

MT 234 The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters

National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT 234 The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters

Consultation Comments table

MTAC date: 22 January 2015

There were 14 consultation comments from 7 consultees (3 NHS professionals, 2 manufacturers [1 company and 1 other], 1 Department of Health and 1 External Assessment Centre representative.) The comments are reproduced in full.

Table 2

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	4. East Kent Hospitals University NHS Foundation Trust	Section 1	1. Provisional Recommendations:	<p>Thank you for your comment.</p> <p>For clarity and ease of response, the remainder of this comment has been subdivided by the Medical Technologies Evaluation Programme team and is shown as comments 1a to 1d. No changes have been made to the text.</p>
1a	4. East Kent Hospitals University NHS Foundation Trust	1.1	The published evidence equally supports the use of ECG tip location systems generally and NOT specifically the Sherlock system.	<p>Thank you for your comment.</p> <p>NICE medical technologies guidance evaluates a single medical technology based on the claimed advantages of introducing the specific technology compared with current management of the condition. It is not a multiple technology assessment and does not compare evidence for all similar technologies in a broader class.</p> <p>These principles are described in further detail in the Medical Technologies Evaluation Programme methods guide, and in the block of text at the beginning of the medical technology guidance. This text states that the case for adoption is based on claimed advantages of introducing the specific technology compared with current management of the condition. It also states that the specific recommendations in the medical technologies guidance on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.</p>
1b	4. East Kent Hospitals University NHS	1.2	With proper additional training it is possible to utilise the same technology to assist with placement, even in	Thank you for your comment.

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	Foundation Trust		patient in atrial fibrillation. We have been using our system, successfully, in this group of patients.	<p>The company's instructions for use indicate that use of the Sherlock 3CG TCS is limited (but not contraindicated) in patients for whom it is difficult to identify a P wave and states that an additional method is required to confirm PICC tip location in these patients. Expert advice was that although the system can be used to assist in the positioning of a catheter, a chest X-ray may still be needed to confirm tip location if a P wave cannot be identified.</p> <p>The Committee considered that atrial fibrillation was the most common condition that would make it difficult to identify a P wave. For this reason, it decided that the specific references to the condition were appropriate and helpful. No changes were made to the medical technology guidance.</p>
1c	4. East Kent Hospitals University NHS Foundation Trust	1.3	The cost of using a generic ECG tip location system is considerably cheaper than using the Sherlock system. This is one of the major criticisms of this proposal. See below.	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p>
1d	4. East Kent Hospitals University NHS Foundation Trust	2.1	The description of how the technology works is accurate.	Thank you for your comment.
2	4. East Kent Hospitals University NHS Foundation Trust.	Section 2	2.The technology	<p>Thank you for your comment.</p> <p>For clarity and ease of response, the remainder of this comment has been subdivided by the Medical Technologies Evaluation Programme team and is shown as comments 2a to 2e. No</p>

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				changes have been made to the text.
2a	4. East Kent Hospitals University NHS Foundation Trust.	2.1	This statement is misleading. The Sherlock 3CG Tip Confirmation System is designed to ONLY confirm the correct tip placement of a Bard PowerPICC SOLO catheter. It will not work with any other PICC catheter. There are at least 8 manufacturers of PICC lines commercially available in the UK. It must be clearly stated/understood that this particular ECG tip location systems will ONLY work with one single type of PICC line, which is marketed by the same company that market the Sherlock system. Purchase of a Sherlock TCS will force the user/Trust/NHS into a situation where they will be only able to buy their PICC lines from CR Bard. CR Bard will then be able to charge the NHS whatever price they wish for the PICC lines as the user will no longer be able to negotiate a competitive price for the line.	<p>Thank you for your comment.</p> <p>Section 2.1 is a general outline of the mode of action of the technology. Section 2.2 is a more detailed description, and states that the system includes a PowerPICC SOLO catheter with a Sherlock 3CG Tip Positioning stylet.</p> <p>The Committee decided that this was an appropriate and useful clarification. Section 2.1 has been updated to further specify that the Sherlock 3CG TCS is designed to be used only with a Bard PowerPICC SOLO Catheter.</p>
2b	4. East Kent Hospitals University NHS Foundation Trust.	2.2	This description of the Sherlock system is correct	Thank you for your comment.
2c	4. East Kent Hospitals University NHS Foundation Trust.	2.3	This paragraph is valid, bearing in mind the possible use in patients with atrial fibrillation.	<p>Thank you for your comment.</p> <p>Please see the response to comment 1b.</p>
2d	4. East Kent Hospitals University NHS Foundation Trust.	2.4	Here again we see evidence of why this proposal is anti-competitive and DOES NOT represent good value for money for the NHS. Because we use an ECG tip confirmation system that can be used with any PICC line, we have been able to negotiate a better price for the cost of consumables related to each PICC insertion. Our like for like consumable cost is approximately £94 per insertion. If we were using the Sherlock system, as described, we would be costing the NHS more than £180,000 per annum in unnecessary expenditure. I cannot see how this recommendation to INCREASE	<p>Thank you for your comment.</p> <p>The specific recommendations on the Sherlock 3CG TCS are not intended to limit the use of other relevant technologies which may offer similar advantages.</p> <p>Please see the response to comment 1a.</p>

