A nurse-led implantable loop recorder service is safe and cost effective

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Abstract

Introduction: Implantable loop recorders (ILR) are predominantly implanted by cardiologists in the catheter laboratory. We developed a nurse-delivered service for the implantation of LINQ (Medtronic; Minnesota, USA) ILRs in the outpatient setting. This study compared the safety and cost-effectiveness of the introduction of this nurse-delivered ILR service with contemporaneous physician-led procedures.

Methods: Consecutive patients undergoing an ILR at our institution between 1st July 2016 and 4th June 2018 were included. Data were prospectively entered into a computerised database, which was retrospectively analysed.

Results: 475 patients underwent ILR implantation, 271(57%) of these were implanted by physicians in the catheter lab and 204 (43%) by nurses in the outpatient setting. 6 complications occurred in physician-implants and 2 in nurse-implants (p=0.3). Procedural time for physician-implants (13.4±8.0 minutes) and nurse-implants (14.2±10.1 minutes) were comparable (P=0.98). The procedural cost was estimated as £576.02 for physician-implants against £279.95 with nurse-implants, equating to a 57.3% cost reduction. In our centre, the total cost of ILR implantation in the catheter laboratory by physicians was £10,513.13 p.a. vs £6,661.55 p.a. with a nurse-delivered model. When overheads for running, cleaning and maintaining were accounted for, we estimated a saving of £68,685.75 was performed by moving to a nurse-delivered model for ILR implants. Over 133 catheter lab and implanting physician hours were saved and utilised for other more complex procedures.

Conclusion: ILR implantation in the outpatient setting by suitably trained nurses is safe and leads to significant financial savings.

Keywords: Syncope; arrhythmias; implantable loop recorder

Introduction

An implantable loop recorder (ILR) is a cardiac monitor that is implanted in the subcutaneous tissue of the chest wall. Its ability for long term continuous monitoring makes it invaluable in assessing the correlation between symptoms/manifestations such as unexplained syncope and arrhythmias [1-4].

Recent guidelines [1] have broadened indications for implantable loop recorder utilisation. They have also highlighted their role in the investigation of patients with suspected intermittent arrhythmias, unexplained falls and patients with suspected epilepsy, but ineffective treatment. Furthermore, ILRs are recommended over implantable cardioverter defibrillators (ICD) in patients with inherited cardiomyopathy or channelopathy presenting with recurrent syncope and low risk of sudden cardiac death [1]. Data from the CRYSTAL-AF [5] study demonstrated the effectiveness of ILRs in diagnosing AF in patients presenting with cryptogenic stroke. The rising number of indications, has therefore been accompanied by an increase in the number of referrals to our centre, and, consequently, in the waiting list for this procedure.

Traditionally, ILR implantation has taken place in the catheter laboratory by a cardiologist and is considered a minor surgical procedure. The most recent iteration of these devices are significantly smaller than previous generations, for instance the Reveal LINQ ICM (Medtronic, Minnesota, USA) is 87% smaller than its previous versions, and includes an implanting kit that allows the device to be injected. This new implant technique negates the requirement for a minor surgical procedure [6], and permits implantation to be undertaken in the outpatient setting [7 8]. We hypothesised that this new implant method would be compatible with a nurse-delivered implant service in the outpatient setting that would: (a) save physician-time,

releasing them and the catheter laboratory so other types of more complex procedures could be done, and (b) reduce overall cost.

In the present study, we report the process undertaken to establish this, and evaluate safety and cost-effectiveness of the service.

Methods

Patient population

Patients undergoing an ILR implantation during the period 1st July 2016 to 4th June 2018 were included. Data were collected prospectively at the time of implant and during patient follow-up at one month post implant. Written consent for the procedure was obtained from all patients. This study was prospectively registered and approved by the Clinical Effectiveness Unit at Bart's and the London NHS Trust (ID9883).

