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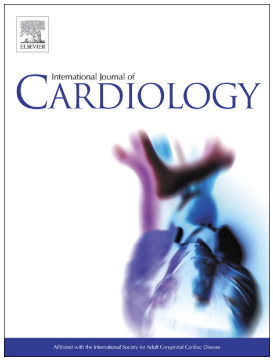

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International Expert Consensus on a Scientific Approach to Training Novice Cardiac Resynchronization Therapy Implanters Using Performance Quality Metrics

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Conflict of Interest

J.M. is an employee of Medtronic. L.M., M.S., A.P., H.R., A.G.G. and the members of the CRT-PROBIT group (C.A., L.B., M.G.B., E.D.I., F.G., D.G., P.M., J.M., O.P., A.R., H.S., D.V.K.) report consulting fees by Medtronic for this project.

Keywords

Pacing, Cardiac Resynchronization Therapy (CRT), implant, metrics, training, proficiency-based progression

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INTRODUCTION

In procedural-based medicine, clinician case volumes and outcomes appear correlated,[1,2] although how exactly the quality of the procedure performance changes with increasing volumes is not well understood. It is however clear that clinician procedure volume on its own is a weak predictor of good clinical outcomes.[3] Variability of therapy outcomes are significant across institutions[4,5] and such data allow targeted quality initiatives. Procedure performance metrics would be necessary to exactly determine which specific procedural aspects may need improvement, and how these aspects affect outcomes. The same performance metrics would be critical to quality assure that novice operators reach a pre-defined skills level during training before transitioning to in-vivo practice, since therapy outcomes are significantly worse at the beginning of the learning curve.[6–8] The European Society of Cardiology (ESC) considers assessing trainees a priority in its roadmap for cardiovascular education, starting discussions on assessing competence away from the bedside.[9] Despite these efforts, today learning procedural skills from senior operators in a real clinical setting often remains the most common viable option for Cardiac Implantable Electronic Device (CIED) training, which comprises pacing, defibrillation and cardiac resynchronization therapy (CRT) systems. Curricula and therapy approaches vary with the provider and so does the definition of "competence". No common system exists to objectively assess trainee ability to perform required tasks at predetermined performance levels across teaching institutions. To make that possible, trainees should first learn routine implants, in a risk-free environment, according to a *reference* procedure, which should specify what to do, how to do it, and what to avoid. In this regard, a system of measurement (*metrics*) of the procedure execution should be developed to objectively quantify and detail compliance with the reference procedure. The metrics of skilled performance do not have to capture every aspect of the operation but they should at least be sufficient in number and sensitive enough to differentiate between different levels of performance as described by Dreyfus and Dreyfus[10] (Fig. 1).

----------Figure 1 about here----------

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Subsequently, a *proficiency* threshold should be established based on these metrics, to determine when trainees have reached an adequate performance level. This approach is known as Proficiency-Based Progression simulation training (Fig. 2).

----------Figure 2 about here----------

The purposes of this study were twofold: 1) to establish the metrics and their operational definitions necessary to characterize a reference approach to a complete triple chamber CIED system implant procedure (from now on, referred to as CRT); 2) to seek consensus from experienced CRT implanting physicians on the appropriateness of the metrics identified (i.e., the steps, as well as errors).

METHODS

Metrics Team and Technology

After ethical approval from the Cork Teaching Hospitals (#ECM 4 (x) 07/11/17) and participant consent, a CRT Metrics Core Team composed of three experienced cardiologists (L.M., M.S., A.P.) implanting CRT systems in three different European institutes, a behavioural scientist (A.G.G.), a biomedical engineer (J.M., project leader) and an electrical engineer (H.R., project consultant) was established. The three cardiologists had been identified according to criteria previously described.[11] To facilitate the characterization of the whole CRT procedure, video recordings of complete, routine CRT implants were acquired after written informed consent was obtained from all the subjects.

CRT Metrics Development

A detailed task analysis and deconstruction process[11–13] was used to break down the whole CRT procedure in small non-overlapping parts and identify the behavioural units constituting optimal system implantation. These operationally defined units can be used as metrics to quantify performance during training. The goal of the CRT Metrics Core Team was to characterize a reference CRT procedure representative of a straightforward, uncomplicated implant. The performance

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characterization was guided by (1) CRT guidelines and recommendations published by medical professional societies,[14,15] (2) manufacturer manuals on use of devices and implant tools, and (3) decades of practice and teaching by the three cardiologists, as well as some prior expert analysis of pacemaker implants.[16] Five 1.5-day face-to-face meetings and two 3-hour online conferences were conducted to shape the procedural metrics. For the online sessions, videoconferencing allowed the investigators (L.M., M.S., A.P., A.G.G.) to real-time review CRT implant videos. Six anonymized video recordings of complete in-vivo CRT procedures performed by different implanters were reviewed in detail by the CRT Metrics Core Team to allow the development and stress testing of the metrics.

