The intracavitary ECG method for positioning the tip of central venous catheters: results of an Italian multicenter study

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ABSTRACT
Purpose: The aim of this multicenter study was to assess the feasibility, safety, and accuracy of the intracavitary ECG method for real-time positioning of the tip of different types of central venous catheters.

Methods: A total of 1444 catheter insertions in adult patients were studied in eight Italian centers (539 ports, 245 PICCs, 325 tunneled CVCs, 335 non-tunneled CVCs). Patients with no visible P wave at the standard baseline ECG were excluded. Depending on the type of catheter and its purpose, the target was to position the tip either (a) at the cavo-atrial junction, or (b) in the lower third of the superior vena cava, or (c) in the upper part of the atrium. The final position was verified by a post-procedural chest x-ray.

Results: The method was feasible in 99.3% of all cases. There were no complications potentially related to the method itself. At the final x-ray control, 83% of all tips were positioned exactly at the target; 12.4% were positioned within 1-2 cm from the target, but still in a correct central position; only 3.8% were malpositioned. The mismatch between intra-procedural ECG method and post-procedural x-ray was significantly lower when the x-ray was taken in supine position.

Conclusions: Our multicenter study confirms that the intracavitary ECG method for real time verification of tip position is accurate, safe, feasible in all adult patients and applicable to any type of short-term or long-term central venous access device.

Key words: Central venous catheters, Intracavitary ECG, Malposition, PICC, Port, Tip position

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INTRODUCTION

Verification of the correct position of the tip of central venous access devices (VAD) is of major importance because malposition, defined as a tip not located in the lower part of the superior vena cava (SVC) or in the upper part of the right atrium (1), is associated with a high risk of malfunction, venous thrombosis, vessel erosion, visceral and other complications (1-7). A tip location on the upper third of the superior vena cava, particularly if the VAD is inserted on the left side, is also dangerous, since the tip of the catheter may be stuck against the lateral wall of the SVC and cause local endothelial damage and venous thrombosis (8,9).

Tip position is often assessed at the end of the procedure by a standard chest x-ray. Historically, such radiologic control was also based on the need to rule out pleura-pulmonary complications. However, nowadays an increasing number of central VADs are inserted using approaches that exclude the risk of this type of complications (peripheral insertion at mid-arm) or that minimize it (ultrasound guided venipuncture).

The guidelines of the European Society of Parenteral and Enteral Nutrition (1) have recently stated that radiologic control after central venous cannulation should be considered essential only (a) if an insertion technique that entailed a risk of pneumothorax is used and/or (b) if the position of the tip of the catheter is not verified via other methods during the procedure. This implies that the combination of a method that carries zero risk of pleura-pulmonary complications (e.g. positioning of a central venous catheter by means of cannulation of an arm vein, or
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through ultrasound-guided cannulation of a central vein) plus an intra-procedural method for verifying the position of the tip would make post-operative radiologic controls superfluous (10-13). In addition, intra-procedural assessment of tip position would avoid the need to resort to post-operative repositioning maneuvers that may be complicated, expensive, and potentially risky.

Intra-procedural assessment of tip position can be attained by several techniques, such as fluoroscopy, trans-thoracic echocardiography (TTE), trans-esophageal echocardiography (TEE), and intracavitary electrocardiography (ECG). The most accurate intra-procedural method appears to be TTE (14,15), but it is obviously not cost-effective. TTE is accurate only when the tip is observed in the right atrium and it carries logistic issues that reduce its cost-effectiveness (12). Fluoroscopy carries some concerns in terms of safety (because of x-ray exposure) and is obviously not cost-effective for central VADs inserted bedside and not in the operating theatre or in the radiologic suite (12,16).

ECG has many potential advantages however: it is effective, inexpensive, safe, easy to perform, easy to teach, and easy to learn (12,13,17-25). The only major limit of the method is that it can be applied only when a P-wave is evident on basal ECG, which nevertheless includes the vast majority of patient candidates for VAD insertion. Nonetheless, ECG is not used as much as would seem reasonable, mostly because of some concerns in terms of its feasibility and accuracy if compared to radiologic methods.

