Full Title:

Exclusively Cephalic Venous Access for Cardiac Resynchronisation: A Prospective Multi-Centre Evaluation

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Short Title:

Exclusively cephalic access for CRT

Conflicts of Interest:

Dr Gallagher has received research funding from Medtronic and Boston Scientific, and has acted as a consultant for Medtronic

Ethical approval:

Institutional ethical committee approval was obtained.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/pace.14046.

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Abstract word count: 223

Word count (excluding references): 2000

STRUCTURED ABSTRACT:

Background: Small series have shown that cardiac resynchronization therapy (CRT) can be achieved in a majority of patients using exclusively cephalic venous access. We sought to determine whether this method is suitable for widespread use.

Methods: A group of 19 operators including 11 trainees in 3 pacing centres attempted to use cephalic access alone for all CRT device implants over a period of 8 years. The access route for each lead, the procedure outcome, duration and complications were collected prospectively. Data were also collected for 105 consecutive CRT device implants performed by experienced operators not using the exclusively cephalic method.

Results: A new implantation of a CRT device using exclusively cephalic venous access was attempted in 1091 patients (73.6% male, aged 73±12 years). Implantation was achieved using cephalic venous access alone in 801 cases (73.4%) and using a combination of cephalic and other access in a further 180 (16.5%). Cephalic access was used for 2468/3132 leads implanted (78.8%). Compared to a non-cephalic reference group, complications occurred less frequently (69/1091 vs 12/105; p=0.0468) and there were no pneumothoraces with cephalic implants. Procedure duration and fluoroscopy duration were shorter (procedure duration 118±45 vs 144±39 minutes, p<0.0001; fluoroscopy duration 15.7±12.9 vs 22.8±12.2 minutes, p<0.0001).

Conclusions: CRT devices can be implanted using cephalic access alone in a substantial majority of cases. This approach is safe and efficient.

Key Words: Cephalic vein; venous cut down; Cardiac Resynchronization Therapy; Subclavian vein; Seldinger technique; Pneumothorax

CONDENSED ABSTRACT

Cardiac resynchronisation devices are usually implanted using venous puncture, creating a risk of pneumothorax or vascular injury. We have described an implantation method using exclusively cephalic venous access. We used this method in 1091 consecutive patients treated by 19 operators of varying experience. Procedures were safe and efficient with no pneumothorax or haemothorax.

INTRODUCTION

Cardiac resynchronisation therapy (CRT) is an effective adjunct in the treatment of heart failure, widely indicated for prognostic and symptomatic benefit in the setting of systolic impairment(1). Implantation of CRT devices is technically demanding, associated with a significant risk of acute complications including a risk of pneumothorax of up to 5%(2–5). Subclavian access is associated with subclavian crush phenomenon and the use of extra-thoracic axillary access is predictive of the development of lead failure(6).

The use of direct venous cut down to access the cephalic vein in the deltopectoral groove eliminates the risk of pneumothorax, but it requires additional surgical skills. Although it is the first choice for simple pacing device implants it is not conventionally used for left ventricular lead implantation(7–9). Basic trigonometry dictates that the additional vein circumference needed to accommodate a third lead in the cephalic is minimal, as illustrated in the central figure; triple cephalic access for CRT is feasible in single center case series of up to 200 patients(9–11). Following a previous single-operator pilot study, here we report our experience rolling out the cephalic approach to include over 1,000 CRT implants by physicians of varying experience.

METHODS

Institutional ethical committee approval was obtained. From October 1st 2009, a group of 19 implanting cardiologists in 3 neighbouring centres including operators of widely different levels of experience attempted to use exclusively cephalic access for all leads in all *de novo* CRT defibrillator (CRT-D) or CRT pacemaker (CRT-P) implants. Patient-related and

procedural data were collected prospectively in all patients. We evaluated the outcome of all CRT implantation procedures by this group. All operators self-reported their prior experience at CRT implant before starting the study.