The metrics were built for complete "skin-to-skin" CRT procedures with three transvenous leads implanted respectively into right atrium, right ventricle and coronary vein. The entire CRT procedure was first broken down into procedural phases consisting of groups of related steps. Beginning and end points were identified and specified for each phase. Development proceeded phase by phase. Each metric element was written using unambiguous operational definitions (rather than descriptions), so that it could be objectively scored as either occurring or not occurring (yes/no) by an independent group of raters with a high degree of reliability. In addition to the phases, the metrics included the steps of the procedure and the order in which they should be performed, as well as the instruments used and how to use them. Supplementary metrics were created to define actions deviating from optimal performance, representing errors that should not be done. The CRT Metrics Core Team defined what actions represented errors, which comprised: 1) important steps performed by the operator not according to the operational definition; 2) inappropriate actions performed by the operator deviating from the reference approach. Particularly serious errors that were considered a risk for the safety or success of the therapy were classified in a separate category and called critical errors metrics. It was agreed that an event (step or error) should be objectively observable on the video to be scored, to eliminate the ambiguity of assumptions.

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Metric Stress Testing and Inter-Rater Reliability

Once the CRT Metrics Core Team was satisfied with the quality of the procedure characterization, the metrics were stress tested by measuring how reliably they could be scored by single blinded reviewers.[11,13] The function of this stress testing was to ensure that the performances that were defined in the metrics were observable and scoreable reliably, before they were presented to the Delphi Panel. Two video recordings of complete CRT procedures performed by different implanting physicians were independently reviewed and scored, one procedural phase at a time. Each metric had to be scored as either occurring or not occurring by each reviewer. Results were compared and the inter-rater reliability (IRR) was measured on the overall set of metrics of the CRT procedure. IRR was expressed as percent agreement, i.e. the number of ratings that were in agreement divided by the total number of ratings. IRR could potentially range between 0 (no agreement at all) and 1 (complete agreement). After the IRR calculation, the reviewers could debate the discordantly scored metrics and iteratively refine their definitions until they were considered sufficiently accurate, objective and unambiguous to characterize the observed performance step. The scoring was not repeated after the modifications. The entire metrics set was considered acceptable only if IRR resulted >0.8 over two consecutive assessments of different CRT video recordings.

Face and Content Validity of CRT Metrics by Modified Delphi Panel

The Delphi method may be described as a technique for "structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem".[17] This method is an iterative process that uses a systematic progression of repeated rounds of voting to converge towards the desired result. It is an effective process for determining expert group consensus where there is little or no definitive evidence and where opinion is important.

For the CRT Metrics, we modified the original Delphi method by scheduling a highly regulated in-person meeting with eponymous voting cycles. This aimed to allow participant view exchange and uncertainty resolution during the refinement process. In the case of the CRT procedure

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characterization, the desired result (consensus on the appropriateness of the metrics) was reached phase by phase through repeated cycles of enquiring, debating, editing, and voting on the appropriateness of each refined metric definition. Face and content validation of the CRT characterization was sought by having a group of fifteen very experienced CRT implanters (the 3 from the CRT Metrics Core Team and 12 additional, named CRT-PROBIT group) participate to a 1-day CRT Delphi Panel meeting, and having them evaluate, discuss and consent each phase of the reference CRT procedure proposed by the CRT Metrics Core Team. The selected CRT implanters represented 9 countries (Supplementary Table S1 online), which accounted for 73.3% of the total CRT device implantations performed in the 49/56 member countries of the European Society of Cardiology (ESC) that provided data in 2016.[18] The fifteen voting attendees had more than 10 years of CRT implant practice each and cumulatively accounted for more than 10,000 CRT procedures performed.