The aim of this multicenter study was to assess the safety, feasibility, and accuracy of the intracavitary electrocardiographic method when positioning different types of VAD (short-, medium-, and long-term central venous accesses) in the adult patient.

MATERIALS AND METHODS

The study was proposed by GAVeCeLT, the Italian Group for Long-Term Venous Access Devices and designed as a prospective, multicenter, non-controlled study. Anesthesiologists and surgeons from eight Italian hospitals participated in the study: Bolzano Hospital (CB), Castelnovo ne’ Monti Hospital (Reggio Emilia) (BCM), Cremona Hospital (BC), University of Florence/Careggi Hospital (PF), University of Pisa (DSP), Catholic University Hospital in Rome (PUC), Fracastoro Hospital at San Bonifacio (SSB), Varese Hospital (BV). The study was coordinated by the center located at the Catholic University Hospital. Each center had at least one year of experience with the ECG method.

The study protocol was examined and approved by the Ethics Committee of the Catholic University of Rome as Ethics Committee for the Coordinating Center, and approved by all the other local Ethics Committees.

Aims of the study

The study was designed so as to assess the ECG method for positioning the tip of central VADs in adult patients, in terms of feasibility, safety, and accuracy:

- The feasibility of the ECG method in technical and operative terms, referring to the specific standardized methodology described below, was defined as the possibility of detecting an ‘atrial P-wave’ during the procedure.
- The safety was assessed in terms of incidence of potential rhythm disturbances or any other type of risk, for the patient or the operators, directly related to the performance of the ECG method.
- The accuracy of the method as regards the correct verification of the position of the catheter tip was assessed taking the post-procedural chest x-ray as the current standard for verifying tip position. In particular, the post-procedural radiological control focused on the incidence of malpositions and on the agreement between the position estimated by the ECG method and that assessed by the radiography.

Patients

All patients eligible for central venous catheterization were included in the study, regardless of the type of VAD (short-term non-tunneled VADs; medium-term non-tunneled VADs such as Hohn or PICC; long-term VADs, i.e. tunneled lines such as Groshong, Broviac or Hickman, or port-type implantable systems), with the only exclusion of catheters placed in the inferior vena cava district (via the saphenous or femoral), central venous catheters inserted in neonates and in pediatric patients, as well as patients for whom the P-wave could not be identified in the baseline ECG (non-sinus rhythm, atrial fibrillation, presence of pacemakers except for pacemakers “on request”, P not assessable because of extreme tachycardia, etc.). Short-term non-tunneled central venous catheters placed in emergency situations and double lumen catheters for dialysis and pheresis were included.

Thus, inclusion criteria were: (a) the need for one of the aforementioned VADs, (b) age > 18 years, (c) the possibility of obtaining written informed consent from the patient and (d) the evidence of a recognizable P wave on basal ECG.

The number of patients to analyze in order to verify the accuracy of the ECG method vs. the post-procedural chest x-ray was estimated to be equal or superior to 1200.

Venous access devices

The VAD was chosen in accordance with the protocols of each individual center. Devices were classified as follows: short-term central venous catheters, including non-tunneled dialysis catheters, inserted via direct central venipuncture (puncture in the chest/cervical area) (ST);
medium-term, non-tunneled Hohn catheters, inserted via direct central venipuncture (MT); peripherally inserted central catheters (PICC), inserted via peripheral venipuncture (puncture of arm veins); long-term, tunnelled central venous catheters (Hickman, Groshong, Broviac or similar), including tunnelled VADs for chronic dialysis (LT); totally implantable venous systems (Port).

Each VAD was inserted in accordance with each center’s protocol; positioning techniques were classified as follows: central blind venipuncture, either supra-clavicular (subclavian, internal jugular, or external jugular vein) or infra-clavicular (subclavian vein); peripheral blind venipuncture (basilic, cephalic vein); ultrasound-guided central venipuncture, either supra-clavicular (brachiocephalic, subclavian, internal jugular, or external jugular vein) or infra-clavicular (axillary or cephalic vein); ultrasound-guided peripheral venipuncture (basilar, brachial or cephalic vein).

