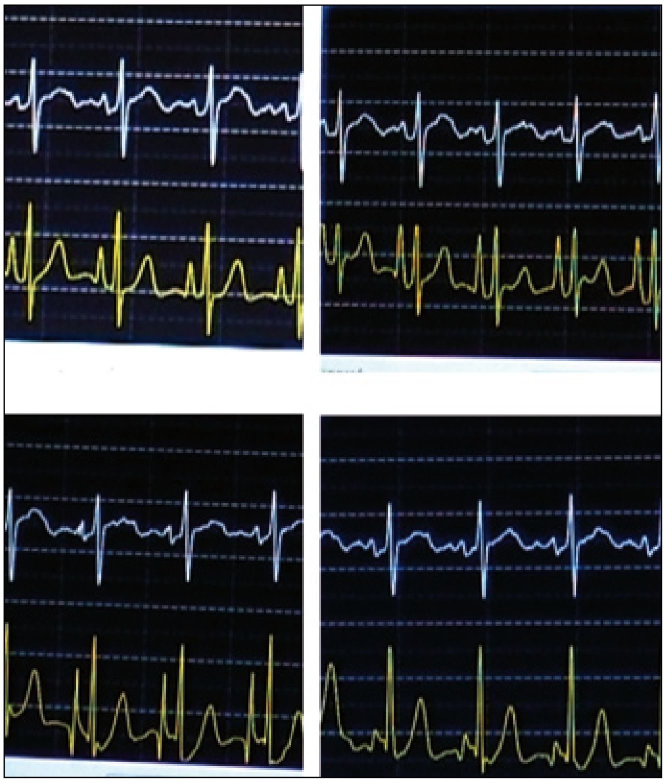

Fig. 5 - *Changes in P-wave while moving to and across the right atrium (intracavitary EKG = yellow line, lead II): increasing height (i.e. lower portion of the superior vena cava: upper left box), maximal height (i.e. cavo-atrial junction: upper right box), negative incision (i.e. upper portion of right atrium: lower left box), diphasic pattern (i.e. lower portion of the atrium: lower right box). The white line is the surface EKG (lead III).*

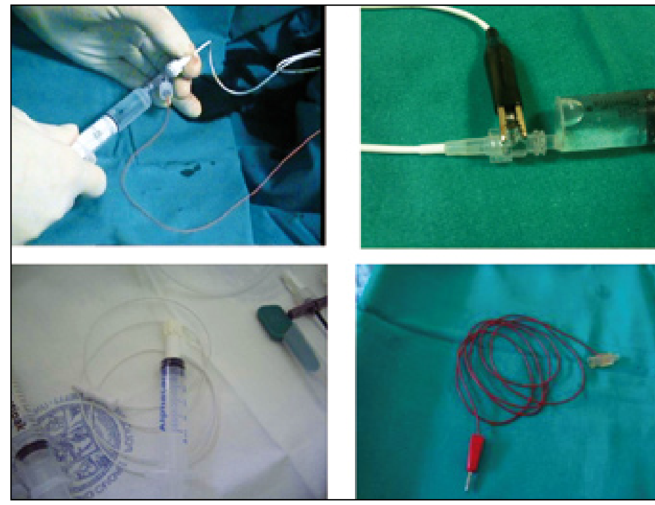

Fig. 6 - *Commercially available transducers for the saline technique: VygoCard (Vygon), upper left; Arrow-Johanns (Teleflex), upper right; AlphaCard (BBraun), lower left; saline adapter (Romedex), lower right.*

if they are designed for this purpose). In such cases, according to the modified Seldinger technique, an introducer-dilator is inserted over the metal guidewire. Once the dilator has been removed, the catheter is inserted over the metal guidewire until the marking on the metal guidewire is level with the proximal end of the catheter. The catheter, mounted on the guide, is then reinserted in the introducer. The positioning of the catheter level with the black markings on the metal wire corresponds to the protrusion of the "J" from the tip, which will make it possible to record the intracavitary electric potential. The desired position of the catheter tip is defined as described above. The introducer is then withdrawn and the catheter is secured so that the tip remains in the desired location, recording the distance in centimeters (read on the actual catheter) while the housing is prepared for the reservoir.