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			our cost to the NHS (by only recommending the more expensive BARD branded consumables) is a viable proposal.	
2e	4. East Kent Hospitals University NHS Foundation Trust.	2.5	The claimed benefits of the Sherlock TCS are valid. Exactly the same benefits are realised using any one of the other ECG tip location systems on the market. This statement is correct	Thank you for your comment. The specific recommendations on the Sherlock 3CG TCS are not intended to limit the use of other relevant technologies which may offer similar advantages. Please see the response to comment 1a.
3	4. East Kent Hospitals University NHS Foundation Trust	Section 3	3. Clinical Evidence	Thank you for your comment. For clarity and ease of response, the remainder of this comment has been subdivided by the Medical Technologies Evaluation Programme team and is shown as comments 3a to 3e. No changes have been made to the text unless otherwise specified.
3a	4. East Kent Hospitals University NHS Foundation Trust	3.2	In our practice we can confirm that all of these bullet points are valid.	Thank you for your comment.
3b	4. East Kent Hospitals University NHS Foundation Trust	3.3	Although we have not published our findings, the results of our own internal audit show that as well as the proven benefits of this technology, we have also been able to show a reduced time to treatment commencement.	Thank you for your comment. The consultee has confirmed to the MTEP team that the intervention studied in the internal audit was not the Sherlock 3CG TCS and so outside the scope of the evaluation.
3c	4. East Kent Hospitals University NHS Foundation Trust	3.4 – 3.11	As read. It must be noted that there are many more gold standard peer reviewed published studies that show the same results using other ECG tip location systems. It is NOT the Sherlock TCS system that is	Thank you for your comment. The specific recommendations on the Sherlock 3CG TCS are not intended to limit the use of

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			<p>being validated, but ECG tip location systems in general.</p> <p>The information supplied in this comment has been moved to Appendix 1 for ease of reading. The structure of parts of the comment has been updated, with the approval of the consultee.</p>	<p>other relevant technologies which may offer similar advantages.</p> <p>Please see the response to comment 1a.</p> <p>The External Assessment Centre assessed the papers by Moureau et al (2010) and Pittiruti et al (2012) (see Appendix 1) and judged that, as they did not provide information on the Sherlock 3CG TCS, they were outside the scope of the evaluation.</p>
3d	4. East Kent Hospitals University NHS Foundation Trust	3.13	<p>It is not surprising to read that the Committee found “the overall quality and quantity of the clinical evidence was low”. This is because most of high quality research undertaken in this field does not use the Sherlock system, but instead uses other ECG tip location systems. Most of this high quality evidence will not have been submitted to the committee by the sponsor because the studies would have used an alternative ECG tip location system, manufactured by a competitor. This is another example of why NICE should consider only recommending the proven and validated data that shows that it is GENERIC ECG tip confirmation technology that is safe and cost effective to the NHS and not specifically the Sherlock TCS.</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p>
3e	4. East Kent Hospitals University NHS Foundation Trust	3.14	<p>Agreed. We no longer use chest X-rays for confirmation of PICC tip position.</p>	<p>Thank you for your comment.</p>
4	4. East Kent Hospitals University NHS Foundation Trust.	Section 4	<p>NHS Considerations</p>	<p>Thank you for your comment.</p> <p>For clarity and ease of response, the remainder of this comment has been subdivided by the Medical Technologies Evaluation Programme</p>