The ideal tip position was also decided according to the center’s protocol and the type and function of the VAD. The site chosen was classified as follows: junction between right atrium and superior vena cava; upper part of right atrium; lower third of the superior vena cava.

**Intra-procedural positioning of the tip according to the ECG method**

The ECG method uses the catheter itself as an intracavitary electrode (12). This can be obtained via two different techniques, the so-called ‘guidewire technique’ (when the intracavitary electrode is the metal guidewire inserted inside the catheter) and the so-called ‘saline technique’ (when the intracavitary electrode is the column of liquid, i.e., the normal saline solution, contained in the catheter) (26). For centrally inserted catheters, it is theoretically possible to use both methods, according to choice. For PICCs only the saline column option is available.

In this study, the guidewire technique was to be adopted only for those VADs already pre-arranged for the ECG method (and therefore equipped with a marked metal guidewire for this purpose), i.e., the short-term central venous catheter ‘Certofix’ (BBraun) and the port ‘Celsite-EGC’ (BBraun). For all the other VADs (Hohn catheters, catheters for dialysis, PICCs, tunnelled catheters, etc.) the so-called ‘saline technique’ was used, utilizing transducers already on the market, such as AlphaCard (BBraun), VygoCard (Vygon) or equivalent. To facilitate the interpretation of the ECG tracking, a universal commuter such as Certodyn (BBraun) was sometimes used, since it gives the possibility of shifting between the two electrodes, comparing the surface ECG and the intracavitary ECG. In many cases, where available, the saline technique was performed utilizing a PC-based ECG monitor specifically produced and marketed for this purpose, the ‘Sapiens Tip Locator System’ (Romedex), which enables simultaneous-

ly visualizing the surface ECG and the intracavitary ECG.

The guidewire technique and the saline technique were performed as previously reported in detail in a recent review on the ECG method (12). The method is based upon the principle that advancing the catheter along the superior vena cava (SVC) towards the right atrium (RA) leads to predictable variations in the width of the P-wave, as long as the catheter is functioning as a ‘moving electrode’, i.e., if it is properly connected to the ECG cable which usually goes to the right shoulder. Such connection can be achieved via an alligator clip clamped to the guidewire (guidewire technique) or via a transducer (saline technique). In both cases, the catheter may be indirectly (via a commuter) or directly connected to a standard ECG monitor or to the Sapiens TLS. The DII lead is used, since it magnifies the changes of the P wave. The P-wave gradually rises as the catheter enters the intrapericardic part of the SVC (i.e., the lower third of the SVC) and reaches maximal height when the catheter is at the transition between SVC and RA (which corresponds to the crista terminalis); as the catheter passes over this point, either towards the RA or towards the inferior vena cava, the P-wave decreases and/or becomes diphasic (negative-positive) and then negative (15,27).

Each VAD inserter was left free to choose the desired position of the tip, according to the patient and type of VAD, in one of three zones: zone 1 - lower third of SVC (P-wave rising); zone 2 - SVC-RA junction (maximal P-wave); zone 3 - upper third of right atrium (P wave decreasing and/or with initial negative component).

**Post-procedural radiologic control of tip position**

The post-procedural radiologic control of the tip position was performed using a standard chest x-ray, so as to rule out possible malpositions and to verify the position of the tip compared with the pre-established objective. Although the radiologist’s report was necessary for an overall assessment of the x-ray, the specific assessment of the radiograph as regards the position of the tip was performed by the same physician who inserted it, adopting the following criteria, reported in the most recent literature as particularly accurate (9) (28-32):

- radiologic landmark of the SVC-RA junction (zone 1): 3 cm under the tracheal carina;
- radiologic landmark of the lower third of the SVC (zone 2): under the carina but within the first 3 distal cm;
- radiologic marker of the upper third of the RA (zone 3): from 3 to 5 cm under the carina.

