*Original research article*

JVA The Journal of Vascular Access

The Journal of Vascular Access
1–9

DOI: 10.1177/11297298221085228
journals.sagepub.com/home/jva
SAGE

# A randomised trial of intracavitary electrocardiography versus surface landmark measurement for central venous access device placement

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## Abstract

**Background:** Malpositioned central venous access devices (CVADs) can lead to significant patient injury including central vein thrombosis and dysrhythmias. Intra-cavitary electrocardiography (IC ECG) has been recommended by peak professional bodies as an accurate alternative for bedside CVAD insertion, to reduce risk of malposition and allowing immediate use of the device. Our objective was to compare the effect of IC ECG on CVAD malposition compared to traditional institutional practice for CVAD placement.

**Methods:** Randomised controlled trial of IC ECG CVAD insertion verses traditional CVAD insertion (surface landmark measurement with post insertion x ray). Patient recruitment was from December 2016 to July 2018. The setting was a 900-bed tertiary referral hospital based in South Western Sydney, Australia. Three hundred and forty-four adult patients requiring CVAD insertion for intravenous therapy, were enrolled and randomly allocated (1:1 ratio) to either IC-ECG ($n = 172$) or traditional ($n = 172$) CVAD insertion. Our primary outcome of interest was the rate of catheters not requiring repositioning after insertion (ready for use). Secondary outcomes were comparison of procedure time and cost.

**Results:** Of the 172 patients allocated to the IC ECG method, 170 (99%) were ready for use immediately compared to 139 of the 172 (81%) in the traditional insertion group (difference, 95% confidence interval (CI): 18%, 11.9–24.1%). The total procedure time was mean 15 min (SD 8 min) for IC ECG and mean 36 min (SD 17 min) for traditional CVAD insertion (difference−19.9 min (95% CI−14.6 to −34.4). IC ECG guided CVAD insertion had a cost reduction of AUD $62.00 per procedure.

**Conclusions:** Using IC-ECG resulted in nearly no requirement for post-insertion repositioning of CVADs resulting in savings in time and cost and virtually eliminating the need for radiographic confirmation.

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**Trial registration:** This trial is registered at the Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au). The registration number is ACTRN12620000919910.

**Keywords**
Central venous access device, intracavitary ECG, catheter tip confirmation

Date received: 12 October 2021; accepted: 12 February 2022

## Introduction

Peripherally inserted central catheters (PICCs) and centrally inserted central catheters (CICCs), collectively referred to as central venous access devices (CVADs), are still commonly placed at the bedside using surface landmark measurement with final catheter position confirmed by chest X-Ray (CXR).[1,2] Confirmation of correct CVAD position is required before commencement of irritant or vesicant intravenous therapy.[2,3] Most international guidelines recommend that the tip of a CVAD (excluding femorally placed catheters) should terminate at or between the lower third of the superior vena cava (SVC) and the upper right atrium (RA).[3–5]

Confirmation by CXR requires radiology personnel to transport a portable X-Ray machine to the bedside or for the patient to be transported to the radiology department, after which the image is reviewed and reported, and only after the catheter is deemed to reside in a suitable position is it released to commence therapy.[2] While the gold standard for many years, this method of interpretation has been challenged as it can be time consuming and costly with variable image quality produced. The interpretation can also be subjective, with accuracy determined by the level of training and experience of the interpreting clinician.[6,7]

A malpositioned CVAD may lead to significant complications that includes venous thrombosis of the central veins, dysrhythmias and catheter malfunction.[6,7] If malposition is identified by CXR after insertion, the catheter usually needs to be repositioned or reinserted and a subsequent X-ray(s) is required. This process leads to increased costs for personnel and consumables, increased radiation exposure due to repeated X-rays, time delays, missed medication doses, and the potential for further complications, including catheter related bloodstream infection as a result of interrupting the integrity of the sterile dressing.[8–10]

Intra-cavitary electrocardiography (IC ECG) guided CVAD placement has been recommended as an alternative to traditional CVAD insertion (with CXR confirmation).[11–13] This method is based on the identification and changing amplitude of the native P-Wave using the distal tip of the CVAD as an intra-cavitary electrode. This is achieved with specific sterile adaptors that bridge the catheter to an ECG monitor via an alligator clip to the metal guide wire inside the catheter and or by the use of a column of physiological saline contained within the catheter.[6]