Modified Delphi Panel Procedure

The CRT Delphi Panel was held at Amsterdam Schiphol airport on 23/02/18. Before starting the review, it was pointed out that the reference CRT procedure might not reflect exactly the way individual panellists perform it in their mature practice, but their expertise was required to review, amend if necessary, and confirm that the final set of metrics and their operational definitions were valid and captured the essential components of the CRT implant, with the aim of training novice operators. Each procedural phase was evaluated individually. A confirmative vote by a panel member indicated that the metrics presented in that phase were accurate and acceptable as written (although he/she may have been operating differently in his/her clinical setting). Consensus was defined as the panellist majority agreeing that the metric definitions in that phase were "not wrong or inappropriate". When suggestions of metric modifications arose during the review process, panel members voted on whether the metric should be maintained as written or changed as proposed. Metrics could also be deleted and, if necessary, new metrics could be defined and added. At the end of these iterations within a phase, when the panel was satisfied, a final consensus vote on the whole phase was asked

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before proceeding to the following phase of the procedure. The main outcome measure was consensus/percentage agreement among experts. The Delphi process was considered successful if consensus was reached in every procedure phase.

RESULTS

'Reference' Procedure Proposed by CRT Metrics Core Team

The CRT procedure was divided into 13 separate phases (in Roman numerals), covering the CRT intervention from the local anaesthesia to the wound closure (Table 1). Each of the 13 phases is bounded by specific non-overlapping beginning and ending points and contain observable, unambiguous, operationally defined procedure events (steps, errors, critical errors). During the stress testing process, the inter-rater reliability for the whole set of metrics resulted superior to 0.9 for both the CRT video recordings reviewed. At the end of the stress testing, the reference CRT procedure proposed by the CRT Metrics Core Team consisted of 196 unique steps, 122 unique errors, and 50 unique critical errors.

----------Table 1 about here----------

'Reference' Procedure Validated by Delphi Panel

The Delphi panel reviewed the proposed reference CRT procedure. The separation into the 13 phases was accepted as exhaustive and sequential. In this regard, two notes were added by the panel to the phase list: the first specifying that the "Pocket creation" part included in Phase I may be performed, as an alternative, right after the "Leads fixation" (Phase XI); the second note allowed the option of advancing the "Right atrial lead implantation" (Phase IX) immediately after the "Right ventricular lead implantation" (Phase IV). The panel reviewed the content of one procedural phase at a time. Only a limited number of operational definitions and metrics required a debate, and a satisfactory solution was always found and consented through an iterative process (Supplementary Table S2 online).

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From the proposed 13-phase, 196-step reference procedure, 3 steps were added, 5 deleted and 26 modified, finally resulting in 194 unique steps. The total number of procedure errors remained the same (122) before and after the process, however 7 were added, 7 deleted and 9 modified. Finally, the number of critical errors increased from 50 to 56 through the Delphi process: 6 were added, 0 deleted and 8 modified. Examples of changes applied to the metrics by the Delphi panel are shown in Supplementary Table S3 online, describing the type of change, the status before and after the meeting and the level of consensus.

At the end of meeting, compared to the CRT reference procedure proposed by the CRT Metrics Core Team, 16 metrics were added by the Delphi panel, 12 were deleted, and 43 were modified overall. After the deliberations, 100% consensus among the Delphi Panel was reached for each individual phase. Subsequently, a total of 194 unique steps, 122 unique errors, and 56 unique critical errors, as well as their operational definitions were validated unanimously by the panel (face and content validity).

To give an example of metrics and their operational definitions, the "Coronary sinus venography" Phase (VI) of the CRT reference procedure as well as a sample performance check during a video-recorded procedure are illustrated in Table 2. The first column contains the operational definitions of the performance metrics of the procedure. The blank cells in the "steps", "errors", and "critical errors" columns indicate the type of metric associated to each unit of performance. For example, action "6.1" was defined as a step, action "6.2" was defined both as a step as well as an error in case it is not performed according to the definition (or not performed at all). It's worth noting that an action could be associated to either an error or a critical error, but not to both at the same time. At the end of the Phase, there is a list of additional errors addressing deviations from the optimal performance which are not covered in the steps of the reference implant procedure. The blank cells are the ones to score when tracking trainees' performance and progression during training. In Table 2, the "X" marked inside the cells show a sample scoring of a video-recorded performance.

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----------Table 2 about here----------

DISCUSSION

In this study, the skilled performance of a CRT system implant procedure was characterized to facilitate the creation of a reference approach and performance metrics for training novice implanters. The generated CRT metrics (i.e., procedure phases, steps, errors, critical errors) were stress-tested by measuring how reliably they could be scored by single blinded reviewers watching full procedure video-recordings, resulting in an inter-rater reliability >0.9. Next, the proposed CRT procedure characterization and metrics were reviewed by an international group of very experienced CRT implanters during a one-day face-to-face meeting through a modified Delphi Panel method resulting in strong consensus. Furthermore, Pre- and Post- panel metric characterizations were highly correlated.