**Comparison between the intra-procedural ECG method and post-procedural chest x-ray**

As explained above, each inserter chose the desired position of the tip, according to the patient and type of
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Data collection and statistical analysis

Using a computer-based archive prepared for this purpose (Excel or Access-type database), the following data will be included for each patient:

- case history: age, weight, height, body mass index, sex, underlying disease and/or referring department, baseline ECG tracking
- type of VAD, according to the above classification, with additional information (specific model, single or multiple lumen, diameter, material, etc.);
- method of insertion (blind vs. US-guided venipuncture), vein cannulated, side of insertion (right or left);
- desired position of the tip according to intra-procedural assessment by ECG (zone 1, 2 or 3);
- type of ECG method used: guidewire technique vs. saline technique;
- intra-procedural events related to the ECG method: arrhythmias, complications that arose during ECG verification of the tip position; difficult or impossible detection of the ‘atrial P-wave’; etc.
- complications unrelated to the ECG method
- position of the tip as verified by chest x-ray (either in one or two projections; in supine or standing position) classified according to the following scheme:
  Malpositioned catheter; the tip was NOT in the section between the lower third of the inferior vena cava and the upper third of the atrium (‘mismatch’) (M);
  Correctly placed catheter, but the tip was in a different location than that estimated with the ECG method (‘correct match’) (C);
  Perfect match between ECG and chest x-ray (P);
  other chest x-ray alterations related to the procedure.

Out of these collected data, the feasibility of the ECG method was expressed as the percentage of patients in which the ECG method was accomplished (i.e.: identification of ‘atrial P-wave’). Safety was measured as the incidence of complications potentially related to the ECG method. Accuracy was expressed by the match/mismatch between tip position according to the intra-procedural ECG method vs. tip position according to post-procedural chest x-ray.

All the computer-based files were analyzed using the appropriate statistical tests according to the type of variables. The quantitative variables (age, weight, height, etc.) were reported in terms of mean and standard deviations, whereas the qualitative variables (type of VAD, mode of VAD insertion, type of ECG method used, etc.) were reported in percentage terms. A multiple chi-square test was performed to study the possible statistical relationship between the match/mismatch between the two methods vs. different variables (type of VAD, type of ECG method used, etc.).

RESULTS

In total, 1444 patients were enrolled in the study, 634 men (44%) and 810 women (56%). Mean age was 64 ± 15 years (range 18 to 99). Most patients (70%) had an underlying oncologic disease.

The study included 288 short-term non-tunneled central venous catheters (ST) (19.9%), 47 Hohn catheters (MT) (3.25%), 245 PICC (16.9%), 325 tunneled catheters (LT) (22.5%), 539 ports (37.3%). Table I shows the distribution of the type of VADs in the different centers. Most VADs were inserted on the right side (80.3%) and virtually all were inserted by ultrasound guidance (99.2%). The ECG method was performed in half of the cases via the guidewire technique (50.6%) and in the other half via the saline technique (49.4%). In 332 cases out of 713 cases performed with the saline technique, the Sapiens TLS was used.

TABLE I - VADS IN THE DIFFERENT CENTERS

<table>
<thead>
<tr>
<th>Port</th>
<th>PICC</th>
<th>ST</th>
<th>MT</th>
<th>LT</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSB</td>
<td>6</td>
<td>108</td>
<td>147</td>
<td></td>
</tr>
<tr>
<td>PUC</td>
<td>182</td>
<td>114</td>
<td></td>
<td>36</td>
</tr>
<tr>
<td>PF</td>
<td>165</td>
<td>4</td>
<td></td>
<td>169</td>
</tr>
<tr>
<td>DSP</td>
<td>89</td>
<td>7</td>
<td>48</td>
<td>38</td>
</tr>
<tr>
<td>CB</td>
<td>-</td>
<td>3</td>
<td>9</td>
<td>158</td>
</tr>
<tr>
<td>BV</td>
<td>41</td>
<td>1</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>BCM</td>
<td>27</td>
<td>4</td>
<td>84</td>
<td>3</td>
</tr>
<tr>
<td>BC</td>
<td>29</td>
<td>1</td>
<td></td>
<td>55</td>
</tr>
<tr>
<td>Total</td>
<td>539</td>
<td>245</td>
<td>288</td>
<td>47</td>
</tr>
</tbody>
</table>

BC, Cremona Hospital; BCM, Castelnuovo Monti Hospital (Reggio Emilia); BV, Varese Hospital; CB, Bolzano Hospital; DSP, University of Pisa; PF, University of Florence/Careggi Hospital; LT, long-term, tunneled central venous catheters; MT, medium-term, non-tunneled Hohn catheters; PICC, peripherally inserted central catheters; Port, totally implantable venous systems; PUC, Catholic University Hospital in Rome; SSB, Fracastoro Hospital at San Bonifacio; ST, short-term central venous catheters;
There was no complication potentially related, either directly or indirectly, to the ECG method. The overall incidence of arrhythmias during the procedure was low (0.7%).