Many studies on IC ECG CVAD insertion to date have shown benefit compared to CXR interpretation but have focused on testing the effectiveness of the method on either PICC or CICC placement and in homogenous patient populations such as those with cancer or in neonates.[11,14–16] Our experiment aimed to evaluate the accuracy and cost benefit of IC ECG compared to traditional bedside CVAD insertion for patients referred to a nurse led vascular access team that provides central venous access to a broad hospital population and utilises a variety of CVADs. It was hypothesised that the IC ECG method for CVAD insertion would be more accurate than current practice, resulting in shorter procedure times, less catheter malposition and cost savings.

## Materials and Methods

### *Study design and participants*

This was a pragmatic, open label randomised controlled superiority trial comparing accuracy, timing, and cost between traditional and IC ECG CVAD insertion. The study was conducted by the Vascular Access Team (VAT) of the intensive care unit (ICU) of a 900-bed tertiary referral hospital based in South Western Sydney, Australia (Liverpool Hospital). The VAT is staffed by advanced practice nurses who are accredited to insert acute and chronic central venous catheters. The study was planned, conducted and reported with the CONSORT 2010 guidelines that included the CONSORT guidelines for reporting economic evaluation alongside randomised controlled trials.[17,18] Ethical approval to commence this study was given by the South Western Sydney Local Health District Human Research Ethics Committee (HREC/15/LPOOL/552) and conducted in accordance with the Helsinki Declaration for conducting medical research involving human subjects.[19] Participants or persons responsible were given and required to read an information sheet, provided opportunity to ask questions and receive answers before signing a consent form to participate in the study.

Consecutive patients referred for CVAD insertion to the VAT were screened for eligibility. Inclusion criteria were age of at least 18 years, a native P wave on 12 lead ECG assessment and ability to provide written informed consent in English. Exclusion criteria were patients less than

18 years, pacemaker dependency or no native P wave on ECG or inability to provide informed consent for themselves or via a responsible person at the time of catheter insertion. Eligible patients were randomly assigned in a 1:1 ratio (no block randomisation or stratification) to have their catheter placed by traditional landmark surface measurement or IC ECG. Random allocations were computer generated using R version 3.1.2 (R Core Team Vienna, Austria)[20] and concealed to investigators and patients until enrolment. All data was entered into a study specific Microsoft Access® database.

The primary outcome measure was the rate of catheters not requiring repositioning (ready for immediate use) after insertion as interpreted on CXR at the bedside. Catheters that terminated in the lower third of the SVC (within 3cm above of tracheal carina on CXR), the CAJ (up to 3cm below tracheal carina) or upper RA (3–5cm below tracheal carina) were deemed clinically to be in a satisfactory position, however optimal positioning was considered as the CAJ and upper RA. All CXRs were performed using a mobile X-ray machine with an anterior—posterior projection (X-ray plate behind patient) with patients in the high Fowler's position.

Secondary outcomes were a comparison of: (1a) procedural time (initial skin puncture with needle until sterile dressing applied), (1b) **total** procedural time (procedural time, waiting time for CXR, and any post insertion re-manipulation time) and (2), procedural cost (clinician time, cost of CXR, and catheter and consumables required for initial procedure and any subsequent re-manipulations and porter time) between the groups. Unit costs were sourced from the Liverpool Hospital finance department, and clinician cost was the pro rata hourly rate.

## Protocol

The CVAD insertion procedures for both groups incorporated maximal sterile technique with the use of ultrasound to gain venous access and to scan vessels during the procedure for suspected malposition. Choice of catheter (CICC versus PICC) was based on patient assessment, treatment regime and anticipated dwell time. For the intervention, a portable, wireless IC-ECG navigation system (Nautilus Delta Tip Confirmation System—BARD Access Systems, Salt Lake City USA) was used to monitor changing R wave progression as well as increasing amplitude of the P wave to confirm position. When maximum P wave amplitude was achieved, the catheter tip was deemed to be located at the cavo-atrial junction (CAJ) or upper RA and the CVAD was then secured and dressed. This IC-ECG read out device was already established and has been used across hospitals in Europe. Safety monitoring for this study was undertaken using local organisational governance procedures (documenting, escalating, and reviewing any procedural or latent complications). All catheter insertions were successful, and no mechanical complications were reported during the study period, as such the trial ran its entirety. Due to the low risk nature of the trial, no stopping rules were implemented as part of the study protocol.