Implant technique

After incising the skin and constructing a pocket for the generator, the cephalic vein was exposed in the deltopectoral groove. The distal end was tied off and a transverse venotomy performed. A 150-cm angled 0.97-mm hydrophilic guidewire (Radiofocus RF * GA35153M, Terumo Corporation, Tokyo, Japan) and two standard 50-cm 0.97-mm guidewires (St. Jude Medical, Minnetonka, MN, USA) were introduced into the cephalic vein and advanced toward the heart (figure 1). A left ventricular lead delivery system (Medtronic Attain LDS 6216A, Medtronic Inc., Minneapolis, MN, USA) was advanced over the hydrophilic wire and used to perform contrast venography of the coronary sinus, then to position a pacing lead in a suitable cardiac vein. Right atrial and ventricular leads were then implanted using 7Fr peel-away sheaths, or 9Fr for ICD leads, placed using a retained guidewire technique. Cephalic access was preserved until the end of the procedure. Significant cardiac pauses during CS lead placement were managed by unipolar pacing using a long guide wire.

If the cephalic vein could not be identified or if it was found to be too small to accommodate all the leads required, a modified Seldinger technique was used to access the axillary or subclavian vein for one or more leads. We aimed to place as many leads as possible via the cephalic vein even if it was impossible to use it for all.

Post procedure care was at physician discretion but included as a minimum a chest radiograph and a device interrogation performed at 2-24 hours after implantation.

Reference Group

Five experienced operators in one of the participating centres declined to trial the fully cephalic technique, preferring to use either hybrid or fully subclavian access. Data from consecutive *de novo* CRT implant procedures undertaken by these operators were collected in the same way as for the operators using cephalic access and used as a non-cephalic CRT comparator group. Procedure reports, catheter lab electronic records and post procedure chest radiographs were used to determine procedure parameters and complications.

Follow-up

All patients were followed at intervals of not more than 12 months to check for pacing lead performance and the occurrence of complications. Any need for revision of any of the leads within the lifespan of the generator implanted on the index procedure was considered as a complication of that procedure.

Statistics

Statistical analysis was performed in Prism (GraphPad Software Inc., USA). Means of continuous data were compared using Student's t-test and categorical data were compared using Fisher's exact test or Pearson's Chi squared where the expected count exceeded five. Bilateral p values less than 0.05 were considered significant.

RESULTS

After exclusion of cases with insufficient data, the study group comprised 1091 consecutive CRT implantation procedures performed between October 1st 2009 and June 30th 2017 by a group of 19 operators including 11 trainees who attempted to use cephalic access exclusively for all procedures (table 1, figure 2). The non-cephalic comparator group comprised 105 implants by 5 operators collected over the same time period.

Procedural success

Implantation of all attempted leads was achieved at the index procedure in almost all patients (1083/1091; 99.3%); in a majority of patients (801/1091, 73.4%) this was done using cephalic venous access only. In a further 180/1091 (16.5%) of cases, one or more of the leads was implanted by the cephalic route, so that in total 2468/3132 (78.8%) of the leads implanted in this cohort were implanted via the cephalic route. The most successful (and most active) operator achieved full cephalic implants in 411/448 (91.7%) of cases.

Two versus three lead systems

The achievement of exclusively cephalic access was greater for systems that included an atrial lead (75.8% for 3-lead systems vs 66.9% for 2-lead systems; p=0.0330). Patients undergoing 2-lead implants were older (76.4±13.9yrs vs 72.7±12.4yrs; p=0.0017) and 2-lead procedures tended to be done more frequently by trainees (39/113 vs 148/958; p=0.0002).

Predictors of cephalic success

The proportion of implants accomplished by exclusively cephalic access was greater among accredited independent operators than trainees (75.5% vs 65.6%; p=0.0038) but no different in patients implanted with CRT-P compared to CRT-D (76.5% vs 72.0%; p=ns). Success at

achieving a full cephalic implant varied highly between operators, from 12.5% to 88.3% but as shown in figure 3, success rate for individual operators did not correlate with procedural volume (R^2=0.04; p=ns) when trainees were included in the analysis. When trainees were excluded from the analysis, however, a trend to higher success with more volume was seen (R^2=0.47) but the analysis was under-powered to reach statistical significance (p=ns). Operators' CRT implant volume prior to the study period was, in general, far lower than their implant volume during the study period (range 0-200); implant volume prior to the study period was not predictive of volume during the study period (R^2=0.17; p=ns), or of full cephalic success rate (R^2=0.03; p=ns).

Performance vs the non-cephalic access reference group

105 *de novo* CRT implants performed by operators who declined to use the cephalic approach were identified over the study period. Patient characteristics were similar to the non-cephalic reference group. Accredited independent operators were over-represented in this group compared to the study group (table 1). Despite the more experienced operators in the reference group, procedure duration and fluoroscopy duration were significantly longer for non-cephalic procedures (procedure duration 118±45 vs 144±39 minutes, p<0.0001; fluoroscopy duration 15.7±12.9 vs 22.8±12.2 minutes, p<0.0001) and a greater proportion of procedures in the cephalic group were completed successfully within 2 hours (57% vs 21%, p<0.01, figure 4).