In 252 cases (17.4%) the operators chose to position the tip, using ECG guidance, at the lower third of the SVC (zone 1) (mostly, long-term VADs); in 1167 cases (80.8%) at the SVC-RA junction (zone 2); in 25 cases (1.7%) in the upper part of RA (zone 3) (mostly short-term CVCs in ICU patients or dialysis catheters).

The post-procedural chest x-ray was taken in standing position in 951 patients (65.9% - mostly walking, non-hospitalized patients) and in supine position in 493 cases (34.1% - mostly bedridden, hospitalized patients). A standard anterior-posterior view was performed in all patients; 18% required an additional x-ray in lateral view for better localization of the tip.

Table II shows the comparison between the intra-procedural ECG method vs. post-procedural x-ray, expressed as ‘perfect match’ (same zone for ECG and x-ray), ‘correct match’ (different zone between ECG and x-ray), ‘mismatch’ (tip not in zone 1-2-3 at x-ray). An appropriate tip localization of the tip, using ECG guidance, at the lower third of the SVC (0.7%).

TABLE II - OVERALL ACCURACY

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>P – Perfect match</td>
<td>1199</td>
<td>83.0%</td>
</tr>
<tr>
<td>C – Correct match</td>
<td>179</td>
<td>12.4%</td>
</tr>
<tr>
<td>S – Mismatch</td>
<td>55</td>
<td>3.8%</td>
</tr>
<tr>
<td>NA – Not applicable</td>
<td>11</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

Table III shows the details of the 179 cases (12.4%) of ‘correct match’.

As regards the 55 ‘mismatch’ cases (3.8%) the tip was located – according to x-ray - either in the upper/mid third of the SVC (40 cases, 2.8%) or in the brachiocephalic veins (4 cases, 0.3%) or in the lower part of RA (> 5 cm below the carina) (11 cases, 0.7%).

In 11 cases, the comparison between ECG and x-ray was not possible ('not applicable'): in eight cases, the typical ‘atrial’ P wave was not detected during the intracavitary ECG, either for artifacts or for difficult interpretation of the tracking (this occurred almost exclusively, seven cases out of eight, with the guidewire technique); in three cases, the tip could not be seen at x-ray, not even in lateral view.

We have tested the statistical relationship between accuracy and different parameters. Table IV shows the effect of the type of VAD upon accuracy: accuracy was significantly lower for ports (P<.001). Table V shows the effect of center upon accuracy: accuracy was significantly lower (P<.001) in two centers (BV and PF, which were the centers with the highest percentage of ports). Table VI shows the effect of the ECG technique: guidewire technique and saline technique have the same accuracy, but the feasibility was significantly different (P<.03), being higher with the saline technique (99.9%); in the subset of 332 patients where the saline technique was performed with Sapiens TLS, the feasibility rose to 100%. Table VII shows the effect of the side of insertion: there was a significantly higher incidence of mismatch on the left side (P<.05). Table VIII shows the effect of the patient’s position during post-procedural x-ray: there was a significantly higher mismatch between ECG and x-Ray when the latter was performed in the standing position (P<.001). Finally, Table IX shows the effect of the choice of target upon accuracy: we reported a more accurate match between ECG and x-ray when zone 1 was chosen as the target (P<.001).