Patients were assigned to physician-led or nurse-led based on the availability of nurse-led clinic, and on the type of referral (elective patients were implanted by the nurses, and in-patients or patients referred directly from A&E were implanted from physicians in the initial months. Later, during the study, spaces were also made available for these patients in the nurse-led service).

Nurse-delivered ILR insertion

The Barts Heart Centre nurse-delivered ILR implantation service commenced in August 2016. Five nurses undertook a training program to ensure competency in implantation. Procedures were performed in an outpatient clinic room, with a cardiac physiologist assisting and interrogating the device. Briefly, the training scheme was as follows: nurses observed a training video followed by a 10-minute demonstration on implant method, delivered by company representatives. Implanters then practiced 4

implants on demonstration kits, and completed a manufacturer's online training module [9]. This was followed by observation of 5 implants by trained and experienced physician implanters in the catheter laboratory. Five implants were then performed under direct consultant physician supervision. A further five implants were performed with indirect supervision i.e. the supervisor was present in an adjacent clinic room.

Once this was successfully completed, nurses were left with indirect supervision from a consultant cardiologist who will regularly review the progress. The consultant cardiologist was always present in a clinic room in very close proximity, and available to provide help or troubleshooting advice during all ILR implants. Nurses required annual competency testing and updating.

Nurse led implants were all done in a minor procedures clinic room (Figure 1). The implant team consisted of a nurse implanter and a cardiac physiologist. Wound closure was performed using steri-strips alone. The physiologist role was to provide support during implantation, check ILR function, teach device activator use to the patient and set up CARELINK™ home monitoring.

Doctor-led ILR insertion

ILRs implanted by doctors in the catheter laboratory during the same time period were used as the control group. Wound closure could either be with sutures or steri-strips alone. Doctor-led implants, involved the participation of the catheter laboratory team, also including a physiologist, one scrub nurse and one runner nurse to administer sedation if needed.

Endpoints

The primary endpoint of our study was complication rates. This was defined as the presence of any complication related to the implant, occurring within the first 30-days, and included infection, erosion, migration and poor R-wave (< 0.2 mV) needing re-position [10].

Secondary endpoints were: procedure duration, lab/room time utilisation and R-wave sensing (amplitude). Procedure time was recorded at the time of implant by the physiologist. This was defined from the point of needle-to-skin to dressing-on time. Lab time was also recorded and this was defined as total time spent with patient from the initial entry to leaving the catheter laboratory or outpatient clinic room.

Finally, we performed a cost analysis-comparison of both approaches taking into account staff needed to be present, lab and material costings, as well as income from additional cases done in the catheter laboratory because of newly-created slots resulted from moving ILR cases to nurse-led clinic.

Cost analysis was done by taking the mean number of ILRs implanted in our centre per annum and the mean lab time used by nurses and doctors. We then calculated total cost by including staff cost and associated cost to determine the overall cost of ILR implantations in the catheter lab and outpatient settings. This allowed estimation of total costs, and also cost per procedure. Staff salaries were taken from Royal College of Nursing and NHS Careers. [11, 12] We made the assumption that all staff members were full time 45 weeks per year and 30% added on for national insurance/pensions. Associated cost which included cleaning, materials and overheads calculation was based on Kanters et al [13].

We then compared the 2 different scenarios and their associated costs: during 1 year all ILR LINQ implants being done by nurses vs. all ILR LINQ implants being done by doctors.

For estimating the income from additional cases done in the catheter laboratory because of newly-created slots resulted from moving ILR cases to nurse-led clinic, we: a) multiplied the total duration of an ILR case performed in the catheter laboratory by the annual number of ILR implants (i.e. total time gained per year); b) Using data for procedural duration from the FIRE & ICE trial [14] we determined how many additional cryoballoon ablation procedures (scenario I) or permanent pacemaker implants (scenario II) could be performed annually; and c) using Tariff data for pacemaker implants and cryoballoon ablation procedures performed we estimated the additional annual income for both scenarios (additional cryoballoon ablations or pacemaker implants).