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				team and is shown as comments 4a to 4g. No changes have been made to the text.
4a	4. East Kent Hospitals University NHS Foundation Trust.	4.1	This efficiency claim is supported by our own practice.	Thank you for your comment.
4b	4. East Kent Hospitals University NHS Foundation Trust	4.2	Our own experience supports the findings as stated in this paragraph.	Thank you for your comment.
4c	4. East Kent Hospitals University NHS Foundation Trust	4.3	Our Trust uses a “Nautilus” ECG tip location system (TLS) (marketed by Vygon UK). I can confirm that we have also discontinued routine chest X-ray confirmation following PICC placement.	Thank you for your comment.
4d	4. East Kent Hospitals University NHS Foundation Trust	4.4	I fully support this statement. This is our experience in our Trust.	Thank you for your comment.
4e	4. East Kent Hospitals University NHS Foundation Trust	4.5	I fully support this statement. This is our experience in our Trust.	Thank you for your comment.
4f	4. East Kent Hospitals University NHS Foundation Trust	4.6	I have trained at least 8 nurses to use the Nautilus ECG TLS. This has been relatively easy to achieve.	Thank you for your comment.
4g	4. East Kent Hospitals University NHS Foundation Trust	4.7	Within our own overall patient population the incidence of patients with difficult P wave morphology, requiring a PICC is less than 1%. The quoted figure of 16.5% seems high but this may represent a more specific patient population.	Thank you for your comment. The External Assessment Centre confirmed that the figure of 16.5% of patients where ECG tip confirmation was not used comes from the abstract presented by Adams (2013). It includes cases where ECG tip confirmation did not function correctly due to technical problems, as well as those with a “difficult P wave morphology”. No further information on the patient population is provided in the abstract.

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				<p>In the table below, the External Assessment Centre have presented a range of other values for unsuccessful ECG tip placement from the clinical evidence, but stated that these are also based on publications available only as posters or abstracts, and so are also subject to considerable uncertainty.</p> <table border="1" data-bbox="1498 560 2123 954"> <thead> <tr> <th><i>Paper</i></th> <th><i>Number where ECG tip confirmation not successful</i></th> </tr> </thead> <tbody> <tr> <td>Barton 2014</td> <td>11/225 (4.9%) ECG excluded</td> </tr> <tr> <td>Stewart 2013</td> <td>Unknown</td> </tr> <tr> <td>Parikh 2013, phase 1</td> <td>3/62 (4.8%) excluded</td> </tr> <tr> <td>Parikh 2013, phase 2</td> <td>35/147 (23.8%) excluded</td> </tr> <tr> <td>Parikh 2013, post-trial</td> <td>109/437 (24.9%) required X-ray for confirmation</td> </tr> <tr> <td>Johnston 2014</td> <td>11/250 (4.4%) excluded</td> </tr> </tbody> </table> <p>The External Assessment Centre also confirmed that varying this figure has only a small impact on the cost modelling.</p> <p>The Committee noted that accepting the proportion of the patient population suggested by the consultee (<1%) would strengthen the case for adoption for the Sherlock 3CG TCS, as it would make the technology appropriate for a larger population. The Committee also noted that the figures reported for unsuccessful rates did not exclusively refer to unsuccessful tip confirmation rates, but included technical issues and other problems.</p>	<i>Paper</i>	<i>Number where ECG tip confirmation not successful</i>	Barton 2014	11/225 (4.9%) ECG excluded	Stewart 2013	Unknown	Parikh 2013, phase 1	3/62 (4.8%) excluded	Parikh 2013, phase 2	35/147 (23.8%) excluded	Parikh 2013, post-trial	109/437 (24.9%) required X-ray for confirmation	Johnston 2014	11/250 (4.4%) excluded
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				<p>The Committee considered that the use of 16.5% was appropriate, but decided to update section 5.19 to summarise the additional work carried out by the EAC in relation to rates of unsuccessful tip placement.</p>
5	4. East Kent Hospitals University NHS Foundation Trust	Section 5	<p>Cost considerations</p> <p>We agree with the overall view that it is difficult to exactly quantify the cost savings that may be released by adopting this technology into clinical practice. In order for our Trust to purchase our own ECG TLS (Nautilus) we were required to undergo an extensive financial appraisal of the technology and the perceived cost savings. This process suggested that using an ECG TLS rather than post procedural chest X-ray would be approximately £56 cheaper per insertion. This was based solely on:</p> <p>Cost of chest X-ray Cost of portering the patient to the radiology department and back.</p> <p>We also chose to purchase the Nautilus System, rather than the Bard Sherlock System because it would allow the greatest cost saving in the long term. We currently pay approximately £60 for a standard 4Fr PICC in comparison to the quoted price for a Bard Power PICC of approximately £120 (which we would have had to use if we purchased the Sherlock TCS). We are able to secure this very competitive price for our PICC lines solely because we are able to use any PICC line from any manufacturer, and this has given us a very strong negotiating advantage.</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p>