TABLE III - CORRECT MATCH - 179 CASES

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>ECG</td>
<td>x-ray</td>
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<tr>
<td>Zone 1</td>
<td>7</td>
<td>Zone 2</td>
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<tr>
<td></td>
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<td>Zone 2</td>
</tr>
</tbody>
</table>

TABLE IV - EFFECT OF TYPE OF VAD

<table>
<thead>
<tr>
<th></th>
<th>ST</th>
<th>LT</th>
<th>MT</th>
<th>PICC</th>
<th>Port</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>88.5%</td>
<td>94.7%</td>
<td>93.6%</td>
<td>86.9%</td>
<td>70.3%*</td>
</tr>
<tr>
<td>C</td>
<td>6.6%</td>
<td>2.1%</td>
<td>6.4%</td>
<td>10.2%</td>
<td>23.2%*</td>
</tr>
<tr>
<td>S</td>
<td>3.5%</td>
<td>2.7%</td>
<td>-</td>
<td>1.6%</td>
<td>5.9%*</td>
</tr>
<tr>
<td>NA</td>
<td>1.4%</td>
<td>0.3%</td>
<td>-</td>
<td>1.2%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

C, correct match; LT, long-term, tunneled central venous catheters; MT, medium-term, non-tunneled Hohn catheters; NA, not applicable; P, perfect match; PICC, peripherally inserted central catheters; Port, totally implantable venous systems; S, mismatch; * P<.001

DISCUSSION

To the best of our knowledge, this is the first multicenter study to investigate the clinical effectiveness of the ECG method, as well as the largest case series published on this subject.

We only studied adult patients with evident P-wave on the basal ECG tracking: in this kind of patient population, which may represent > 90% of all patients candidate for VAD insertion, our data revealed that the feasibility of the method (i.e., the possibility of identifying the progressive changes of the P-wave as the intracavitary electrode
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As regards the safety of the method, our large multicenter study (1444 pts) could not detect any complication potentially related to the use of an intracavitary electrode. As a matter of fact, the overall incidence of heart rhythm disturbance was very low (0.7%), considering that continuous ECG monitoring was adopted in all patients (which is not the rule with VAD insertion, especially at the bedside). It is much more likely that the adoption of the ECG method entails per se a major protection from premature beats arising from the atrium or the ventricle: in fact, when using this method, the operator knows in each moment the position of the tip of the catheter, and there is no danger of going too deep, close to the plane of the tricuspid valve.

As regards the accuracy, our study has not compared the ECG method with the most accurate methodology for assessing tip position (i.e. TEE), since this is not cost-effective in common clinical practice, but with the most common method for most VADs, i.e. the post-procedural chest x-ray. As a matter of fact, chest x-ray is not particularly accurate in detecting the cavo-atrial junction, if compared to TEE or MRI (14,33). However, our data revealed very good correspondence between the ECG and x-ray: in 95.4% of cases, x-ray confirmed that the tip was correctly positioned. A ‘mismatch’ between the ECG and x-ray was only reported in 4.6%, where the tip appeared to be in a wrong location on x-ray. It is interesting that the difference between x-ray and ECG in most cases implied a ‘higher’ location of the tip at x-ray if compared to the location assessed by ECG: out of 179 cases of ‘correct match’, in 153 cases the tip was higher than expected (in zone 1 rather than in zone 2-3 or in zone 2 rather in zone 3) (Tab. III). In addition, most malpositions (44 out of 55) were because of a shorter than expected catheter.

This difference between ECG and x-ray might be secondary not only to the accuracy of the methods, but also to the fact that one method of tip assessment (ECG) is performed during the procedure, while the other (x-ray) is performed after the procedure. This contention seems to be confirmed by another observation: the difference be-

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**TABLE V - EFFECT OF CENTER**

<table>
<thead>
<tr>
<th></th>
<th>BC</th>
<th>BCM</th>
<th>BV</th>
<th>CB</th>
<th>DSP</th>
<th>PF</th>
<th>PUC</th>
<th>SSB</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>92.1%</td>
<td>82.2%</td>
<td>61.7%*</td>
<td>92.3%</td>
<td>99.2%</td>
<td>51.5%*</td>
<td>75.6%</td>
<td>93.9%</td>
</tr>
<tr>
<td>C</td>
<td>4.9%</td>
<td>11%</td>
<td>28.3%*</td>
<td>3.6%</td>
<td>-</td>
<td>36.1%*</td>
<td>21.7%</td>
<td>2.5%</td>
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<td>S</td>
<td>3.7%</td>
<td>3.4%</td>
<td>10%</td>
<td>3.5%</td>
<td>0.8%</td>
<td>10.6%*</td>
<td>2.7%</td>
<td>2.6%</td>
</tr>
<tr>
<td>NA</td>
<td>-</td>
<td>3.4%</td>
<td>-</td>
<td>0.6%</td>
<td>-</td>
<td>1.8%</td>
<td>-</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