Column of saline technique

In this case, the intracavitary electrode is the column of saline contained in the catheter, and not the metal guidewire. The main advantage of the column of saline technique is that it can be applied to any central venous access device, even if not specifically designed for this purpose.

Once the chosen vein has been identified and incannulated, the catheter is inserted over its metal guidewire (direct Seldinger method: standard CVCs) or - after having removed the guidewire and dilator - inside the introducer (indirect Seldinger method: PICCs, tunneled catheters, totally implanted VADs (venous access device). The catheter is threaded only partially into the venous system. After removing the metal guidewire (direct Seldinger) and/or the introducer (indirect Seldinger), the catheter - filled with saline - is connected proximally to a cable which is connected directly to the "red" line of the EKG monitor or indirectly, by means of a commuter, exactly as described for the metal guidewire method. The connection between the saline-filled catheter and the EKG monitor can be achieved in a number of ways: using specific transducers marketed for this purpose (AlphaCard, BBraun; VygoCard, Vygon; Saline Adapter, Romedex; Arrow-Johanns Adapter, Teleflex) (Fig. 6), using cables with clips which can be attached to the stylet of the catheter (Fig. 7), etc.

At this point, the catheter is advanced further into the venous system. The differences in signals recorded as the catheter advances through the superior vena cava towards the right atrium will show up as variations in the width of the P-wave. In the case of closed-ended valved catheters (ie Groshong catheters, Bard), a continuous infusion of saline solution through the catheter (using a hand-activated syringe) will be necessary, in order to keep the valve open and read such signal differences. The interpretation of the variations of the P-wave follows the same scheme described for the metal guidewire technique. In the end,

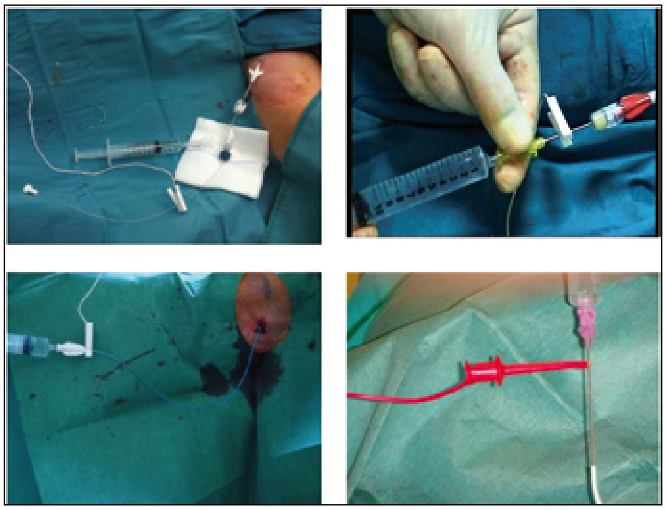

Fig. 7 - *Saline technique using cables with clips: BBraun cable clipped to the stylet of a VascuPICC (Medcomp) (upper left); BBraun cable clipped to a needle inserted in the catheter through a perforable cap (upper right); BBraun cable clipped to the stylet of a Groshong PICC (Bard) (lower left); PaceViewer cable connected to a needle directly inserted in a silicon catheter (lower right).*

the catheter is then secured so that the tip remains in the desired location.

Clinical experience suggests that the column of saline technique has several advantages over the marked guidewire technique:

– it can be applied to any central VAD, even if not specifically designed for the EKG method;
– it can be applied even to closed-ended valved catheters;
– it is safer, since the procedure is performed moving a catheter - and not a guidewire - into the venous system;
– it is more precise, since the tip of the catheter and the tip of the intracavitary electrode coincide. On the contrary, in the guidewire technique the "J" might be deeper - 1 cm or more - than the actual tip of the catheter; and therefore, the depth of the catheter may be overestimated.

Recently, several devices have been proposed in order to standardize the EKG method and make it even simpler and easier to use. One of these devices is the Sapiens Tip Locator System (Sapiens TLS, Romedex); it consists of a piece of hardware (a small box with cables connecting it to a PC and to the EKG electrodes) plus software (which is installed on a laptop) (Fig. 8). Advantages of the Sapiens TLS are that it can be used on any VAD (since it uses the saline technique); it displays simultaneously both the surface and the intracavitary EKG (ie there is no need of a commuter); the detection of P-wave changes is easy ("freezing" of the screen helps in detecting P changes when advancing the tip); it allows a final documentation of tip position, by printing a label containing the intracavitary EKG tracking (Fig. 9).