Statistical analysis

Qualitative variables were presented as relative frequencies. Continuous variables were tested for normal distribution using the Kolmogorov–Smirnov test. Normally distributed data were expressed as mean±standard deviation (SD). For categorical variables, the X^2 or Fisher exact test, were used to compare the distributions for 2 or more groups. Non-paired student T-test or Mann–Whitney U test were used for comparisons of continuous variables. A $p<0.05$ was considered significant. All statistical analyses were performed with SPSS (IBM© SPSS© Statistics version 22.0).

Results

During a 23 months' period (1st July 2016-4th June 2018) a total of 491 patients underwent an ILR implant. 287(58%) ILRs were implanted by a doctor in the catheter laboratory and 204 (41%) ILRs were implanted by trained nurses in the outpatient setting.

In 16 of the implants done by doctors, 14 patients had an old ILR explanted and a new one re-implanted, 1 patient had an ILR implanted following a negative electrophysiology study, 1 patient had an ILR in conjunction with ajmaline test. These cases were excluded from our analysis. Therefore, 475 patients were included in the study with 271 (57%) in the doctors' group and 204 (43%) performed by nurses.

The baseline characteristics of the study population are presented in Table 2. There was no significant difference in the gender between the study groups However, there were significant differences in the age, pre-implantation symptoms (syncope, palpitations, others) as well as in the aetiology/background of patients (no heart disease, cardiomyopathy, congenital heart disease, others) as shown in Table 1.

Procedural parameters/features

A significant proportion of patients (12%) who had an ILR implanted by doctors, had intravenous (IV) sedation with Midazolam or Diamorphine compared to none done by nurses ($P<0.001$) Table 2.

Moreover, our results showed that nurses used the "operation" room significantly longer than doctors ($P<0.001$). However, the actual procedure of implantation did not differ among the 2 groups ($p=0.986$) (Table 2).

Importantly, there was no difference between the two groups with regards to R-wave values during/after ILR implant for doctors and nurses (0.50±0.33mV vs 0.45±0.27mV, p=0.567)

Procedural safety/complications

Overall, a total of 8 complications were recorded (1.7%) in the overall cohort. Of those 8 cases, 6 were performed by doctors and 2 cases were performed by nurses (p=0.301) (Table 3). Infection and erosion were documented only in 3 patients and 1 patient respectively (Table3).

Current practice and cost analysis of ILR implantation in our centre

Our data demonstrated significant financial savings when ILRs are implanted by nurses in the outpatient setting. Our cost analysis revealed that a single doctor-led procedure in the catheter laboratory when staff and associated cost are added up, would incur a cost of £576.02 as opposed to £279.95, when done by nurses in the outpatient setting. This would equate to a £296.07 cost difference per procedure

In our centre where we implant 245 ILRs a year, staff cost alone for a doctor-led procedure would amount to £10,513.13 compared to £6,661.55. Adding staff cost to overheads which include running, cleaning and maintenance a doctor-led catheter laboratory service would cost £130,611.95 vs £61,926.20 if done by nurses in the outpatient setting. This would amount to a grand total of £68,685.75 saved per annum by taking ILR out of the catheter lab to an outpatient setting done by nurses. (Table 4)

Apart from cost savings, our analysis also showed significant savings in regards to lab and implanting physician time. With an average time of 37.3 minutes spent in the

catheter lab implanting 245 ILRs per year, over 133 catheter laboratory hours can be saved and utilised for other procedures like ablations or pacing.

With an average cryoablation for atrial fibrillation taking up to 120 minutes [14] 133 hours would equate to over 66 additional AF ablations performed. With the tariff for an AF ablation set at £4000 [15], an income of £264,000 could be made before overheads. In the context of pacing, with an average dual chamber pacemaker implantation time of an hour, and a tariff of £2900, an income of £385,700 could be made [15]. This shows how hours saved could potentially generate an additional income stream.