To our knowledge, this is the first metrics-based, detailed characterization of a reference approach to a CRT procedure created and validated by expert consensus using structured methodology. Because CRT implantation characterization reported here includes all steps necessary to implant single- and dual-chamber pacing systems, this reference procedure may be applicable to the entire spectrum of conventional cardiac pacing devices.

Medical practice conditions have significantly changed in the last 30 years, making the apprenticeship training model introduced by Halsted more than a century ago not optimal for modern education, which needs to keep the pace of fast changing medical technology. Our current medical era requires a more systematic approach to medical training. Despite that, Graduate Medical Education still assesses competence through crude process measures (number of procedures, time in training, etc.) vs meaningful outcomes.[19] Such process measures provide little insight on procedural quality. The reference CRT procedure and its metrics defined in the present study may represent the foundations of a more outcome-driven, proficiency-based training for novice implanters. In such a training model, the learner should demonstrate the ability to perform required tasks at specific

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performance levels before being able to progress in the curriculum. Validated and reliable metrics underpin these benchmarks definition and training progression.

In todays' medical education, trainees' clinical performances are often characterized and measured using qualitative descriptions associated to graduated Likert-type scale (rating performance on 1 to 5 or 1 to 7-point scales): the rater uses his/her experience, perception and interpretation of the description to assign a numerical value of the scale to the observed performance. Terms like "accurate" or "inappropriate" in Likert scales descriptions may be very subjectively interpreted, leading to lack of specificity of feedback and to levels of inter-rater reliability lower than the acceptable threshold of 0.8. In contrast, the binary nature of metrics like the ones presented in this study, together with their unambiguous operational definitions, simply require the rater to score whether that discrete event occurred or not (yes/no), allowing a more objective and reliable rating of trainees' performances.[20] Unlike Likert-scale assessments the metrics evaluated here were specific, explicit, transparent and fair. The proposed CRT characterization was solidly built on professional societies' guidelines, manufacturers' manuals and extensive clinical practice experience of the three CRT implanters. This approach to the development of metrics also appears to facilitate consensus amongst experts.[13,21]

Detailed CRT metrics should be able to distinguish between novice and expert implantations (construct validity). Additional research will investigate which of these CRT metrics best distinguish between the two performances. This information will facilitate the definition of a realistic proficiency level that trainees should achieve during simulation-enhanced training before progressing to in-vivo practice. Simulation represents a viable tool to support a structured learning curriculum and facilitate, through deliberate practice,[22] the acquisition of the necessary knowledge and skills to perform the desired tasks at a pre-defined level of proficiency.

The present study underpins the development of such a structured training curriculum. This educational approach will allow the training to be systematic, repeatable and scientifically grounded. Learners will benefit from an objective, transparent, event-based, and explicitly defined feedback that

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does not depend on individual faculty techniques or vary depending on training location habits. Ultimately, for a training to become scalable enough and cost-effective in the long-run, the implementation of metrics into high-fidelity simulators should be seriously considered. Metrics and validated detailed procedural steps are imperative for the design of efficient and effective simulation tools. Prospective, randomized and blinded clinical studies have shown that metric based simulation training to proficiency (i.e., proficiency-based progression or PBP) is a better way to training procedure skills. In minimally invasive surgery, arthroscopic surgery, endovascular medicine and anaesthesia it has been shown that PBP simulation training significantly reduces intra-operative errors (>40%).[23–25] Furthermore, it has also be shown metric based training to proficiency reduces epidural failure rate by > 50%.[21]

The present methodology for developing a reference procedure has been applied here to an established device therapy like CRT. Such an approach may be at least as valuable to support the introduction of new therapies or technologies requiring a different skill set, even for experienced operators. It would help set up a robust training and regulate transition from simulation to patients based on proficiency criteria, so reducing the risk of jeopardizing promising innovations.

Limitations

One limitation relates to defining metrics as observable behaviours, although some steps of the procedure involve cognitive non-observable elements. It was decided that prompting operators to verbalize their interpretation or reasoning during the CRT procedure for training purposes would introduce significant cognitive demands and may cause deviations from normally real-practice occurrence; therefore, non-observable behaviours were excluded. It was however agreed that if such reasoning leads to action (or to skipping an essential action), that consequent behaviour may be assessable and mitigate the previous gap.

Additionally, the number of potential errors is unknown and so is their frequency. Thus, rare mistakes might have been excluded. Nevertheless, the Delphi panel confirmed the errors listed, with minor modifications, were those most likely to occur.