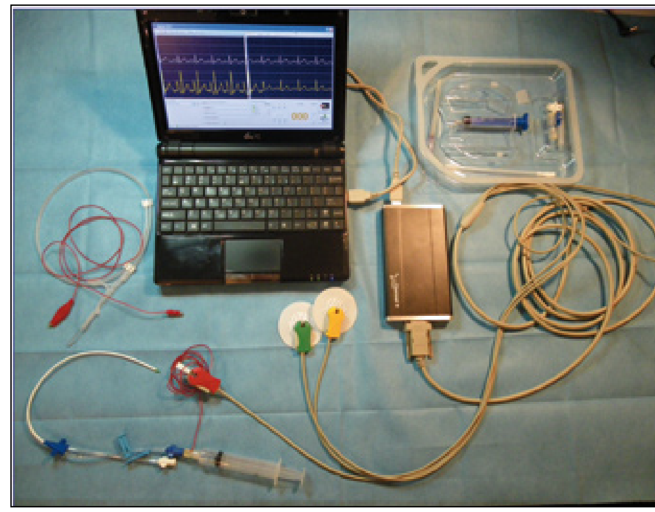

Fig. 8 - *Sapiens Tip Locator System (Romedex).*

Fig. 9 - *Final documentation of tip position, by means of a printed label showing the intracavitary EKG tracking (Sapiens TLS, Romedex).*

Our experience with PICCs

The EKG method has been used for intra-procedural location of the tip of central VADs in our institution (Catholic University Hospital, Rome, Italy) since the late 1980s, mostly utilizing the guidewire technique. In the 1990s, the method was applied almost exclusively to non-tunneled short-term CVCs and to totally implantable ports already prepared for such a technique (ie BBraun kits containing the pre-marked guidewire). In a retrospective review carried out in 2001 (unpublished data), we found that several hundred catheters had been implanted in our institution using this method, although in most cases a post-procedural chest x-ray was also performed for documentation purposes. As expected from the literature, in this large series no complications related to the method itself could be reported. The EKG method was found to be applicable in 93% of patients (7% accounting for patients who had no clear and evident P-wave recognizable at the baseline EKG tracking). In 1% of patients, although the P-wave was apparently normal at the baseline EKG, the intracavitary EKG did not show any significant variation in its height, while the post-operative chest x-ray showed no evidence of malposition. The reason for such rare "false negative" cases is difficult to explain, although it might be sometimes related to an inappropriate placement of the electrodes or to vascular abnormalities. No false positive was observed.

In recent years, soon after the start of a vast program of implementation of PICC usage in our hospital (53) and more generally in Italy (54), our attention has focused on the possibility of utilizing the EKG method - adopting the so-called "column of saline" technique –- also for verifying the position of the tip of PICCs. Since 2007, our group has standardized the application of the EKG method - constantly adopting the technique of the column of saline, although utilizing different types of cables - to the intra-procedural location of the tip of any central venous access, either centrally or peripherally inserted (non-tunneled CVC, tunneled CVC, port, PICC). Patients with EKG abnormalities of the P-wave (approximately 7% of our hospitalized patients) were excluded. It is interesting to stress that - although the EKG method has been quite popular in German-speaking countries since the 1980s - our group reported the first clinical experience of the application of the method to PICCs.

The first two studies in this field were presented by our group at the 2008 Meeting of the Infusion Nursing Society in Phoenix and at the 2008 Meeting of the European Society of Intensive Care Medicine in Lisbon; a summary of both studies was published in the Journal of the Association for Vascular Access in 2008 (55). The first study (56) investigated the EKG method in 12 consecutive insertions of open-ended PICCs: at a post-procedural radiological control, no malpositions were observed. The second study was carried out in six closed-ended Groshong PICCs, with similar results, although one patient was excluded because of electrical artefacts (57). A third study - presented at the 2008 Meeting of the IV Therapy Forum of the Royal College of Nursing in Cardiff - was carried out in 35 consecutive insertions of both open-ended and closed ended PICCs: the appropriate tip position was confirmed by a post-procedural chest x-ray in all cases; no malposition was observed (58). Finally, a fourth study from our group was presented at the 2009 Meeting of the Association of Vascular Access in Las Vegas: 114 consecutive central venous access devices (67 CVCs + 47 PICCs) were positioned by ultrasound guided venipuncture and EKG-guide location of the tip: there were no insertion-related complications; post-procedural chest x-ray showed that all catheter tips were at the desired location (59). All four studies were exclusively carried out utilizing the column of saline technique. Consistently, there was no complication directly or indirectly related to the EKG method. In addition, no false positives and no false negatives were observed.