Discussion

In the present study, we found that REVEAL LINq implantation by nurses in the outpatient setting is both safe and cost effective.

ILRs are increasingly being used in clinical practice [16]. Their ability for long term monitoring allows symptom-rhythm correlation, making them very attractive for specific indications that were mentioned before [17]. As the indications for ILRs expand, it is likely that their uptake will increase in the future. Therefore, the ability to implant an ILR in a less resource intensive setting by nurses is of importance and has the ability to confer significant long-term savings. The evolution of ILR LINq implants over the course of this study suggests that the majority, if not all future ILRs, could be successfully implanted in an outpatient setting.

The recent REVEAL-LINq In Office 2 (RIO-2) [18] randomised control trial compared ILR implants in hospital versus (vs) in an office environment. This study demonstrated an excellent safety profile for ILR implant irrespective of the insertion environment/setting.

In our study, we went one step further by introducing a nurse-led office-based LINQ-ILR service. Our results for in-office implants are comparable with published data, showing similar infection and complication rates [18, 19].

Our data suggest that the nurse-led approach is a safe alternative to a physician-led service. This is more likely driven by the ease of implantation of modern day ILRs, where operators can be proficient after a short period of training. The low complication rate among nurses could also be due the fact that nurses are more likely to adhere to standard operating protocols than doctors. As such, when a nurse becomes more proficient in device implantation, the service can slowly move out of the catheter laboratory completely. This is consistent with the results reported by Kipp et al [8] where ILR implanted in an ambulatory setting by advanced practise providers had a high success and low complication rate with a single dose of IV antibiotics. Our study differs in that we did not administer IV antibiotics peri-procedure. In addition, we demonstrated that the outcomes and complications in a nurse-led service are comparable to a physician-led service.

Importantly, changing from a catheter laboratory physician-led service to an office-based nurse-led service constitutes cost savings of £296.07 per procedure. In a high-volume centre like Barts Heart Centre, this resulted in up to £72,000 savings annually. In the current cash-tight environment existing in the UK health service and worldwide, such savings could enable investment in the development of other areas of service. Further to the cost savings, we demonstrated that an extra 133 catheter laboratory hours could be saved and this could allow more patients to gain access to more EP procedures in a timely manner.

In our study, we found that cases performed by nurses did not require IV sedation. This could be the result of patients feeling more relaxed in the outpatient setting, or

because a small minority of patients deemed to be more anxious were likely identified earlier by the referrer and hence done in the catheter laboratory. Having the procedure done in a more office-like environment with less staff around could also be less intimidating and stressful for the patients.

To the best of our knowledge, our study is the first to assess the above parameters and to suggest a possible introduction of a nurse-led outpatient ILR implanting service. One of our key strengths is that we are reporting 'real-world data in a relative large number of patients. All data were collected prospectively and all patients were seen one month post implant, with all complications being logged and recorded.

The main limitation of our study was that this is not a randomized controlled comparison and a retrospective analysis of the two ILR implanting approaches has been performed. However, no differences in complications were observed among the two groups, and it is highly unlikely that minor differences in age, or other non-accounted characteristics could have a major impact on the observed results. It is also worth noting that this was a prospective non-randomized study, and there may have been a minimal selection bias resulting in assignment of patients with structurally normal heart mainly to the nurse-led team. Even though these are less complicated patients, which makes them more suitable to be done in an ambulatory setting, it resulted in non-significant difference in procedural time.

Conclusion

Our data show that ILRs can safely be implanted in the office environment by trained nurses. This operating model resulted in significant cost and time savings and allowed optimal deployment of resources for more complex procedures that would improve

service delivery for patients, while creating a stream of additional revenue for the centre.