Complications

The overall incidence of complications was lower in the cephalic group compared to the non-cephalic access reference group (table 2); there were no pneumothoraces in the cephalic access group. Despite the well-documented risk of symptomatic venous occlusion on the

ipsilateral upper limb, particularly with 3-lead systems, this complication was not reported following any implant.

DISCUSSION

This study shows that CRT can be delivered safely and efficiently using exclusively cephalic access in a majority of patients by a range of operators, and in a large proportion of patients by operators of varying levels of experience. Our series is the largest to date to address CRT implantation using solely cephalic access.

Overall, our success at cephalic implantation was 73.4%, lower than other smaller series, including our own single operator pilot study(9–12). This probably represents the mixed experience levels in our group of implanters, and different levels of enthusiasm for the technique, compared to other reports including only experienced operators with a high level of commitment. The largest previously published series of 3-lead CRT implants included 171 *de novo* implants achieving triple cephalic access in 87.7%, reflecting the extensive experience of a single operator at the McGill University Health Centre, QC, Canada(9). By comparison, our largest volume operator achieved triple cephalic access in 91.7% in the current case series. The main differences in implant technique between the McGill series and ours, are the order of lead placement, McGill's use of three short peel-away sheaths in the cephalic, and that McGill leave the RA sheath and CS delivery system *in situ* until all leads are in place. An extra short sheath is presumably made necessary to maintain maneuverability of the CS delivery system when implanting the CS lead after the right ventricular lead. We avoid the need for a third short sheath by implanting the CS lead first via a delivery system without a short sheath and we slit the CS delivery system before

implanting RV then RA leads. We do not use an over-sized sheath (11Fr) for RV defibrillator lead placement as *per* the McGill method.

Employing advanced methods such as venodilatation and use of specialized equipment can increase cephalic success rates to 96%(13–15). Counterintuitively, our full cephalic success rate was lower for 2-lead vs 3-lead CRT systems; this may be explained by the older population undergoing 2-lead system implants related to the increased prevalence of permanent atrial fibrillation with age, and also these implants tended to be undertaken more frequently by trainees.

Previously, the largest single study comparing access methods for non-CRT implants found longer procedure times associated with the cephalic implant route than with a subclavian approach(16). We found the opposite, with shorter procedure and fluoroscopy times using the cephalic route, and a more reliable achievement of success within a reasonable procedure duration.

The incidence of complications related to direct access to the subclavian or axillary vein is reduced when guided by ultrasound or by venography(17), but individual studies show risks of up to 5%(3,12,16). In contrast, a recent meta-analysis of pacing trials estimated the risk of pneumothorax with the cephalic approach 0.19%, related in most cases to use of a higher risk access method once cephalic access has failed(7). By implanting the CS lead first, in theory we risked higher rates of intraprocedural CS lead displacements, however the retention of guidewires for RA and RV lead placement meant that we were able to retain

cephalic access even after CS lead displacement and reduce conversion to higher risk access. The avoidance of pneumothorax is particularly vital in elderly patients, who are more than twice as prone to pneumothorax during pacing procedures(18) and be more severely affected by their occurrence. Our study confirms that using the cephalic route minimizes the risk of this complication.

Although cephalic access is the preferred route of access for 61% of device implanting physicians in a recent EHRA survey, it was also reported that sole cephalic access is not commonly pursued for CRT implants (8). This appears to be due to concerns that the cephalic vein is unable to accommodate three leads, that lead maneuverability might be compromised, or that the process of cephalic cutdown could prolong procedures unnecessarily. Our experience suggests that these concerns are unfounded.

LIMITATIONS

This was a non-randomised series, with procedures performed by operators with substantial prior experience of CRT and of the use of cephalic venous cut-down, or by trainees supervised by experienced operators. Operator activity varied significantly, with the most active performing over 500 implants and the least active under 10. Varying operator experience may have contributed to differences in success rates in the cephalic implants vs the non-cephalic reference group. However very high success rates were achieved across a range of operators with the cephalic approach.

CONCLUSION

CRT devices can be implanted using cephalic access alone in a majority of cases. This approach is safe and efficient.