BC, Cremona Hospital; BCM, Castelnovo Monti Hospital (Reggio Emilia); BV, Varese Hospital; C, correct match; CB, Bolzano Hospital; DSP, University of Pisa; NA, not applicable; P, perfect match; PF, University of Florence/Careggi Hospital; PUC, Catholic University Hospital in Rome; S, mismatch; SSB, Fracastoro Hospital at San Bonifacio; * P<.001

**TABLE VI - EFFECT OF ECG TECHNIQUE**

<table>
<thead>
<tr>
<th></th>
<th>Guidewire</th>
<th>Saline</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>83.3%</td>
<td>82.7%</td>
</tr>
<tr>
<td>C</td>
<td>11.2%</td>
<td>13.6%</td>
</tr>
<tr>
<td>S</td>
<td>4.1%</td>
<td>3.5%</td>
</tr>
<tr>
<td>NA</td>
<td>1.4%*</td>
<td>0.1%*</td>
</tr>
</tbody>
</table>

C, correct match; NA, not applicable; P, perfect match; S, mismatch; P<.03

**TABLE VII - EFFECT OF SIDE OF INSERTION**

<table>
<thead>
<tr>
<th></th>
<th>Right side</th>
<th>Left side</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>83.1%</td>
<td>82.7%</td>
</tr>
<tr>
<td>C</td>
<td>13.0%</td>
<td>9.8%</td>
</tr>
<tr>
<td>S</td>
<td>3.2%*</td>
<td>6.3%*</td>
</tr>
<tr>
<td>NA</td>
<td>0.7%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

C, correct match; NA, not applicable; P, perfect match; S, mismatch; * P<.05

**TABLE VIII - EFFECT OF PATIENT’S POSITION DURING POST-PROCEDURAL X-RAY**

<table>
<thead>
<tr>
<th></th>
<th>Standing</th>
<th>Supine</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>78.4%*</td>
<td>91.9%</td>
</tr>
<tr>
<td>C</td>
<td>16.6%</td>
<td>4.2%</td>
</tr>
<tr>
<td>S</td>
<td>4.5%*</td>
<td>2.4%</td>
</tr>
<tr>
<td>NA</td>
<td>0.4%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

C, correct match; NA, not applicable; P, perfect match; S, mismatch; * P<.001

**TABLE IX - EFFECT OF CHOICE OF TARGET**

<table>
<thead>
<tr>
<th></th>
<th>Lower third SVC</th>
<th>C-A junction</th>
<th>Upper atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>93.2%*</td>
<td>80.9%</td>
<td>80.0%</td>
</tr>
<tr>
<td>C</td>
<td>2.8%</td>
<td>14.4%</td>
<td>16.0%</td>
</tr>
<tr>
<td>S</td>
<td>3.17%</td>
<td>3.9%</td>
<td>4.0%</td>
</tr>
<tr>
<td>NA</td>
<td>0.8%</td>
<td>0.8%</td>
<td>-</td>
</tr>
</tbody>
</table>

C, correct match; NA, not applicable; P, perfect match; S, mismatch; *P<.001
between ECG and x-ray is significantly more relevant if the post-procedural radiologic control is taken when the patient is in standing position (Tab. VIII). It is well known that in standing position and particularly during inspiration the tip of any VAD appears to be in a ‘higher’ location if compared to the supine position, the difference being even 2-3 cm (34). As a matter of fact, the type of VAD which accounted for the greater difference between ECG assessment and x-ray assessment was the central venous port: this finding is easily explained by the fact that ports are particularly prone to slide downward in the tissues when the patient rises to the standing position. In addition, most patient candidates for port insertion are walking patients who are most likely to receive the radiologic control in standing position.