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			Based on 2000 PICC insertions per annum, this represents a PICC line cost saving of over £120,000 per year to our Trust.	
6	3. Vygon UK	Section 6	<p>There is a lot of evidence in terms of the accuracy, cost and the safety benefits of using ECG technology for tip confirmation in central venous devices. I would like to ask the committee to consider adding in a broader statement to include ECG technology rather than one supplier (Bard 3CG). There are several hospitals that have already employed this technology to determine tip position and are reaping the benefits of no longer performing a chest x-ray. However there are still more hospitals that are using this technology, as they appreciate it is more accurate and has the benefit of real time placement, but are still paying the extra money for an unnecessary chest x-ray. Having the backing of a national public body would provide some hospital units the support they feel they need to stop chest xrays on sinus rhythm patients when a maximum p wave is seen and identified. The largest study to date I am aware of is an Italian multicentre study performed on 1440 patients (J Vasc Access 2012;13 (3): 357-365 2012).</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p> <p>Please see the response to comment 3c for confirmation that the Italian multicentre study Pittiruti et al (2012) referred to here and in Appendix 1 is outside the scope of this evaluation.</p> <p>The Committee noted that topics for medical technology guidance produced by NICE are generated as a result of the notification of technologies to the Medical Technologies Evaluation Programme and selection by the Medical Technologies Advisory Committee for medical technologies development. NICE actively welcomes engagement with technology developers and other with information about new or novel products with potential benefits for patients and/or the NHS.</p>
7	4. East Kent Hospitals University NHS Foundation Trust	Section 6	<p>Conclusion</p> <p>Worldwide there has been widespread acceptance of this technology. It is very encouraging to see that NICE has undertaken a review of this area of practice. Our Trust was an early adopter of the technology and, in the UK, we have probably placed more PICCs under ECG guidance than any other Trust. It is undoubtedly proven to be a safe and effective technology that</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p>

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			<p>should be recommended for use with PICC placement.</p> <p>The evidence to support the specific use of the CRBard Sherlock TCS is much less compelling. Nearly all, good quality, published studies do not recommend the use of one particular system over another.</p> <p>There are no clear grounds for NICE to recommend one specific system over another. Indeed recommending a system that ties the user into only being able to order a single compatible consumable could be seen as promoting an anti-competitive monopoly that would leave the way open for CRBard to price the associated PICC line however they wished.</p>	
8	7. Cedar (External Assessment Centre)	6.1	There is no evidence of realised changes to x-ray department workload or time savings to staff.	<p>Thank you for your comment.</p> <p>Although there is no published evidence quantifying these time savings, the Committee's decision was also informed by the expert advice received from the expert adviser questionnaires and the lead team experts (see sections on "Committee considerations").</p> <p>The Committee considered that the text in section 6.1 was sufficiently clear to indicate that the information was provided by a clinical expert. No changes were made to the medical technology guidance.</p>
9	7. Cedar (External Assessment Centre)	6.2	A change of service from fluoroscopy to Sherlock 3CG TCS guided PICC will require a service redesign and additional training costs that are not considered in the model. Therefore the cost saving of £106 per patient	<p>Thank you for your comment.</p> <p>Section 6.2 currently states "...use of the Sherlock 3CG TCS could generate cost savings</p>