ACKNOWLEDGEMENTS

Sue Jones and Tamara Daily contributed to the collection of data.

REFERENCES

1. Normand C, Linde C, Singh J, Dickstein K. Indications for Cardiac Resynchronization Therapy. JACC Hear Fail [Internet]. 2018 Apr 1 [cited 2019 Mar 31];6(4):308–16. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2213177918301203

2. Olechowski B, Sands R, Zachariah D, Andrews NP, Balasubramaniam R, Sopher M, et al. Is cardiac resynchronisation therapy feasible, safe and beneficial in the very elderly? J Geriatr Cardiol [Internet]. 2015 Sep [cited 2016 Aug 11];12(5):497–501. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26512240

3. Aggarwal RK, Connelly DT, Ray SG, Ball J, Charles RG. Early complications of permanent pacemaker implantation: no difference between dual and single chamber systems. Br Heart J [Internet]. 1995 Jun 1 [cited 2019 Feb 9];73(6):571–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/7626359

4. Șoșdean R, Pescariu S, Enache B, Macarie R, Marca R. Implantation of Biventricular Cardiac Devices Using a Double Venous Approach — An Alternative Implantation

Technique. Acta Medica Marisiensis [Internet]. 2014 Apr 1 [cited 2019 Mar 31];60(2):57–60. Available from: http://content.sciendo.com/view/journals/amma/60/2/article-p57.xml

5. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Pneumothorax in cardiac pacing: a population-based cohort study of 28,860 Danish patients. Europace [Internet]. 2012 Aug 1 [cited 2019 Apr 13];14(8):1132–8. Available from: https://academic.oup.com/europace/article-lookup/doi/10.1093/europace/eus054

6. Aizawa Y, Negishi M, Kashimura S, Nakajima K, Kunitomi A, Katsumata Y, et al. Predictive factors of lead failure in patients implanted with cardiac devices. Int J Cardiol [Internet]. 2015 Nov 15 [cited 2019 Apr 13];199:277–81. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26218183

7. Benz AP, Vamos M, Erath JW, Hohnloser SH. Cephalic vs. subclavian lead implantation in cardiac implantable electronic devices: a systematic review and meta-analysis. EP Eur [Internet]. 2019 Jan 1 [cited 2019 Mar 31];21(1):121–9. Available from: https://academic.oup.com/europace/article/21/1/121/5055370

8. Bongiorni MG, Proclemer A, Dobreanu D, Marinskis G, Pison L, Blomstrom-Lundqvist C, et al. Preferred tools and techniques for implantation of cardiac electronic devices in Europe: results of the European Heart Rhythm Association survey. Europace [Internet]. 2013 Nov 1 [cited 2019 Apr 1];15(11):1664–8. Available from: https://academic.oup.com/europace/article-lookup/doi/10.1093/europace/eut345

9. Hadjis A, Proietti R, Essebag V. Implantation of cardiac resynchronization therapy devices using three leads by cephalic vein dissection approach. EP Eur [Internet]. 2017 Sep 1 [cited 2019 Mar 31];19(9):1514–20. Available from: https://academic.oup.com/europace/article/19/9/1514/3073886

10. Romeyer-Bouchard C, Da Costa A, Abdellaoui L, Messier M, Thévenin J, Afif Z, et al. Simplified cardiac resynchronization implantation technique involving right access and a triple-guide/single introducer approach. Hear Rhythm [Internet]. 2005 Jul [cited 2019 Apr 1];2(7):714–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15992727

11. Ussen B, Dhillon PS, Anderson L, Beeton I, Hickman M, Gallagher MM. Safety and Feasibility of Cephalic Venous Access for Cardiac Resynchronization Device Implantation. Pacing Clin Electrophysiol [Internet]. 2011 Mar 1 [cited 2016 Aug 11];34(3):365–9. Available from: http://doi.wiley.com/10.1111/j.1540-8159.2010.02975.x

12. Vogler J, Geisler A, Gosau N, Hakmi S, Willems S, Rassaf T, et al. Triple lead cephalic versus subclavian vein approach in cardiac resynchronization therapy device implantation. Sci Rep [Internet]. 2018 Dec 7 [cited 2019 Mar 31];8(1):17709. Available from: http://www.nature.com/articles/s41598-018-35994-0