## Data collection

In both groups, a CXR was taken immediately after catheter insertion to compare catheter tip position. Two credentialled radiologists, (blinded to patient allocation) trained in CXR film interpretation, independently reviewed all CXRs to confirm catheter tip position using digital callipers and the tracheal carina as the consistent measuring landmark on the computerised film.[21–24]

An independent observer documented the procedural start time (first needle puncture of skin) and conclusion time (the sterile dressing was applied). Although post procedure CXRs were performed in both groups (to compare catheter tip position), total procedure time was complete in the IC ECG group when sterile dressing was applied to skin, since this is when the catheter would normally be released for use after ECG confirmation. In patients undergoing traditional CVAD insertion, total procedure time was measured *after* the CXR was performed and reviewed. If catheters required repositioning after CXR in either group, time was measured for this additional procedure and added to the total procedure time.

## Statistical analysis

All analysis was undertaken using an intention-to-treat (ITT) approach. The sample size was based on our existing central venous access service catheter malposition rate of 16.75%[25] being reduced to 5% using IC ECG. It was estimated that 163 patients were required in each group for >90% power and Type I error of 5%. With an estimated 5% attrition rate, 172 patients were randomised in each group (total of 344 patients). Characteristics of study participants based on allocation to traditional or IC ECG groups are presented using descriptive statistics. For our primary outcome of interest (catheter malposition), we calculated the percentage difference and associated 95% confidence intervals (CI) between groups. A similar approach was used to compare the mean procedure time and reason for catheter removal.[26] All data management and analyses were undertaken using the R language for statistical computing, version 3.1.2 (R Core Team Vienna, Austria).

**Results** Between December 2016 and July 2018, a total of 344 patients were randomly allocated and sequentially enrolled for CVAD insertion using either IC-ECG ($n = 172$) or surface landmark ($n = 172$) guided insertion (see Figure 1). Patient and device characteristics are presented in **Table 1**. The main types of catheters used in this study were PICCs, that were placed in the basilic vein. Antibiotic therapy was the primary reason for