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Competing interest: None declared

Table 1. Baseline characteristics of patients
Table 2. Comparison of procedural characteristics between the study groups
Table 3. Complications between the study groups

Figure 1. A. Photo of the clinic room with curtain separating the 2 areas; 1.B. photo of the equipment used by nurses

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Table 1. Baseline characteristics of patients

	Doctor-led procedure	**Nurse-led procedure**	p value
Number of patients	271	204	
Sex (male)	121(45%)	91(45%)	0.742
Age (years)	50.0±18.5	54.0±17.5	0.020
Syncope/	138(51%)	133(65%)	0.006
Palpitations/	78(29%)	38(19%)	
Other*	55(20%)	33(16%)	
No heart	180(66%)	147(72%)	0.003
disease/CMP/GUCH/Other**	25(9%)	27(13%)	
	32(12%)	6(3%)	
	34(13%)	24(12%)	

Values presented as mean±SD.
Abbreviations. N: numbers; CMP: cardiomyopathy (ischaemic, hypertrophic/dilated); GUCH: grown up congenital heart disease; other**: vertigo/pre-syncope/dyspnoea; other **: Long QT syndrome/Brugada syndrome/valve disease/ post-ablation/ myotonic dystrophy/

Table 2. Comparison of procedural characteristics between the study groups

	Doctor-led procedure	**Nurse-led procedure**	p value
IV sedation	32 (12%)	0(0%)	<0.001
Lab Time (min)	35.5±23.1	39.0±14.3	<0.001
Procedure time (min)	13.4±8.0	14.2±10.1	0.986
R-wave (mV)	0.50±0.33	0.45±0.27	0.567

Values presented as mean±SD.

Abbreviations. IV: intravenous; min: minutes; Lab: laboratory

Table 3. Complications between the study groups

	Doctor-led procedure	**Nurse-led procedure**	p value
Total complications	6 (2.2%)	2 (1%)	0.301
Infection	2	1	
Erosion	0	1	
Migration	1	0	
Reposition/low R	2	0	
Protrusion	1	0	

Table 4. Cost Analysis–Savings taking ILR out of lab

Catheter laboratory hours saved

	In-Lab	Out of lab
Number of ILR	245	245
Time per procedure (min)	32.80	38.50
Time per annum (Hours)	133.93	157.21

Staff cost saved
In-LAB

	No. of staff	Time per procedure (min)	Salary per annum	Salary per minute	Cost per procedure	Cost per annum
Consultant	0	32.8	£84 667	£1.02	£33.43	£ 0
SpR	1	32.8	£50 000	£0.60	£19.74	£4836.48
Nurse	2	32.8	£27 901	£0.34	£11.02	£2699.90
Physiologist	1	32.8	£30 764	£0.37	£12.15	£2976.75

Total: £10,513.13

Out of LAB

	No. of staff	Time per procedure (min)	Salary per annum	Salary per minute	Cost per procedure	Cost per annum
Consultant	0	38.5	£84 667	£1.02	£39.24	0
SpR	0	38.5	£50 000	£0.60	£23.17	0
Nurse	1	38.5	£27 901	£0.34	£12.93	£3167.85
Physiologist	1	38.5	£30 764	£0.37	£14.26	£3493.70

Total: £6,661.55

Total staff cost saved - £3,851.58

Associated Cost
Based on Kenters et al 2016

	In-Lab	Out of Lab
Materials	EUR 245	EUR 245
Instruments	EUR 100	EUR 5
Cleaning	EUR 57	EUR 4
Overhead cost	EUR 197	EUR 30
Total per procedure	EUR 599	EUR 284
Total in pounds	£533.11	£252.76
Total associated cost per annum	£130,611.95	£61,926.20

Total associated cost saved – 68,685.75

Total cost saved £3,851.58 +£68,685.75 = £72,537.33

Figure 1. A. Photo of the clinic room with curtain separating the 2 areas; 1.B. photo of the equipment used by nurses