13. Kolettis TM, Lysitsas DN, Apostolidis D, Baltogiannis GG, Sourla E, Michalis LK. Improved “cut-down” technique for transvenous pacemaker lead implantation. Europace [Internet]. 2010 Sep 1 [cited 2019 Apr 1];12(9):1282–5. Available from: https://academic.oup.com/europace/article-lookup/doi/10.1093/europace/euq173

14. Gonna H, Domenichini G, Zuberi Z, Adhya S, Sharma R, Anderson LJ, et al. Femoral implantation and pull through as an adjunct to traditional methods in cardiac resynchronization therapy. Hear Rhythm [Internet]. 2016 Jun [cited 2019 Apr 13];13(6):1260–5. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1547527116001272

15. Domenichini G, Zuberi Z, Gallagher MM. A pacing lead repositioned without incising the skin: a simplified approach. Europace [Internet]. 2014 Feb 1 [cited 2019 Apr

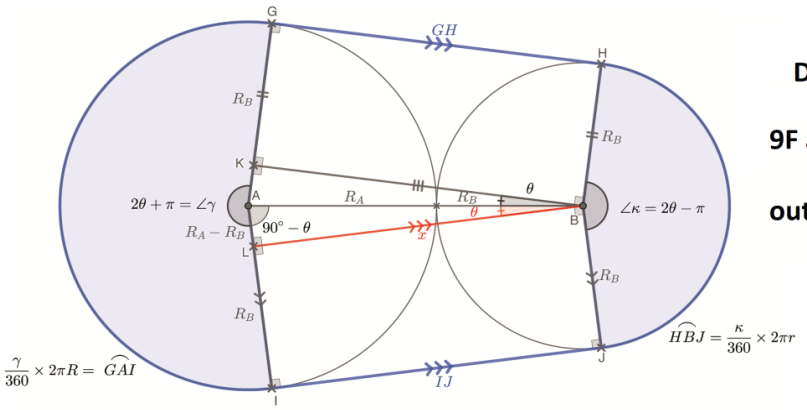
13];16(2):305. Available from: https://academic.oup.com/europace/article-lookup/doi/10.1093/europace/eut273

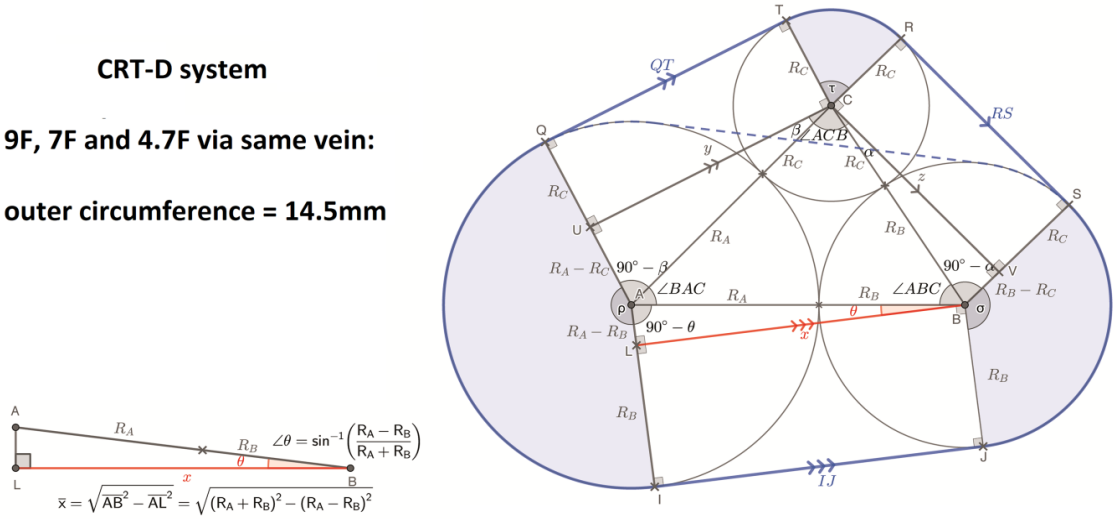
16. Calkins H, Ramza BM, Brinker J, Atiga W, Donahue K, Nsah E, et al. Prospective Randomized Comparison of the Safety and Effectiveness of Placement of Endocardial Pacemaker and Defibrillator Leads Using the Extrathoracic Subclavian Vein Guided by Contrast Venography Versus the Cephalic Approach. Pacing Clin Electrophysiol [Internet]. 2001 Apr 1 [cited 2019 Feb 9];24(4):456–64. Available from: http://doi.wiley.com/10.1046/j.1460-9592.2001.00456.x