A recent clinical trial carried out in the USA on 417 PICCs (60) has confirmed our experience, demonstrating the accuracy of the EKG method in verifying the central position of the tip of peripherally inserted central catheters.

In 2009, the Italian Group for Long Term Venous Access Devices (GAVeCeLT) started a multicenter national study on the EKG method which included our center plus eight other centers in different Italian hospitals, enrolling 1,440 central VADs (including 245 PICCs). This multicenter study addressed specifically the issues of accuracy, safety and reproducibility of the EKG method for locating the tip of central venous access, confirming it as a cost-effective alternative to the radiological methods (intra-procedural fluoroscopy and/or chest x-ray; post-procedural chest x-ray) (61).

In 2010, GAVeCelt designed a "bundle" for the safe insertion of PICCs (the so-called SIP protocol), which includes the EKG method as one of the requirements for a complication-free insertion of PICCs.

Advantages of the EKG method

The advantages of the EKG method include (21, 22, 31, 32, 34-36, 49, 55):

– It is safe for the patient:
  - it implies a continuous EKG monitoring during the procedure increasing the overall safety of the procedure.
  - The risk of iatrogenic arrhythmias, usually due to the mechanical stimulation of the wall of the atrium, is completely avoided, since the operator moves into the venous system knowing exactly when the catheter is approaching the atrium.
  - The column of saline technique is obviously even safer than the guidewire technique in this regard, since the atrium is entered by a soft catheter and not by a metal guidewire.
  - As long as the EKG monitor is protected against the risk of electric hazards (as all monitors must be), there is no risk of electrical shock related to performing an intracavitary EKG reading.

– If adopting the column of saline technique, the method can be applied to any type of central venous device (short-term CVC, PICC, dialysis catheters, long-term VADs, ports, etc), both with an open-ended or closed-ended tip. In the case of double lumen dialysis catheters, it can be used for an accurate and simultaneous

check on the position of both tips (38).
- It can be utilized in the vast majority of patients candidates for central venous access, with the only exception of those clinical conditions where the P-wave cannot be recognized on the standard "surface" EKG (ie atrial fibrillation, atrial flutter, etc); although some clinical experiences suggest that the EKG method may also be adopted in patients with atrial fibrillation (62), considering that the baseline pattern of the intracavitary EKG tracking changes significantly when the catheter/electrode enters the fibrillating atrium. In a pilot study carried out in our center (unpublished data), the EKG method - as performed with a Sapiens TLS, which offers not only the wave form pattern of EKG, but also the total amount of electrical energy recorded by the electrode - was effective in positioning the catheter tip at the cavo-atrial junction in 15/16 atrial fibrillation patients.
- The method is accurate:
    - Many papers from the last 20 yrs have proven the EKG method to be as accurate as the radiological methods, considering that the "gold standard" of accuracy is possibly the TEE, which cannot be routinely adopted because of its invasiveness. In fact, the accuracy of intra-procedural fluoroscopy and of post-procedural chest x-ray is not 100%, since many factors may alter the interpretation of the radiologic image (artefacts, errors of perspective, technical difficulties, etc), leading to a significant incidence of false positive and false negative diagnoses.
    - The occurrence of "false positives" has been described with the EKG method only in a few rare cases (63, 64):
    - false "atrial" P-wave, secondary to a catheter whose tip was positioned in the pleural space or in the arterial system, although close enough to the atrium wall;
    - false "atrial" P-wave, secondary to a guidewire inserted through the left central veins and stuck into the lateral wall of the superior vena cava, close to the pericardial reflection which surrounds it: this may transmit electrical signals from the atrium and be interpreted as a maximal P-wave.