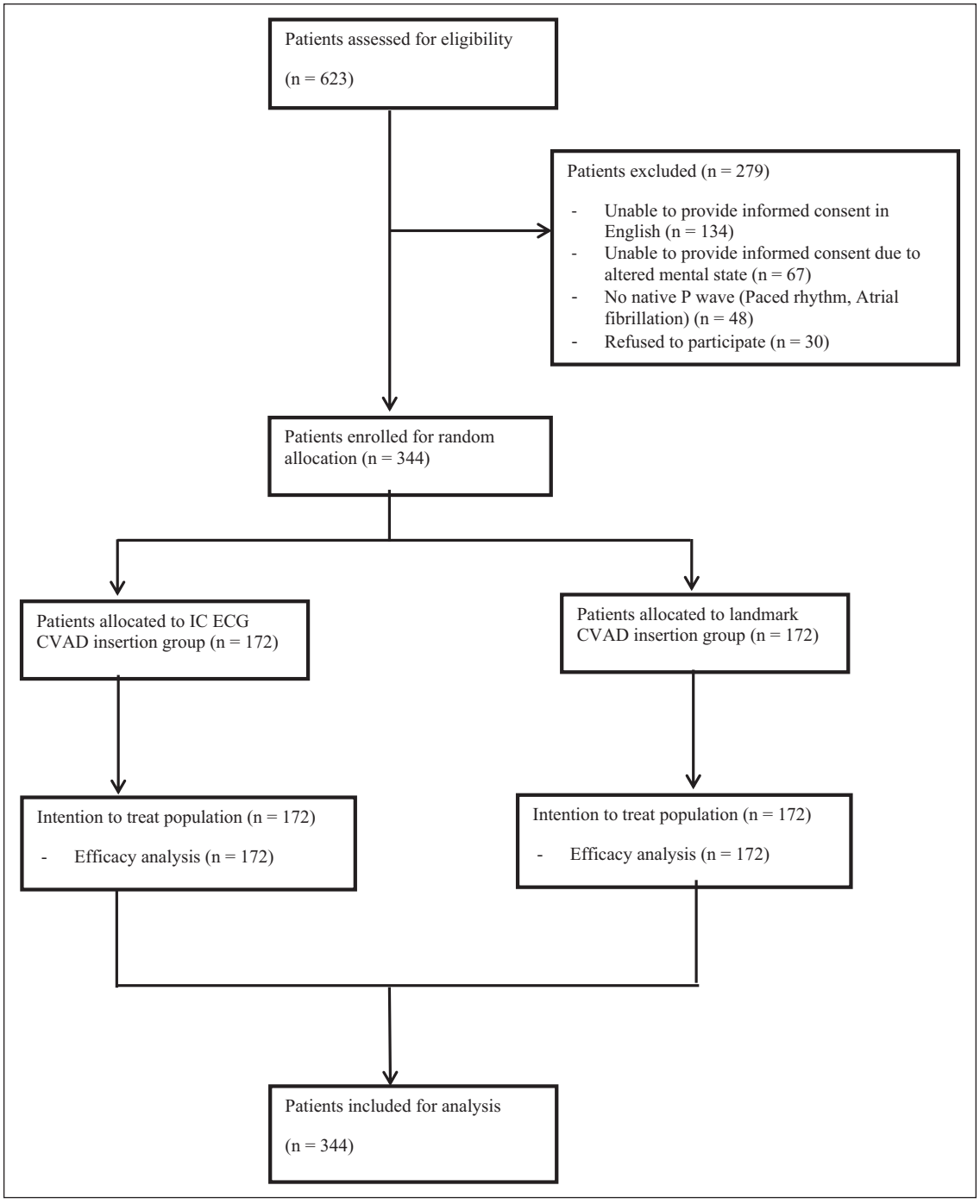


**Figure 1.** Study profile of patient flow.

CVAD insertion in both study groups. No procedural complications were observed in either group.

Of the 172 catheters in the IC ECG group, 170 (99%) were placed successfully and did not require any further manipulation after bedside CXR assessment (Table 2). One of the catheters that required manipulation after insertion in the IC ECG group, was identified during the procedure as not displaying the classic P wave maximum amplitude on the ECG monitor and found to have taken an aberrant pathway on CXR, the other was identified to be too deep in atrium and was withdrawn to optimal position. In contrast, 139 from the 172 CVADs (81%) in the traditional group, did not require any further intervention (percentage difference, 95% CI: 18%, 11.9 to 24.1%). A similar proportion of CVADs not requiring further manipulation after insertion was also found with the blinded radiologist

**Table 1.** Characteristics of study participants based on allocation to IC ECG or Traditional method of central venous access device placement.

| | CVAD placement method | |
|---|---|---|
| | IC ECG ($n=172$) | Traditional ($n=172$) |
| Age years, median (IQR)^ | 58 (49–68) | 60 (51–69) |
| Gender, *n* (%) | | |
| Female | 75 (44) | 69 (40) |
| Male | 97 (56) | 103 (60) |
| BMI, median (IQR) | 28 (24–34) | 28 (24–34) |
| Indication for Catheter, *n* (%) | | |
| Apheresis | 8 (5) | 9 (5) |
| Chemotherapy | 51 (30) | 29 (17) |
| Haemodialysis | 1 (1) | 0 |
| Antibiotics | 97 (56) | 119 (69) |
| Fluid management | 6 (3) | 2 (1) |
| Other | 2 (1) | 1 (1) |
| Parenteral nutrition | 7 (4) | 12 (7) |
| Catheter insertion site, *n* (%) | | |
| Axillary vein | 4 (2) | 1 (1) |
| Basilic vein | 151 (88) | 158 (92) |
| Cephalic vein | 1 (1) | 0 |
| Internal jugular vein | 13 (8) | 10 (6) |
| Subclavian vein | 3 (2) | 3 (2) |
| Catheter Type, *n* (%) | | |
| CVC* double lumen | 0 | 1 (1) |
| CVC triple lumen | 7 (4) | 5 (3) |
| Dialysis catheter | 9 (5) | 9 (5) |
| PICC# single lumen | 102 (59) | 125 (73) |
| PICC double lumen | 54 (32) | 32 (18) |

^IQR = inter quartile range, *CVC = central venous catheter, #PICC = peripherally inserted central catheter.