17. Liccardo M, Nocerino P, Gaia S, Ciardiello C. Efficacy of ultrasound-guided axillary/subclavian venous approaches for pacemaker and defibrillator lead implantation: a randomized study. J Interv Card Electrophysiol [Internet]. 2018 Mar 15 [cited 2019 Apr 1];51(2):153–60. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29335840

18. Mikhaylov EN, Lebedev DS. Cardiac resynchronization in the elderly is beneficial, but could we implant our devices in old patients safer? J Geriatr Cardiol [Internet]. 2016 Mar [cited 2019 Apr 13];13(3):277–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27103926

FIGURE LEGENDS





Central illustration: The calculation of the perimeter of a vein tightly wrapped around two close packed leads can be solved using trigonometric methods. Circles ⊙A and ⊙B with radii R_A and R_B; there will be two external bitangent lines and the point of intersect of these lines with the circle radii will define a major and minor arc for both circles. The total vein perimeter (blue) is equal to the sum of the lengths of the external tangent line segments and exterior circular arcs. With the addition of a third lead, or circle, the exterior arcs of interest are no longer divided equally by a simple reflection through a line connecting the circle centres so that the angles of the exterior arcs are derived from additional input values that can be acquired in a stepwise manner. Solving these equations for two or three leads reveals the additional vein perimeter required to accommodate the third lead is equivalent to a 0.7Fr upsize in the vein – not, we would suggest, a material consideration.