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			would not be realisable in the short term for clinical services where nurse inserted PICCs were not already part of the pathway.	<p>of about £106 per patient compared with using fluoroscopy as a guide to PICC insertion.”</p> <p>The Committee considered that issues raised by the consultee surrounding service redesign are common in the implementation of new or innovative technologies, and that to include this issue in the section 6.2 would imply that it is particularly significant in the case of the Sherlock 3CG TCS, which would be inaccurate. The Committee decided to leave section 6.2 unchanged, but to update section 5.18 to make clear the uncertainty around this figure. The following text was added to section 5.18:”The External Assessment Centre noted at consultation stage that the cost savings presented may be an overestimate in a clinical setting that only uses fluoroscopy-guided PICC insertion, because of the additional service redesign costs and the need to train staff in bedside insertion.”</p>
10	1. East Kent Hospitals University NHS Foundation Trust	General		Thank you for your comment. For clarity and ease of response, the remainder of this comment has been subdivided by the Medical Technologies Evaluation Programme team and is shown as comments 10a to 10d. No changes have been made to the text.
10a	1. East Kent Hospitals University NHS Foundation Trust	General	<p>I am a Nurse Consultant in Vascular Access in the NHS and as an early adopter of ECG technology to place Peripherally Inserted Central Catheters (PICC) and a relative expert in this area I well placed to respond to the potential backing of NICE for the Sherlock device.</p> <p>Using ECG technology to assist PICC placement is undoubtedly a safe, reliable and replicable method that</p>	<p>Thank you for your comment. Please see the response to comment 1a.</p> <p>The production of guidance on the Sherlock 3CG TCS is not intended to preclude the purchase or use of other PICC placement systems.</p>

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			<p>can be used to accurately place all types of central venous access device, including PICCs. There are many international peer-reviewed published studies that support the work we, as a team, have done in the UK regarding the introduction of ECG technology into our clinical practice. As such I have some concerns regarding this current consultation document:</p> <p>My main concern is that the guidance appears to be based around one single commercial product rather than the technology itself. There is no doubt in my mind that ECG guided PICC placement is cheaper, safer, more accurate and improves efficiency (when compared to post-procedural chest x-ray). On that point I completely agree with the proposed NICE guidance.</p> <p>It is my expert view that NICE should be endorsing the technology/concept rather than endorsing one single commercial product. The guidance should not be limited to the Sherlock system in particular. There are numerous other systems commercially available that perform equally well (if not better). For example:</p> <p>Celerity – Distributed by MedComp in the UK Nautilus – Distributed by Vygon in the UK Vasonova – Distributed by Teleflex in the UK Cathfinder – Currently available in USA</p>	
10b	1. East Kent Hospitals University NHS Foundation Trust	General	<p>It is also important for NICE to be aware that it is also possible to utilise this technique simply by using a standard ECG monitor and connector lead. This practice is widespread in other European countries. This involves minimal cost and is another reason why I</p>	<p>Thank you for your comment. Please see the response to comment 1a.</p> <p>NICE medical technologies guidance evaluates a single medical technology based on the</p>

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			<p>stress that NICE should be supporting the technique/technology and NOT a single commercial product.</p> <p>The Sherlock system has two elements; the first part is the electromagnetic navigation element. This in theory is a good idea; however there have been no studies either nationally or internationally on the reliability, accuracy or indeed the actual usefulness of this part of the system. The Sherlock system relies almost entirely on the second part of the system; the ECG element to accurately place the PICC, as do all other generic systems.</p>	<p>claimed advantages of introducing the specific technology compared with current management of the condition. It is not a multiple technology assessment and does not compare evidence for all similar technologies in a broader class.</p> <p>The Committee noted that medical technologies guidance considers a specific technology in its entirety. It is not the role of the Committee to consider separate elements of a technology separately, as such a methodology may discriminate against complex or multi-component technologies. The recommendations made in section 1 refer to the Sherlock 3CG TCS as a whole, not any specific component. No changes were made to the medical technology guidance.</p>
10c	1. East Kent Hospitals University NHS Foundation Trust	General	<p>The Bard Sherlock system ONLY works with a BARD PICC line. This is of critical importance to the NHS and the UK market because it means that BARD will have a monopoly on the PICC line market. At the current time this would mean a loss of free market choice for the NHS and the user. Other ECG systems work with all PICC lines regardless of the manufacturer. This promotes free choice and gives the NHS user the option to choose their preferred PICC line (with cost in mind).</p> <p>There are significant extra costs and changes in practice associated with the Sherlock system which are not necessarily associated with the other systems and are unnecessary in an increasingly overstretched NHS.</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 1a.</p>
10d	1. East Kent Hospitals University NHS Foundation Trust	General	I have referenced two articles we have published in the last year in this area and I have registered myself as a stakeholder. I would also suggest you contact Dr Mauro	<p>Thank you for your comment.</p> <p>Please see the response to question 1a.</p>