**Table 2.** Procedural characteristics based on allocation to IC ECG or traditional method of central venous access device placement.

| | CVAD placement method | | Difference (95%CI) |
|---|---|---|---|
| | IC ECG ($n=172$) | Traditional ($n=172$) | |
| Catheter Manipulations, *n* (%) | | | |
| Not required, ready for use | 170 (99) | 139 (81) | 18.02 (11.92 to 24.12) |
| Manipulated during procedure | 64 (37) | 28 (16) | 20.93 (11.84 to 30.02) |
| Independent X ray review: | | | |
| Optimal Catheter Position, *n* (%) | 162 (94) | 131 (76) | 18.02 (10.76 to 25.29) |
| Procedural time, mean minutes (SD) | | | |
| Actual (needle to skin until dressing applied) | 15 (8) | 12 (5) | 2.8 (1.4 to 4.2) |
| Total procedure time | 15 (8) | 36 (17) | −19.9 (−14.6 to −34.4) |

CI: confidence interval; SD: standard deviation.
Total procedural time: inclusive of chest X-ray waiting time (traditional group) and any catheter re-manipulation post chest X-ray (either group).

CXR review (percentage difference, 95% CI: 18%, 10.8 to 25.3%). Twice the number of catheters required manipulation intra procedure ($n=64$, 37%) in the IC ECG compared to the traditional group ($n=28$, 16%, percentage difference, 95% CI: 20.9%, 11.8 to 30%).

Procedure time was observed to take longer with IC ECG taking an average of 15 min (standard deviation (SD) 8 min) compared to 12 min (SD 5 min) for traditional placement. However, when total procedure time was calculated (procedural time, waiting time for CXR, and any

**Table 3.** Estimated cost based on allocation to IC ECG or Traditional method of central venous access device placement.

| | CVAD placement method | | Overall cost saving using IC ECG |
|---|---|---|---|
| | IC ECG ($n = 172$) | Traditional ($n = 172$) | |
| Costs, $AUD | | | |
| Nurse cost, pro rata | 3147 | 7442 | 4295 |
| Catheter cost with consumables | 28,841 | 29,129 | 288 |
| Catheter positioning cost^ | 4300 | 8110 | 3810 |
| Re-manipulation after CXR | 218 | 2525 | 2307 |
| Porter transport services | 2408 | 2408 | |
| Total | 36,546 | 47,206 | 10,700 |
| Average per patient | 212 | 265 | 62 |

^Catheter positioning cost = cost of ECG adaptor or cost of CXR.

**Table 4.** Catheter Removal outcomes based on allocation to IC ECG or Traditional method of central venous access device placement.

| | CVAD placement method | | *Difference (95%)* |
|---|---|---|---|
| | IC ECG ($n = 172$) | Traditional ($n = 172$) | |
| Reason for Catheter Removal, *n* (%) | | | |
| Deceased | 1 (0.6) | 2 (1.2) | −0.58 (−2.55, 1.38) |
| Dislodgement | 13 (7.6) | 5 (2.9) | 4.65 (−0.03, 9.33) |
| End of Treatment | 143 (83) | 155 (90) | −6.98 (−14.13, 0.18) |
| Occlusion | 3 (1.7) | 0 | 1.74 (−0.21, 3.70) |
| Other* | 3 (1.7) | 6 (3.5) | −1.74 (−5.11, 1.62) |
| Suspected infection | 7 (4.1) | 3 (1.7) | 2.33 (−1.22, 5.87) |
| Symptomatic thrombosis | 2 (1.2) | 1 (0.6) | 0.58 (−1.38, 2.55) |
| CLABSI^, n (per 1000 catheter days) | 0 (0) | 1 (0.2) | −0.15 (−0.44, 0.14) |
| Catheter dwell (days), mean (SD, Total) | 35 (39, 5855) | 39 (74, 6707) | −4.4 (−17.1, 8.2) |

^CLABSI = Central line associated bloodstream infection, *Other = composite of catheter exchange and discharged with line in situ).

post insertion re-manipulation time), IC ECG reduced the average procedure time by more than half (15 min, SD 8 min vs 36 min, SD 17 min).