Both situations are extremely rare. The first is exclusively related to the use of a "blind", non-ultrasound guided venipuncture during CVC insertion. The second seldom occurs using the column of saline method, since it is mainly related to the stiffness of the guidewire; furthermore, this false positive can be easily prevented by checking the presumed distance between the exit site and the cavo-atrial junction by standard anthropometric methods, before the procedure: when a "high" P-wave is detected earlier than expected, the catheter should be threaded deeper, so as to differentiate between a "high P-wave" due to the pericardial reflection effect vs. the "maximal P-wave" associated with the entrance into the atrium.

- It is quick and easy to perform, adding only a few minutes to the procedure (as opposed to the time consuming control by intra-procedural fluoroscopy).
- It is easy to teach and easy to learn; training the health operator to recognize the P-wave and the variation of its height is very simple if compared to training in the use and interpretation of radiological imaging.
- It allows a "real time" verification of the position of the tip during the procedure, avoiding resorting to post-procedural repositioning maneuvers (complicated, expensive and potentially risky). Intra-procedural verification can also be achieved by other methodologies (fluoroscopy, etc) which are certainly more expensive, less safe, longer and logistically more demanding if compared to the EKG method.
- In many instances (short-term CVCs, dialysis catheters, PICCs), the EKG method can be applied not only during insertion, but also days, weeks or months after insertion, for example, in order to verify that the tip has not migrated and is still in the correct position.
- Tip location can be easily documented in the patient's chart, ie by attaching a print-out of the intracavitary EKG reading corresponding to the final position of the tip. Some devices (Sapiens TLS, Romedex) are already equipped with software which prints a label for the patient's chart, containing relevant data related to the insertion as well as the EKG tracking documenting the atrial P-wave as recorded in the final position of the tip.
- It can be applied in clinical situations where radiological verification is contraindicated (pregnancy) or logistically difficult (PICC insertion at home or in a hospice).
- It is inexpensive: it can be performed with minimal costs (cable, wires, transducer and the availability of an EKG monitor), especially if compared to intra-procedural fluoroscopy.
- It saves money. Intra-procedural verification of the position of the tip avoids expensive and time-consuming maneuvers related to the repositioning of a catheter whose malposition has been diagnosed on a post-procedural chest x-ray. In addition, medical societies of anesthesiologists - see the German Association of Anesthesia (65) - and recent international guidelines (6) have advocated the EKG method as a valid alternative to radiologic verification of the position of the tip of central venous lines: this implies the possibility of avoiding a post-procedural chest x-ray (which carries a low but significant cost, as well as logistical problems for the hospital and radiation exposure to the patient). A recent FDA document evaluating the Sapiens TLS (FDA, August 2010; available from the FDA website) has certified that the device is "indicated for use as an alternative method to chest x-ray and fluoroscopy for central venous catheter tip placement confirmation in adult patients".

CONCLUSIONS

Tip position is of paramount importance and should be verified before starting infusion on any central venous line.

Intra-procedural methods for verifying the location of the tip are to be preferred, since they avoid the risks, delays and costs of repositioning the tip. Among the intra-procedural methods, the EKG method has many advantages: it is as accurate as fluoroscopy, but simpler, more readily available, less expensive, safer and more cost-effective. In addition, it has the additional advantage of being applicable for post-positioning control of the tip (even weeks or months after insertion). The only contraindication for utilizing the EKG method is the difficulty in identifying the standard P-wave on a surface EKG (this happens - usually because of severe arrhythmias, such as atrial fibrillation - in only approximately 7% of cases: although such patients are easily identified before the procedure and referred for other methods of tip positioning); in conclusion, the EKG method is applicable - on average - to 93% of patients.

The EKG method removes the need for the post-procedural chest x-ray, as long as there is no expected risk of pleuro-pulmonary damage to be ruled out (example: ultrasound guided central venipuncture for CVC insertion or any kind of PICC insertion). As suggested by some authors (35, 66), the EKG method should be officially adopted as a replacement for the radiological methods for confirming the position of the tip and/or included in a “x-ray-free” bundle for central venous access insertion, which should also include anthropometric measurements, ultrasound venipuncture, ultrasound control of the direction of the catheter and ultrasound examination of the pleura to rule out pneumothorax.

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