The difference between ECG vs. x-ray assessment of the tip position was less relevant when the VAD was inserted on the right side and when the sought after target for tip position was the lower third of the SVC. Positioning of the tip of a central VAD inserted on the left side requires an accurate interpretation of the intracavitary ECG tracking (35): particularly when using a catheter with the guidewire inside or using a rigid catheter, the tip of the intra-cavitary electrode may come in close contact with the lateral wall of SVC and an initial rise of the P-wave (transmitted by the pericardial reflection which wraps the lower third of the SVC) may be erroneously interpreted as a maximal P-wave, with subsequent under-estimation of the length of the catheter. On the other hand, the better match between ECG and x-ray when the sought after location of the tip is zone 1 (lower third of the SVC) is probably because of the fact that this zone is a wider target if compared to zone 2 (SVC-RA junction).

To conclude, in this large multicenter study, the intracavitary ECG method for assessing the position of the tip of central VADs was proven to be absolutely safe and feasible in virtually all adult patients who had an evident P-wave at the basal ECG tracking. In particular, when adopting the saline technique and using the Sapiens TLS, the feasibility was 100%.

Comparing the intra-procedural assessment of tip position by ECG vs. the post-procedural assessment of tip position by chest x-ray, there was a highly satisfactory match between the two methods (in 95.4% of cases).

Much of the difference noted between ECG and x-ray is apparently because of the fact that one method is performed during and the other is performed after the procedure. This explains why ECG and x-ray give similar evaluation of the tip location when the chest x-ray is taken in supine position (i.e., in the same position of ECG assessment). On the contrary, if the patient is not bedridden, post-procedural x-ray is usually performed in standing position and thus the tip appears to be located in a more cranial location (approx. 1-2 cm).

The relatively poor correspondence between ECG and x-ray assessment during and after port insertion has at least two explanations: on one hand, since most patient candidates for port are not bedridden, the x-ray is routinely performed in standing position (which accounts for an upward movement of the tip, at least 1 cm); on the other hand, if the reservoir is not properly secured in its pocket or if the pocket is too far away from the clavicle in the breast fat area when the patient stands up the reservoir may move caudally, driving the tip of the catheter in a more cranial location (which accounts for an additional 1-2 cm upward dislocation of the tip).

In other words, when implanting a port, the accuracy in tip positioning depends not only on the choice of an intra-procedural method (ECG method, fluoroscopy or otherwise) vs. a post-procedural method (chest x-ray) for assessing tip location, but also on the appropriate surgical technique.

From the point of view of common clinical practice, our study may raise a few considerations:
- the intracavitary ECG method is safe and feasible in almost 100% of those patients whose P-wave is identifiable at the basal surface ECG;
- if compared with the most common standard method for assessment of tip location of VADs (post-procedural chest x-ray), it is associated with a minimal incidence of malpositions, which can even be reduced considering that the final position of the tip as measured in supine position during the procedure will be different from the location of the tip in orthostatic position and/or during forced inspiration;
- this implies that when placing a central VAD in a non-bedridden patient, attaining a tip position during the procedure slightly lower (1-2 cm) than the required final position, should be recommended.

As a final consideration, our study further confirms that the tip of a central VAD is always in a dynamic state, with major variations (even > 2 cm) secondary to breathing (36), patient’s position (standing vs. supine) (34), position of the arm and the shoulder on the side of the VAD (37), high-pressure infusion of i.v. solution through the VAD, etc. Thus, some debates about the preferred tip location comparing the lower third of the SVC vs. the cavo-atrial junction, or comparing the cavo-atrial junction vs. the upper third of the atrium may make little clinical sense, since the tip usually moves dynamically up and down in this area. As suggested by some authors (1,3), it may be more reasonable to define that the tip of a central VAD should ideally be in a ‘safe area’ extending from 2 cm above and 2 cm below the cavo-atrial junction, which includes the intra-pericardic tract of the SVC and the upper part of RA: this would guarantee that the tip of the catheter (a) is in an area of maximal blood flow, (b) has no direct contact with the vein wall (parallel to the vein wall), and (c) is in a position which takes into account possible catheter movements of ± 2 cm.
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REFERENCES