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			<p>Pittiruti (email address provided to NICE) [REDACTED] who is based in Italy and is the world expert in this field; he has independently trailed many of these systems and his opinion will be invaluable.</p> <ul style="list-style-type: none"> • Oliver Gemma and Jones Matt (2014) ECG or x-ray as the 'gold standard' for establishing PICC-tip location? British Journal of Nursing, Vol 23, No 19 • Oliver Gemma and Jones Matt (2013) Evaluation of an electrocardiograph based PICC tip verification system. British Journal of Nursing, Vol 22, No 14 	<p>The External Assessment Centre assessed the Oliver and Jones (2013, 2014) papers and concluded that neither contained information about the Sherlock 3CG TCS system.</p>
11	2. Head of Nursing - Mastercall Healthcare	General	<p>I am an ANP with 20 years' experience inserting vascular devices in an acute trust in Manchester with the aid of Fluoroscopy and US.</p> <p>I recently moved jobs and I currently work in the community. I am piloting a PICC service in the community without the aid of fluoroscopy by using the Sherlock 3CG equipment.</p> <p>This equipment has enabled me to insert PICC lines without the patient having to attend hospital for an x-ray after insertion to check position of the PICC line. The technology is so advanced with the P wave monitoring and the visual screen demonstrating location of the tip position so that placement is accurate in real time. To date we have had a 100% success rate with placement and no malposition's.</p> <p>For patients with long term clinical conditions and several co morbidities peripheral cannulas can only be</p>	<p>Thank you for your comment.</p> <p>Please note: ANP is taken to denote Advanced Nurse Practitioner.</p>

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			<p>used for 72 hours then have to be replaced. PICCS can be inserted and left in situ for up to 12 months .This takes a lot of pressure off the patient worrying about cannulation blood samples etc.</p> <p>Once the PICC is placed it can be used immediately for IV antibiotic administration thus providing care closer to home for the patient.</p> <p>BARD provide a very intensive training package and clinical nurse specialists for the training which complies with clinical governance</p> <p>The pilot service we are currently trialling has been nominated for The Innovation In Action Awards 2014 category -Patient Centred Care this would not have been feasible without this portable equipment using real time placement with the Sherlock 3CG and the intensive training packing and clinical nurse specialist support</p>	
12	4. East Kent Hospitals University NHS Foundation Trust.	General	<p>Biography:</p> <p>I am the clinical lead for the IV access service in our Trust. I have been placing Peripherally Inserted Central Lines (PICCs), for over 8 years. I head up a dedicated IV access team of 6 nurses. Our team place over 2000 PICCs per annum. We are one of the largest and busiest PICC placement teams in the UK. We have extensive experience in this field and provide training, support and education to many other NHS teams across the UK.</p> <p>Our current practice is based on years of experience</p>	Thank you for your comment.

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			<p>both in terms of patient selection, PICC placement and aftercare. We run a full programme of aftercare clinics as well as regular training to all staff groups in the care and maintenance of PICC lines. We have been using ECG tip location technology to assist in the placement of PICCs for over 3 years and have now used the technology to successfully confirm the accurate placement of over 4000 PICC lines.</p> <p>Executive Summary:</p> <p>Overall, we fully support the proposal to recommend the use of ECG technology to assist in the accurate and timely placement of PICC lines. We strongly oppose the proposal to solely recommend this specific single ECG tip location system. To propose only the Sherlock system will be expensive to the NHS and will create an unacceptable monopoly of a single company that will, in the long term, not provide value for money for the NHS, when there are other, equally effective systems available that represent better value for money.</p>	
13	5. Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation	Thank you for your comment.
14	6. Sponsor	General	No comments	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."