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Another limitation may be associated with the modified Delphi panel being eponymous, and some participants might have been more conservative in commenting compared to the original Delphi method; nevertheless, such condition probably led to an increased efficiency of the procedure review, which took place and reached consensus over only a few hours, because only the relevant aspects may have triggered a discussion.

Finally, there is need to further examine the set of performance and error metrics described here and future studies are required to evaluate the impact of new training programs on these metrics.

CONCLUSIONS

In this study a core group of experienced CRT implanting physicians, deconstructed the CRT implant and created unambiguous steps and error definitions (metrics) that accurately characterize the essential procedure. A larger international panel of experienced implanters affirmed the metrics thus supporting the face and content validity of these metrics. This can inform the development of a deliberate practice, simulation-based, training curriculum and a quantitatively defined proficiency benchmark for training novice pacing and CRT operators. Integration of these metrics into a proficiency-based progression training curriculum underpins potentially safer, more consistent clinical performance.

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The present research project has been conducted by J.M. as part of his MSc studies in “Technology Enhanced Learning for Health” at University College Cork (UCC), Cork, Ireland. UCC didn’t fund the project. Medtronic PLC externally contributed by taking on consulting fees of the CIED procedural experts, but had no influence in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Conflict of Interest

J.M. is an employee of Medtronic. L.M., M.S., A.P., H.R., A.G.G. and the members of the CRT-PROBIT group (C.A., L.B., M.G.B., E.D.I., F.G., D.G., P.M., J.M., O.P., A.R., H.S., D.V.K.) report consulting fees by Medtronic for this project.

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REFERENCES

[1] König S, Ueberham L, Schuler E, Wiedemann M, Reithmann C, Seyfarth M, et al. In-hospital mortality of patients with atrial arrhythmias: insights from the German-wide Helios hospital network of 161 502 patients and 34 025 arrhythmia-related procedures. European Heart Journal 2018;39:3947–57. doi:10.1093/eurheartj/ehy528.

[2] Yeo I, Kim LK, Lerman BB, Cheung JW. Impact of institutional procedural volume on inhospital outcomes after cardiac resynchronization therapy device implantation: US national database 2003–2011. Heart Rhythm 2017;14:1826–32. doi:10.1016/j.hrthm.2017.09.017.

[3] Mehta T, Allison DB. How much variation in outcomes is too much in a center of excellence for bariatric surgery? JAMA 2018;319:1932–3. doi:10.1001/jama.2018.3801.

[4] Pross C, Busse R, Geissler A. Hospital quality variation matters – A time-trend and cross-section analysis of outcomes in German hospitals from 2006 to 2014. Health Policy 2017;121:842–52. doi:10.1016/j.healthpol.2017.06.009.

[5] Chung S-C, Sundström J, Gale CP, James S, Deanfield J, Wallentin L, et al. Comparison of hospital variation in acute myocardial infarction care and outcome between Sweden and United Kingdom: population based cohort study using nationwide clinical registries. BMJ 2015;351. doi:10.1136/bmj.h3913.

[6] Arai T, Lefèvre T, Hovasse T, Hayashida K, Watanabe Y, O'Connor SA, et al. Evaluation of the learning curve for transcatheter aortic valve implantation via the transfemoral approach. International Journal of Cardiology 2016;203:491–7. doi:10.1016/j.ijcard.2015.10.178.

[7] Eberhardt F, Bode F, Bonnemeier H, Boguschewski F, Schlei M, Peters W, et al. Long term complications in single and dual chamber pacing are influenced by surgical experience and patient morbidity. Heart 2005;91:500. doi:10.1136/hrt.2003.025411.

[8] Knops RE, Brouwer TF, Barr CS, Theuns DA, Boersma L, Weiss R, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace 2016;18:1010–5. doi:10.1093/europace/euv299.

ACCEPTED MANUSCRIPT

[9] Kotecha D, Bax JJ, Carrera C, Casadei B, Merkely B, Anker SD, et al. Roadmap for cardiovascular education across the European Society of Cardiology: inspiring better knowledge and skills, now and for the future. European Heart Journal 2018:ehy058–ehy058. doi:10.1093/eurheartj/ehy058.

[10] Dreyfus HL. Mind over machine: the power of human intuition and expertise in the era of the computer. New York: Free Press; 1986.

[11] Gallagher AG, O'Sullivan GC. Fundamentals of Surgical Simulation: Principles and Practice. London: Springer-Verlag; 2012.

