Safety of ward-based, non-physician-led, cardiac monitor implantation

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Implantable cardiac monitor (ICM) implantation is typically performed in the electrophysiology lab (EP) or outpatient (OP) setting. Performing them in hospital wards (HW) may reduce time to implant and procedural costs. Utilizing non-physician Cardiac Scientists (CSs) may further reduce costs [1] and hospital inefficiencies.[2]

We compared HW-based ICM implants to consecutive EP/OP-based ICM implants from March 2021 to June 2023 at our centre to assess for complications (Barts Health Clinical Effectiveness Unit ID: 13730). HW patients were adults with recent aortic valve intervention. EP/OP patients were all clinically indicated ICM implants over the same time period. Demographics, anticoagulant/antiplatelet prescription, implant setting, operator staff group, and complications were extracted from the ICM records software (Mediconnect, Fleischhacker, Germany). Patients were excluded if the ICM was implanted during another procedure or the procedure was performed in the last 50 days, allowing time for routine wound review.

HW patients were reviewed by a physician to assess clinical stability pre-implant. A sterile field was created on the medical equipment trolley. ECG monitoring was performed throughout. The operator wore a surgical mask and hat, performed hand decontamination, wore sterile gloves, administered antiseptic skin preparation, and used a sterile drape. Local anesthetic (lidocaine hydrochloride 1%) was given subcutaneously to the left pectoral region. Manufacturer-specific implant kit was used to create the incision and implant the ICM. Manual pressure was applied to achieve haemostasis. Sutures were used at operator discretion. Skin closure strips and absorbent dressing were adhered over the wound and were asked to be kept

dry and removed after 7 days. EP/OP procedures followed similar protocols. CS training involved 10 observed implants and 10 implants under direct supervision. CSs required a physician to sign a Patient Specific Direction (PSD) on each day of local anesthetic administration. HW patients were asked to self-report any complications and to send a wound photo before a 6-week post-implant telephone review. Complications included infection, bleeding (requiring medical attention), and dehiscence ± device erosion, and were all reviewed by the principal investigator. EP/OP procedures followed similar protocols.

A total of 656 procedures met inclusion criteria. Median follow-up was 15 [10-21] months. Most procedures (483, 74%) were performed in an OP setting, followed by 89 (14%) in the EP lab and 84 (13%) in a HW. CSs performed twice as many HW procedures as physicians (55, 66% vs. 27, 32%), with the remaining 2 (2%) by nurses (Table 1). The HW-group patients were older than the EP (70 vs. 52 years, $p < 0.001$) and OP (58 years, $p < 0.001$) groups, had more anticoagulant prescription than the OP group (38% vs 10%, $p < 0.001$), and more antiplatelet prescription than the EP group (17% vs. 5%, $p = 0.03$), but less antiplatelet prescription than the OP group (31%, $p = 0.02$). The HW group also had fewer female patients than the EP (24% vs. 45%, $p = 0.01$) and OP (48%, $p < 0.001$) groups, and more patients of White ethnicity (HW: 75% vs EP: 62% ($p = 0.01$) and OP: 60% ($p = 0.01$)) (Table 1).

Complication rate by 6 weeks of follow-up was low (0.9%), and comparable between settings (HW: 1.2%, EP: 2.2%, OP: 0.6%) and operators (CS: 0.5%, physician: 2.3%, nurse: 0.6%) (Table 1). Bleeding was the only complication in the HW-group and only

occurred in patients with anticoagulant/antiplatelet prescription, suggesting extra care should be taken to achieve haemostasis and skin closure in these patients.

Our HW-based complication rate (1.2%) was comparable to Chionchio et al[3] (1.9% – also caused by bleeding). In contrast to Chionchio et al[3], who provided prophylactic antibiotics to all patients, we demonstrate a safe HW-based protocol without prophylactic antibiotics. Our CS-led complication rate (0.5%) was lower than that of Davies et al[4] (4.0%), perhaps due to “delayed healing” and “discomfort requiring removal/reposition” accounting for 50% of their complications. Our CS-led complication rate was also comparable to that of nurses in the United States (2.1%) [3] and our own centre[1] (0.9%). The small number of HW patients of female sex and non-white ethnicity reflects the under-representation of these groups receiving aortic valve replacement in the United Kingdom.[5] Our study was limited by single centre analysis, lack of statistical power, a relatively homogenous HW group, and the retrospective assessment of EP/OP procedures. Time to implant for HW patients could not be assessed as they were pre-planned procedures.

In conclusion, ward-based ICM implants performed predominantly by Cardiac Scientists were as safe as existing standardised protocols. Further research on ward-based ICM implants could assess time to implant and perform a detailed cost-analysis to confirm the feasibility of a ward-based service.

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Tables

Table 1. Demographics and complications of implantable cardiac monitor implants performed in different hospital settings. Data presented as number of patients (% rate) or absolute value [interquartile range]. CS = cardiac scientist, EP = electrophysiology.

	Ward	EP lab	Outpatient	Overall	P
Total patients	84 (12.8%)	89 (13.6%)	483 (73.6%)	656	-
Age – years	70 [63-77]	52 [35-69]	58 [45-71]	60 [46-74]	<.001†
Female sex	20 (23.8%)	40 (44.9%)	230 (47.6%)	290 (44.2%)	<.001†
White ethnicity	63 (75.0%)	55 (61.8%)	291 (60.2%)	409 (62.3%)	.004†
Anticoagulant	32 (38.1%)	29 (32.6%)	47 (9.7%)	108 (16.5%)	<.001†
Antiplatelet	14 (16.7%)	4 (4.5%)	151 (31.3%)	169 (25.8%)	<.001†
CS	55 (65.6%)	5 (5.6%)	148 (30.6%)	208 (31.7%)	-
Nurse	2 (2.4%)	15 (16.9%)	300 (62.1%)	317 (48.8%)	-
Physician	27 (32.1%)	69 (77.5%)	35 (7.2%)	131 (20.0%)	-
All complications	1 (1.2%)	2 (2.2%)	3 (0.6%)	6 (0.9%)	-
Bleeding	1 (1.2%)	2 (2.2%)	1 (0.2%)	4 (0.6%)	-
Infection	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.2%)	-
Erosion	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.2%)	-

†Significant effect of implant setting ($p<0.05$)