Appendix 1 Additional information relating to the general usage of ECG-based PICC placement systems (comment 3c)

Two example, both which demonstrate that it is the TECHNOLOGY that is validated and NOT the specific Sherlock TCS system:

1.

Pittiruti M, Bertollo D, Briglia E, et al. (2012) The intracavitary ECG method for positioning the tip of central venous catheters: results of an Italian multicenter study. Journal of Vascular Access. Jul-Sep;13(3):357-65

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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.

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Moureau NL, Dennis GL, Ames E et al. (2010) Electrocardiogram (EKG) guided peripherally inserted central catheter placement and tip position: results of a trial to replace radiological confirmation. Journal of the Association for Vascular Access; 15(1): 8-14

Abstract

Background

The current standard of care for Peripherally Inserted Central Catheters (PICCs) is radiological confirmation of terminal tip location. Tip location practices in Europe have used electrocardiographic (EKG) guided positioning for central venous catheters for more than twenty years with tip positioning safely confirmed over thousands of insertions (Madias, 2003). The goal of this group was to confirm the findings of a study performed by Pittiruti and his team; and to establish safe function in the use of EKG guidance for verification of terminal tip position with PICCs placed at McKenzie Willamette Medical Center.

Methods

In 2008/2009 McKenzie Willamette Medical Center conducted a study to determine whether or not EKG guidance can be used as a reliable means to accurately place and confirm terminal tip location of PICCs. A group of trained nurses performed PICC placement using EKG guidance followed by radiological confirmation of SVC position. All PICCs placed from October 2008 to December 2009 were included in the study. Tip location was confirmed using either radiological confirmation alone, EKG plus radiological confirmation, or EKG alone.

Results

A total of 417 PICCs were placed during the study period. EKG guidance alone was used in the placement and confirmation of 168 PICCs. Both EKG and chest x-ray confirmation were used in the placement of 82 of the PICCs; 240 of the PICCs were placed with the use of EKG and then position correlated using the traditional chest x-ray procedure.

Discussion

EKG guided PICC placement proved accurate in consistently guiding the terminal tip to the superior vena cava (SVC). The procedure was easily taught and duplicated by members of the PICC team. The study demonstrated a definite correlation between the height (size) of the P-wave and the location of the terminal tip within the SVC. With knowledge of this correlation, transition from placing PICCs using EKG guidance with chest x-ray confirmation to confirmation of tip placement using just EKG guidance without chest x-ray confirmation was attained. Application of EKG placement/ confirmation performed during insertion saves time previously spent waiting for x-ray confirmation readings, saves cost of chest x-ray, prevents patient exposure to radiation and saves time required for tip repositioning of malpositioned tips found after the end of the procedure.

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Photo 1: EKG interpretation of PICC tip location. Note p-wave amplitude near amplitude of inverted QRS. This demonstrates PICC tip location near the Caval Atrial Junction. G Dennis.

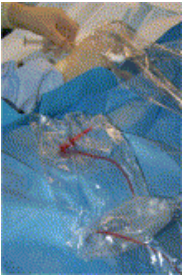


Photo 2: Sterile sleeve covering the EKG alligator cable. G Dennis.

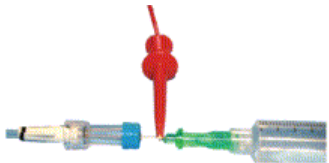


Photo 3: Close up of EKG alligator cable clipped to steel needle shaft for saline-only method of EKG tip placement. G Dennis.

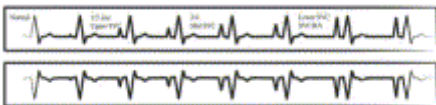


Figure 1: P-Wave Simulated Interpretation (used with permission PICC Excellence, Inc.).

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Photo 4: Pacerview device. Note EKG lead LL attached to Pacerview unit. G Dennis



Photo 5: Vygon/Advanced Medical Vygocard and cable connection for catheter and EKG monitor. PICC Excellence, Inc



Photo 6: B. Braun Alphacard. PICC Excellence, Inc.