[12] Gallagher AG. Metric-based simulation training to proficiency in medical education:- what it is and how to do it. Ulster Med J 2012;81:107–13.

[13] Angelo RL, Ryu RKN, Pedowitz RA, Gallagher AG. Metric Development for an Arthroscopic Bankart Procedure: Assessment of Face and Content Validity. Arthroscopy n.d.;31:1430–40. doi:10.1016/j.arthro.2015.04.093.

[14] Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European Heart Journal 2016;37:2129–200. doi:10.1093/eurheartj/ehw128.

[15] Daubert J-C, Saxon L, Adamson PB, Auricchio A, Berger RD, Beshai JF, et al. 2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management. EP Europace 2012;14:1236–86. doi:10.1093/europace/eus222.

[16] Morgan JM, Burri H, Binner L, Mansour H, Retzlaff H, Roca M, et al. The imperative for metrics in training. Eur Heart J 2011;32:7–9.

[17] Linstone HA, Turoff M. The Delphi method: techniques and applications. Reading, Mass.: Addison-Wesley Pub. Co., Advanced Book Program; 1975.

[18] Raatikainen MJP, Arnar DO, Merkely B, Nielsen JC, Hindricks G, Heidbuchel H, et al. A Decade of Information on the Use of Cardiac Implantable Electronic Devices and Interventional Electrophysiological Procedures in the European Society of Cardiology Countries: 2017 Report

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from the European Heart Rhythm Association. EP Europace 2017;19:ii1–90. doi:10.1093/europace/eux258.

[19] Asch DA, Weinstein DF. Innovation in medical education. N Engl J Med 2014;371:794–5. doi:10.1056/NEJMp1407463.

[20] Gallagher AG, O'Sullivan GC, Leonard G, Bunting BP, McGlade KJ. Objective structured assessment of technical skills and checklist scales reliability compared for high stakes assessments. ANZ J Surg 2014;84:568–73. doi:10.1111/j.1445-2197.2012.06236.x.

[21] Kojima K, Graves M, Taha W, Cunningham M, Joeris A, Gallagher AG. AO international consensus panel for metrics on a closed reduction and fixation of a 31A2 pertrochanteric fracture. Injury 2018;49:2227–33. doi:10.1016/j.injury.2018.09.019.

[22] Ericsson KA, Krampe RT, Tesch-romer C. The role of deliberate practice in the acquisition of expert performance. Psychological Review 1993:363–406.

[23] Seymour NE, Gallagher AG, Roman SA, O'Brien MK, Bansal VK, Andersen DK, et al. Virtual Reality Training Improves Operating Room Performance: Results of a Randomized, Double-Blinded Study. Annals of Surgery 2002;236:458–64.

[24] Angelo RL, Ryu RKN, Pedowitz RA, Beach W, Burns J, Dodds J, et al. A Proficiency-Based Progression Training Curriculum Coupled With a Model Simulator Results in the Acquisition of a Superior Arthroscopic Bankart Skill Set. Arthroscopy 2015;31:1854–71. doi:10.1016/j.arthro.2015.07.001.

[25] Cates CU, Lönn L, Gallagher AG. Prospective, randomised and blinded comparison of proficiency-based progression full-physics virtual reality simulator training versus invasive vascular experience for learning carotid artery angiography by very experienced operators. BMJ STEL 2016;2:1. doi:10.1136/bmjstel-2015-000090.

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FIGURES

Figure 1. Diagrammatic representation of where the different stages of skill development approximate to a 'traditional' learning curve (reproduced with permission from Eur Heart J. 2012;33(17):2127-2134).