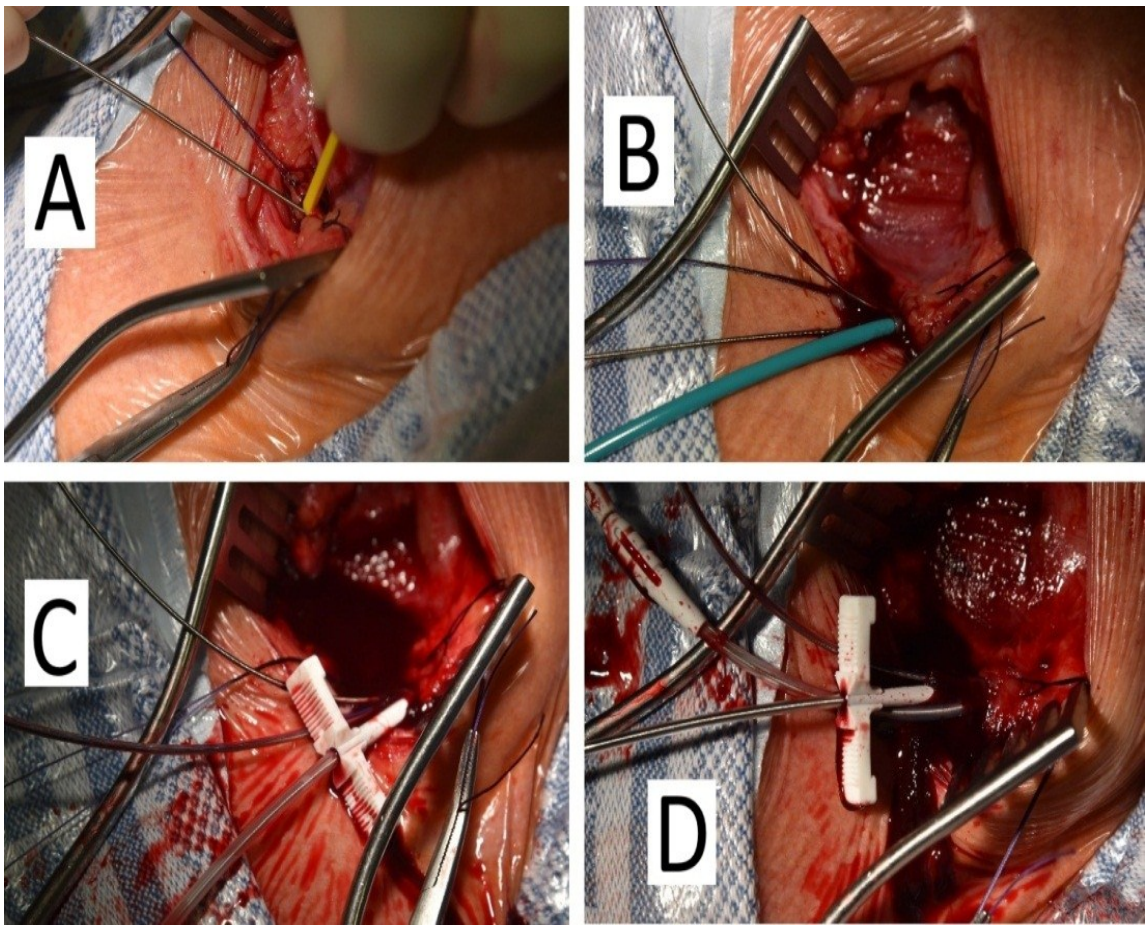


Figure 1: Photographs of a pacing procedure performed by our cephalic implant technique. The cephalic vein is isolated and ligated distally and a short guidewire is placed through it to the right atrium (1A), followed by one other short guidewire and a 150cm hydrophilic guide wire. A delivery system is advanced over the hydrophilic wire (1B). After implantation of the left ventricular lead the delivery system is split and removed, and a sheath is inserted over one of the short guide wires for implantation of the right ventricular lead (1C). A 7F sheath is then advanced over the final guide wire and used to position the atrial lead (1D). In each case, the sheath is removed before the next lead is advanced.

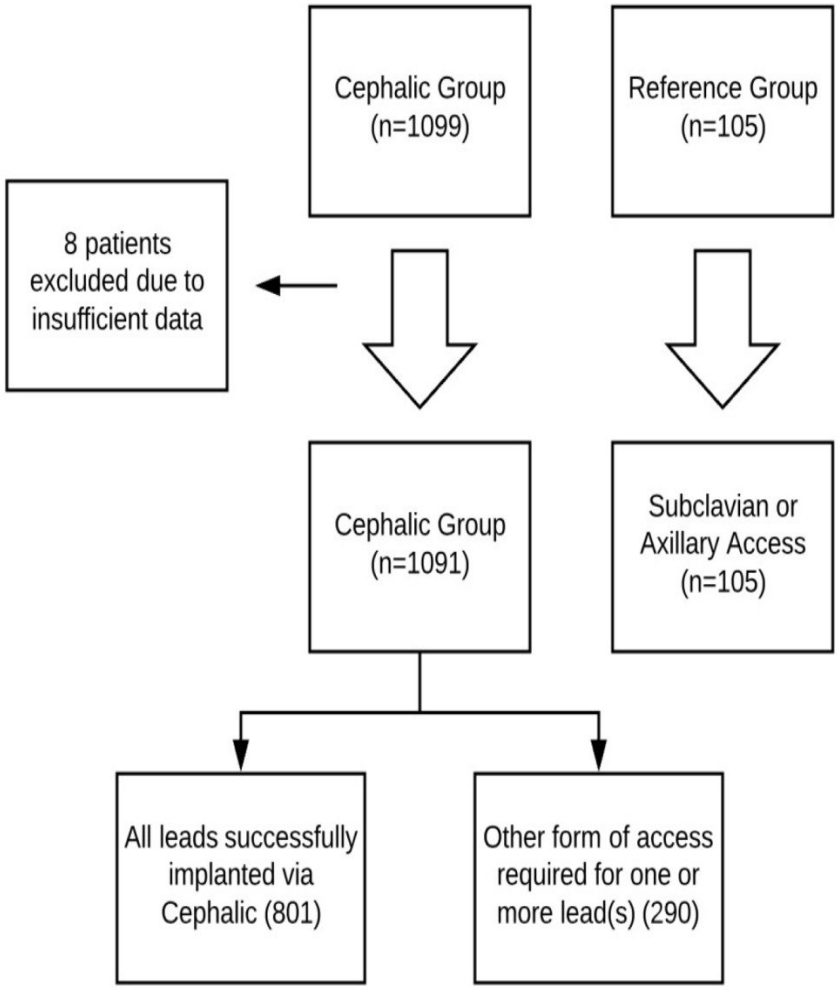


Figure 2: Venous access techniques used in the cephalic access study and reference groups. 290 / 1099 (26%) of cephalic access study group procedures had one or more leads implanted via a non-cephalic route, vs 105 / 105 (100%) of reference group procedures.