When total procedure time, CXR, device and consumables costs were calculated and compared, the use of IC ECG had a cost reduction of AUD $62.00 per procedure, a cumulative saving of AUD $10,700 over the study period (Table 3). No major difference was found in the reason for removal of catheters between groups (and no loss to follow up in either group—Table 4). One central line associated bloodstream infection (CLABSI) was reported (in the surface landmark group) during the study period (0.2/1000-line catheter days, percentage difference, 95% CI: −0.15%, −0.44 to 0.14%) and catheter dwell was similar in both groups (35 days, SD 39 days IC ECG group vs 39 days, SD 74 days in traditional group). No catheters were removed for malposition related complications in either group.

## Discussion

Nearly all catheters inserted using IC ECG were placed successfully without need for manipulation after bedside CXR confirmation. Overall, this method of CVAD insertion was more efficient, reduced procedure costs by decreasing the reliance on CXR confirmation as well as minimising catheter repositioning that has associated direct and indirect costs (including staff time, extra consumables as well as additional radiation exposure).

Although two catheters in the IC ECG group required repositioning, one was identified as malpositioned during the procedure, as no maximal *p* wave was established on the ECG monitor. This catheter therefore would not ordinarily be released for use until position was confirmed with either ultrasound or radiological imaging. The second malpositioned catheter was noted to be deep in the atrium and was withdrawn to optimal position. This may have been user interpretation error or the catheter accidentally re-advanced after confirmation.

A number of randomised control trials (RCTs) and observational studies have been performed to assess the benefit of IC ECG versus traditional methods used to insert CVADs.[24,27–29] A 2015 meta-analysis found IC ECG for CVAD tip termination to be eight times more effective than traditional CXR confirmation, however a number of

studies were deemed to be under powered and were limited to very specific populations of patients.[11] A more recent meta-analysis concluded that IC ECG had a more favourable accuracy compared to traditional CXR confirmation (odds ratio (OR): 2.88, 95% CI: 2.15–3.87, $p < 0.001$), however the authors reported that an incomplete literature search may have led to publication bias.[30] A review by Yu and Yuan concluded that using the IC ECG method to place CVADs was more accurate compared to the anthropometric method (OR: 0.21, 95% CI: 0.14–0.34, $p < 0.001$) however the meta-analysis performed incorporated both randomised and non-randomised studies with significant heterogeneity and risk of selection bias.[31]

Most studies assessing the effect of IC ECG have concentrated on homogenous populations such as neonates and paediatrics or those with cancer, and usually on specific devices (exclusively with PICCs or CICCs).[13–15,32] This includes a multicentre randomised trial in 1000 cancer patients across eight hospitals in China comparing IC ECG to anatomical landmark technique using PICCs from a single manufacturer.[13] The study reported the IC ECG method to be superior with close to 90% of catheters placed first attempt with no need for repositioning. Our randomised trial has addressed an evidence practice gap by evaluating the use of IC ECG across a broad hospital population using a multitude of devices.

Interestingly, we found that procedure time (composite of initial skin puncture with needle to sterile dressing applied) was longer in the IC ECG group. This can be explained by our findings that more than twice as many catheters in the IC ECG group required catheter manipulation during the procedure compared to the traditional insertion group, which would be expected as catheters were manipulated intra procedure until the maximal P wave was observed on the ECG monitor. This however was substantially offset when total procedural time was calculated.

