A Non-Physician, Outpatient Implantable Loop Recorder Explant Service Is Safe And Cost Effective. The OLÉ Audit.

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The transition of implantable loop recorder (ILR) explant procedures from physician to non-physician (NP) and from catheter labs (CL) to outpatient (OP) settings has not been as thoroughly investigated as the ILR implantation transition[1–3]. We implemented a NP, OP ILR explant service in 2021, and hypothesized that it would: have comparable safety outcomes, save time, and reduce costs.

Patients undergoing ILR explants from July 2016 to November 2023 were included. Data were collected prospectively at the time of explant and during a follow-up period of 1-4 weeks post-procedure. The study was approved by an Internal Institutional Review Board at Barts Heart Centre (CEU-ID: 13317)

Patients were assigned to physician-led explants or NP-led procedures based on their date of referral. Those unable to feel their ILR underwent the procedure in the CL to allow for fluoroscopy use if needed. Equipment used was uniform: blade, mosquitos, forceps, needle holder, swabs, scissors, and sterile drape covers. Scars were excised at discretion of the operator along with wound closure technique, using wound closure strips or dissolvable sutures. There was no withholding of anticoagulants or antiplatelets, and no antibiotic prophylaxis was used. Five experienced NP ILR implanters, including nurse practitioners and cardiac scientists, completed a training program. It involved observing 10 procedures and directly performing 5, along with clinical assessments. Once completed, NP operated under indirect supervision from a consultant cardiologist.

ILRs explanted by physicians were used as the control group. Use of fluoroscopy, and intravenous sedation was at the operator's discretion. Physician led explants were performed with a CL team including a consultant physician, trainee physician, scrub nurse, cardiac scientist, radiographer, and a runner nurse to administer sedation. CL procedures were performed as elective day cases, requiring admission to the day-case ward which was

supervised by a nurse & nursing assistant. Patients arrived 2 hours prior to the procedure for clerking & pre-procedure observations. Post-procedure patients were discharged after 2 hours of observations.

OP procedures were performed by NP & clinical support staff as a runner. Post procedure, patients were asked to wait 20 minutes in a shared waiting area. Like our OP ILR implant procedure, sterile gloves are worn without a surgical gown, to reduce anxiety for patients.

Over a period of 100 months, a total of 1076 patients underwent ILR explantation. 720 (66.9%) patients were explanted in the CL and 649 patients (60.3%) were explanted by physicians. NPs completed 427 procedures (39.7%), with significantly fewer performed in the CL (n=73, 17.1%, $p<0.001$). Physician led procedures in OP are not represented. Baseline characteristics showed no significant difference between groups in variables: age, gender, indication for ILR, underlying cardiac disease & presence of anticoagulant or antiplatelet. Table 1 displays the procedural outcomes. With 119 physician operators and 5 NP operators, NPs had shorter procedure times. Since asking patients if they could palpate their ILR, 454 procedures occurred, and 8 patients (1.8%) required fluoroscopy screening. Four complications occurred (0.37%): 2 wound infections managed with oral antibiotics and 2 stitch protrusions requiring reintervention. No haematomas or bleeding complications occurred. All complications occurred in the physician group with none occurring in the NP group ($p=0.16$). Cost analysis using data from NHS careers and Kanters T et.al that showed that a physician led procedure in the CL would cost £524 per procedure, compared to £263 by our NP OP model (50% saving)[4]. Importantly, the NHS tariff costs for CL and OP ILR explant is the same (£660) providing an improved profit margin. This tariff is comparable to the Medicare reimbursement cost for Hospital Outpatients of $649, however, the lower

ambulatory surgical centre reimbursement of $338 would make a loss from our costings, if physician led.

ILR explant procedure complications are rare and ILR devices are commonly palpable, with less than 2% needing fluoroscopy screening to determine location. High volume operators are likely the cause of shorter procedure durations. Excising old scars is likely to contribute to a longer procedural duration, but is not possible in many patients, due to device being located too far from initial incision. This is because ILR implant tools place devices 1 cm from the incision[5]. We were unable to assess patient experience, which could be useful in further analysis. This could lead to a contrary argument for the procedure, if it's not causing discomfort, should the device be removed? We found no evidence that ILRs left dormant have caused harm. However, patients may be keen to remove ILRs because it's a simple, low-risk procedure. One limitation of this study is the un-randomised comparison, but retrospective analysis of two ILR explanting processes. However, both patient groups are similar, and unlikely that non-accounted characteristics would have impacted results.

ILR explant procedures can be safely performed in an OP setting by NPs, offering a more cost-effective procedure that can free up physician and CL time.

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Table 2: Procedural parameters

	Physician Led (n= 649)	Non-Physician Led (n= 427)	P value
IV sedation	104 (16.0%)	0	<.001
Procedure duration (mins)	20.8 ± 11.7	12.8 ± 6.1	<.001
Stitches used	389 (59.9%)	79 (18.5%)	<.001
Scar Excised	83 (12.8%)	9 (2.1%)	<.001
Fluoroscopy used to locate device	23 (3.5%)	0 (0%)	<.01
Operator grade trainee/ Fellow	447 (73.5%)	N/A	
	Cath Lab procedure (n= 720)	Outpatient procedure (n=356)	
IV sedation	104	0	<.001
Procedure duration (mins)	20.4 ± 11.2	12.1 ± 5.9	<.001
Scar Excised	86 (11.9%)	6 (1.7%)	<.001
Stiches used	407 (56.5%)	61 (17.1%)	<.001
Fluoroscopy used to locate device. Fluro time (seconds)	23 (3.2%) 6 ± 9	0 (0%)	<.01