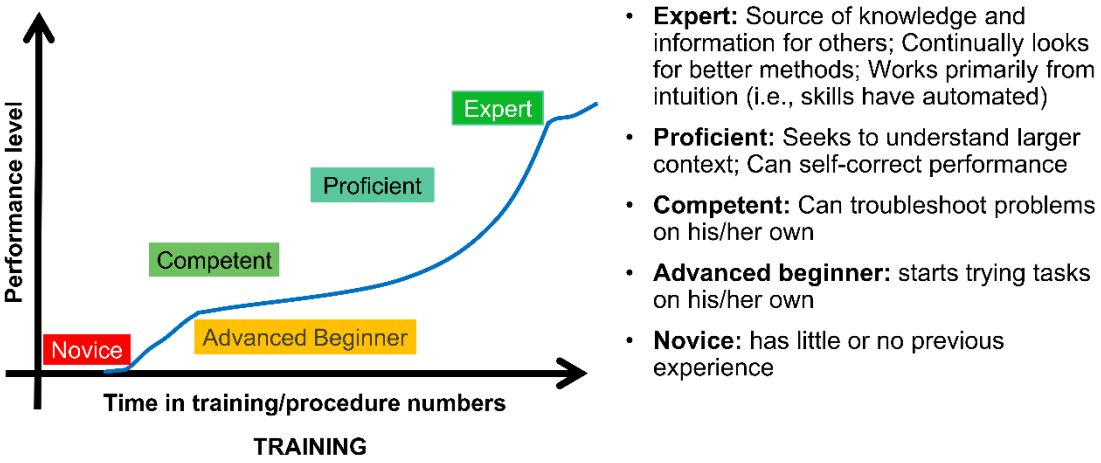

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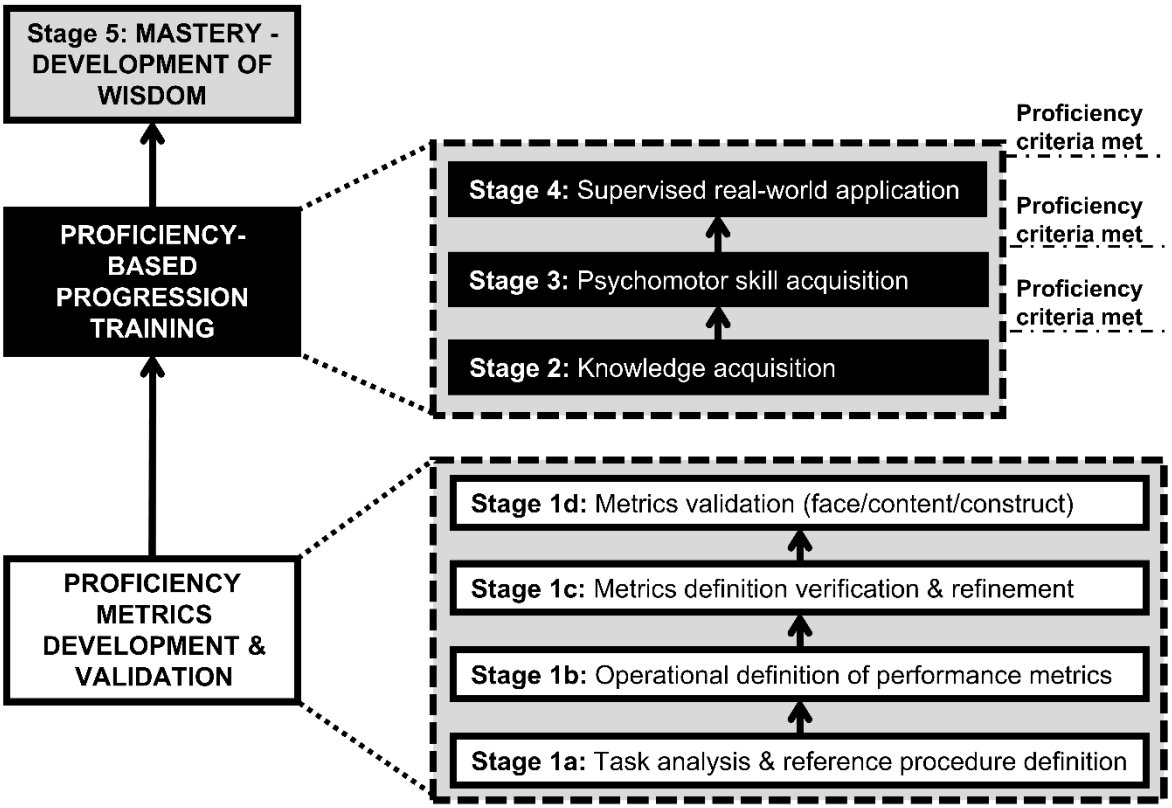
Figure 2. The Proficiency-Based Progression (PBP) training paradigm as an iterative process applied throughout and within training as well as for skill development for new procedures or devices (reproduced with permission from Ulster Med J 2012;81(3):107-113).



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NOTE TO THE EDITORS: Online, Figure 1 would ideally be displayed in colour. Both figures can be printed in black & white.

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Table 1. Beginning/End of the reference approach Phases and changes (highlighted in italic) agreed and voted on by the Delphi panel.