Catheter tip malposition is estimated to occur frequently, one single centre study reported 85% of PICCs ($n = 723$) in a paediatric population to have been placed sub optimally requiring further manipulation.[33] Even with experienced CVAD inserters, up to 1 in 6 catheters can be malpositioned.[25,34] Undiagnosed malposition can have harmful outcomes that can contribute to significant morbidity including dysrhythmias, venous thrombosis and vessel wall erosion.[35] Importantly, when catheters require repositioning, it involves the sterile dressing to be disrupted and the catheter to be physically handled. Even with the use of an aseptic non-touch technique (ANTT) and the use of sterile equipment, the risk of accidental contamination and subsequent bloodstream infection is not completely eradicated.[9,36]

Intra-procedural ultrasound scanning has also been proposed as a clinical strategy to mitigate against an aberrant catheter path during insertion, including scanning the internal jugular vein for evidence of ipsilateral catheter malposition.[37] Studies have also shown that the use of agitated saline with trans thoracic echocardiography (TTE) or transesophageal echocardiography (TEE) and more recently, the ECHOTIP protocol developed by La Greca and colleagues, to be effective in confirming catheter position in the SVC/RA.[38–41] However, these techniques require more advanced ultrasound skills and more than one operator to undertake appropriate ultrasound scanning, and may not be feasible for many institutions. A combination of both intra procedural scanning and IC ECG would be ideal if resources permitted.

We found a cost reduction of AUD $62 when IC ECG is used. The VAT at Liverpool Hospital insert approximately 1800 CVADs annually and hence the cumulative cost saving for this service alone would be in excess of AUD $110,000 every year. Staff time saved has also provided productivity gains for the hospital with approximately six more CVAD insertions realised weekly (or 1 extra working day of productivity).

Cost reduction of IC ECG has been reported in previous investigations. This includes an evaluation of IC ECG by Keller et al. (2019) who reported a lower repositioning rate of 1.5% with IC ECG compared to 86.8% in the traditional group. The cost reduction was calculated to be USD $63 per catheter.[27] A time in motion study undertaken by Tomaszewski et al.[2] found significant time and cost savings with IC ECG as no catheters required repositioning, but 20% (as in our study) required repositioning for those that had PICCs inserted traditionally. The cumulative cost savings over a 3-year period were calculated at USD $215,899.

Our findings showed a significant benefit of IC ECG for placement of various CVADs; however, our results should be considered within the context of some limitations. CVAD insertions were predominant PICCs (approximately 90%) and although a small proportion of devices were CICCs (reflecting the day to day workload of the VAT), it was still effective. This trial was open label and nurses placing the CVADs were not blinded to group, all CXRs were reviewed immediately after insertion (by the inserters) and a decision made at that time whether the CVAD required repositioning. This may have contributed to unconscious bias towards not manipulating catheters in the intervention group. However, all CXRs were independently reviewed and reported by two credentialled radiologists blinded to insertion procedure which found the IC ECG method to be more accurate than traditional CVAD insertion.

A technical limitation for the use of IC ECG is the requirement of an identifiable *p* wave; therefore, our results do not apply to a small group of patients ($n = 48$ (8%) in our study). However, the method was applicable in over 90% of our heterogenous study group, and in fact can be used for patients with atrial fibrillation if the inserter is experienced with using IC ECG.[42]

## Conclusion

This study has shown that the IC ECG method is more accurate and efficient than traditional placement of CVADs and can be used across diverse patient cohorts requiring a wide range of devices. The IC ECG technique saves procedural time and allows the catheter to be used immediately after insertion, contributing to significant direct and indirect cost savings, as well as providing patient safety benefits including reduced reliance on radiological confirmation and limiting radiation exposure.

### Authors' contributions

All authors have made substantial contributions to the study conception and design, acquisition of data and analysis and interpretation of data. Each author has contributed to drafting and editing the manuscript and approves the final version for publishing as per the International Committee of Medical Journal Editors (ICMJE) convention.

### Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by unrestricted investigator-initiated research grants from Cook Medical Australia (IR151001R), Flo Medical Australia (Nil Grant Number) and CR BARD (USA—181019). All funds were paid to Western Sydney University and not to individual researchers.

### Data sharing statement

Due to Local Health District Restrictions, data can be made available on reasonable request

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