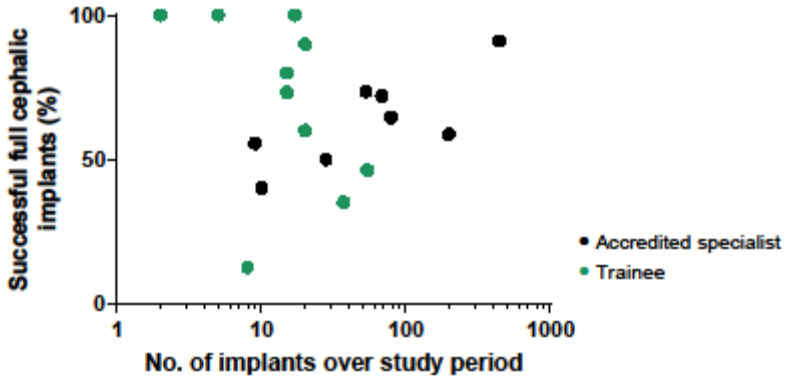


Figure 3: Relationship between success at full cephalic implant technique and procedural volume by first operator implanters in the study group. No correlation is demonstrated with Spearman's test for all operators but when analysis is restricted to accredited specialists alone there is a correlation (R^2=0.47) albeit this does not reach statistical significance due to under-powering.

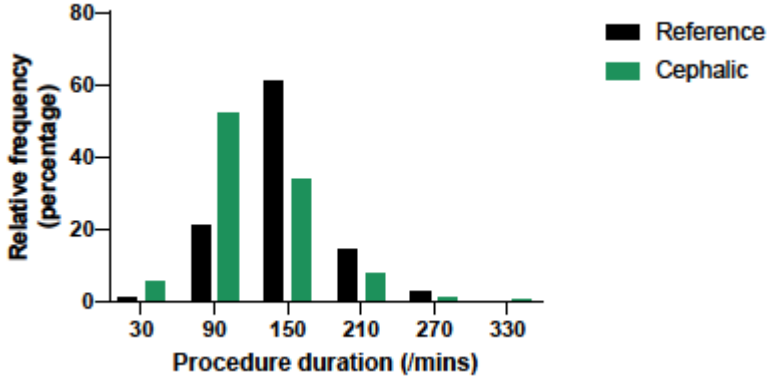


Figure 4: Distribution of procedure duration in the cephalic access study and reference groups. Procedures were significantly shorter in the study group than the reference group (p<0.0001).

Table 1: Baseline characteristics of the study cohort and reference group. Patients are well matched between the groups except for prior cardiac surgery. The study group procedures were shorter in duration and fluoroscopy use and had a lesser proportion of experienced operators. Continuous variables are presented as mean ± SD, discrete variables as number (percentage).

	Cephalic Group	**Reference Group**	**p**
N	1091	105	
Patient Characteristics:			
Age (/yrs)	73±12	72±12	0.3035
Male sex	803 (73.6%)	79 (79.1%)	0.2451
Prior cardiac surgery	262 (24.0%)	16 (15.2%)	0.0420
Prior system or lead extraction	21 (1.9%)	0	0.1515
Prior failed implant attempt	3 (0.3%)	0	>0.9999
Procedure Characteristics:			
CRT-D implants	616 (56.5%)	67 (63.8%)	0.1462
Two lead systems (no atrial lead)	133 (12.2%)	13 (12.4%)	0.9546
Procedure duration (minutes)	118±45	144±39	<0.0001
Fluoroscopy duration (minutes)	15.7±12.9	22.8±12.2	<0.0001
Experienced operator	904 (82.3%)	105 (100%)	<0.0001

Table 2: Procedural complications in the study cohort and a reference group. A higher proportion of the reference group experienced complications, though this was not statistically significant except for failure to place the CS lead. One procedure in the reference group led to two complications, counted as a single complicated procedure for the "any complication" total.

Complications:	**Cephalic Group**	**Reference Group**	**p**
N	1091	105	
Need for CS lead replacement or reposition	37 (3.4%)	3 (2.9%)	>0.9999
Replacement or reposition of other lead	13 (1.2%)	3 (2.9%)	0.1595
Failed CS lead implant	8 (0.7%)	4 (3.8%)	0.0160
Pocket or wound complication	4 (0.4%)	0	>0.9999
Infection requiring removal or extraction	6 (0.6%)	1 (1.0%)	0.4753
Pneumothorax requiring drainage	0	1 (1.0%)	0.0878
Pericardial effusion requiring drainage	1 (0.1%)	1 (1.0%)	0.1679
Symptomatic venous occlusion of upper limb	0	0	>0.9999
Any complication	**69 (6.3%)**	**12 (11.4%)**	**0.0468**