Procedure Phase	Title	Phase BEGINS & ENDS
I	Sedation, incision and pocket creation	BEGINS: With anaesthetic administration
		ENDS: When pocket is clean and dry
II	Cephalic vein access	BEGINS: With cephalic vein isolation
		ENDS: When guidewire or lead is in IVC/RA
III	Axillary vein access	BEGINS: With palpation of the space between clavicle and first rib
		ENDS: When guidewire is in IVC/RA
IV	Right ventricular lead implantation	BEGINS: With RV lead selection
		ENDS: When RV lead electrical parameters are confirmed
V	Coronary sinus access	BEGINS: With 120cm guidewire in position in IVC/RA
		ENDS: When guide catheter is stable in coronary sinus
VI	Coronary sinus venography	BEGINS: With picking balloon catheter
		ENDS: When balloon catheter is removed
VII	Left ventricular lead implantation	BEGINS: With selecting LV target vein
		ENDS: When LV lead is in stable position
VIII	Left ventricular lead electrical testing	BEGINS: With PSA cable connection
		ENDS: When PSA cable is removed
IX	Right atrial lead implantation	BEGINS: With RA lead preparation
		ENDS: When RA lead electrical parameters are confirmed
X	Left ventricular implant tools removal	BEGINS: With positioning the LV lead stylet to slit
		ENDS: When LV lead slack is adjusted
XI	Leads fixation	BEGINS: With advancing anchoring sleeve close to vein entrance
		ENDS: When fixation is verified with lead tug-test
XII	Device insertion	BEGINS: With leads electrical parameters check using PSA
		ENDS: When device is in pocket
XIII	Wound closure	BEGINS: *With swab and suture count*
		ENDS: When wound is sealed
N=13	1 phase begin modified	

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Table 2. Example of the characterization of a Phase of the CRT procedure and a sample performance review during a video-recorded procedure.

PHASE VI. CORONARY SINUS VENOGRAPHY: start with picking balloon catheter, finish with removing it		**STEP**	**ERROR**	**CRITICAL ERROR**
6.1	Flush balloon catheter (on the table)	X		
6.2	Test-inflate balloon	X		
6.3	Insert 0.014" medium support guidewire to the tip of balloon catheter	X		
6.4	Pass guide catheter valve with balloon catheter tip and stop immediately after			
6.5	Advance 0.014" guidewire into distal CS	X		
6.6	Advance balloon catheter <u>over the wire</u> 3 cm out of the guide catheter tip (at least to expose the balloon), OR unsheathe (pull back) the guide catheter to expose the balloon	X		
6.7	Remove 0.014" guidewire	X		
6.8	Inject contrast (≈2mL) to confirm position in main CS and size of CS, avoiding bifurcations	X		
6.9	Set fluoroscopy in 1st view (LAO or RAO or AP), centered on LV	X		
6.10	Inflate balloon under fluoroscopy	X		
6.11	Start fluoro acquisition/cine	X		
6.12	Inject contrast (10-20mL) in a bolus under fluoroscopy	X		
6.13	Maintain fluoro acquisition/cine for a few seconds to allow retrograde flow visualization		X	
6.14	Stop fluoro acquisition/cine	X		
6.15	Venogram displays information of existing side branches going to target region	X		
6.16	Set fluoroscopy in 2nd view (LAO if 1st RAO or AP; AP or RAO if 1st LAO), centered on LV	X		
6.17	Start fluoro acquisition/cine	X		
6.18	Inject contrast (10mL, diluted) in a bolus under fluoroscopy	X		
6.19	Maintain fluoro acquisition/cine for a few seconds to allow retrograde flow visualization		X	
6.20	Stop fluoro acquisition/cine	X		
6.21	Venogram displays information of existing side branches going to target region	X		
6.22	Deflate balloon	X		
6.23	Ensure guide catheter is in a stable position, otherwise advance it no further than balloon tip (while holding the balloon catheter)	X		
6.24	Remove balloon catheter	X		
EXTRA ERRORS				
a)	*Advance balloon catheter in CS without leading guidewire*			X
b)	*Inflate balloon catheter in a side branch or at bifurcation*			
c)	*Failure to reposition balloon catheter (and guide catheter) and repeat venogram when a posterior or postero-lateral vein is obstructed by the balloon during contrast injection*			
d)	*Failure to stop contrast injection in the presence of dissection*			

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HIGHLIGHTS

- Performance metrics underpin simulation-based training curriculum to proficiency
- Detailed CRT reference procedure and performance metrics were defined
- Metrics identified phases, steps and errors constituting optimal CRT implant
- International expert consensus panel concurred with the performance metrics
- The CRT performance metrics are valid and can be objectively and reliably scored

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