

PLACE



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
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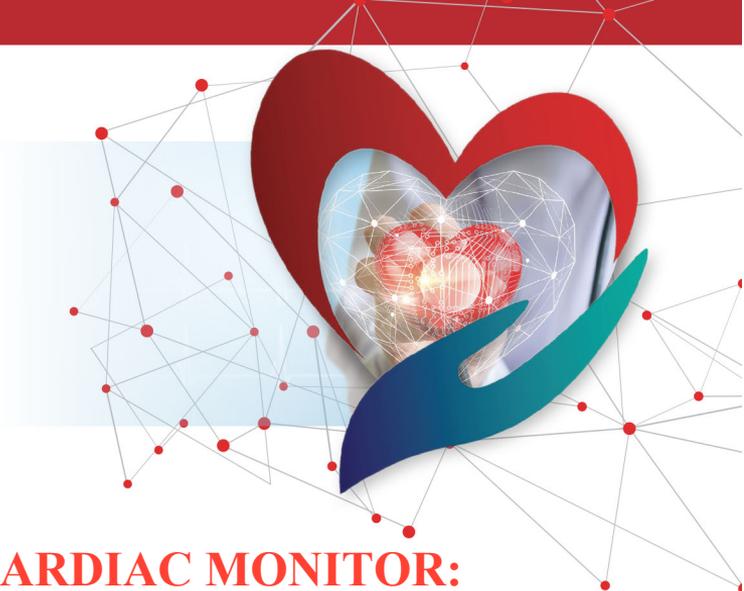
**Auditorium
della Tecnica**

9^a Edizione

30 Settembre

1 Ottobre

2022



**CONSENSUS CONFERENCE IMPLANTABLE CARDIAC MONITOR:
LE NUOVE APPLICAZIONI**

**NUOVI SETTING DI IMPIANTO DEL LOOP RECORDER:
L'AMBULATORIO E' LA SOLUZIONE?**

Dott. Massimiliano Maines

Loop Recorder Impiantabili



CATH LAB

Primo impiantabile



PROCEDURE ROOM



1998



2009



2009



2012



2014



2015



2017



2019



2020



2023?



IMPIANTO DI LOOP RECORDER: SETTING



CATH LAB

COMPLEX SETUP:

- Time-consuming procedures
- Resource-intensive
- Cost impactful
- Limited beds, scheduling & staff availability



PROCEDURE ROOM

SIMPLE SETUP:

- Minimal setup necessary
- Reduced procedure time
- Saving time & costs
- Safe & feasible



MITTAL, PACE 2015¹

- Procedure-related events from a controlled clinical trial (Reveal LINQ™ ICM Usability study) and a real-world Registry (Reveal LINQ ICM Registry)
- N=273 patients
 - 151 Reveal LINQ ICM Usability patients (followed for 1 month) – 16 centers
 - 122 Reveal LINQ ICM Registry patients (all events reported upon occurrence) – 7 centers
- Infection rates were low in both studies. Reveal LINQ ICM Usability (n=2; 1.3%); Reveal LINQ ICM Registry (n=2; 1.6%)
- Total procedure-related SAEs were low (n=3; 1.1%)

Reveal LINQ ICM can be inserted with minimal associated adverse events

Procedure Characteristics		
Procedure Characteristics	Usability (n = 151)	Registry (n = 122)
Location of procedure		
Catheterization or electrophysiology lab	130 (86.1%)	94 (77.0%)
Clean room	15 (9.9%)	28 (23.0%)
Operating room	2 (1.3%)	0 (0.0%)
Practice office	1 (0.7%)	0 (0.0%)
Other†	3 (2.0%)	0 (0.0%)
Anesthesia		
Local anesthetic	150 (99.3%)	98 (80.3%)
General anesthesia	4 (2.6%)	1 (0.8%)
Moderate intravenous sedation	None	24 (19.7%)
None	1 (0.7%)	4 (3.3%)
Preprocedural antibiotics		
Oral	73 (48.3%)	51 (41.8%)
Intravenous	12 (7.9%)	NR
Unknown	60 (39.7%)	NR
None	1 (0.6%)	NR
78 (51.7%)	NR	NR
Incision site preparation prior to insertion		
No	1 (0.7%)	NR
Yes	150 (99.3%)	NR
Betadine	48 (31.8%)	NR
Chlorhexidine	73 (48.3%)	NR
Isoniazid (antibacterial)	17 (11.3%)	NR
Benzyl alcohol	11 (7.3%)	NR
Unknown	1 (0.7%)	NR
Use of provided incision tool	151 (100%)	76 (62.3%)
Use of provided insertion tool	145 (96.7%)	111 (91.0%)
Thoracic anatomical location		
Best	139 (92.1%)	88 (72.2%)
Good	9 (6.0%)	6 (5.3%)
Other	3 (2.0%)	20 (17.5%)
Device fixation with sutures		
Yes	22 (14.6%)	7 (5.7%)
No	129 (85.4%)	112 (91.8%)
Not specified	0 (0.0%)	3 (2.5%)
Wound closure method		
Suture	64 (42.4%)	20 (16.4%)
Staples	None	31 (25.4%)
Surgical glue	14 (9.3%)	29 (23.8%)
Adhesive strips	60 (39.7%)	85 (69.7%)
Other	13 (8.6%)	0 (0.0%)
Suture and adhesive strips or glue	11 (7.3%)	0 (0.0%)
Antibiotics postinsertion	13 (8.6%)	5 (4.1%)

†Other locations were patient room within the hospital, practice office, and outpatient clinic.
NR = not reported for some or all patients.

1. Mittal et al. Safety profile of a miniaturized insertable cardiac monitor: results from two prospective trials. PACE 2015; 38:1464-1469



ILR insertions in CATH LAB vs recovery room

- HARRINGTON, HRS POSTER 2015¹
 - N=83 patients were inserted with Reveal LINQ™ ICM and follow for 172 ± 105 days:
 - 44 in cardiac catheterization lab
 - 39 in sterile recovery room
 - Optional use of peri-procedural IV Cephazolin
 - No infections were observed
 - 2 complications resulting in explant:
 - 1 extrusion due to physical exertion 62 days post-insertion (recovery room group)
 - 1 extrusion due to traumatic injury 21 days post-insertion (cath lab group)

Insertion of Reveal LINQ ICM outside of the cath lab yet within the walls of the hospital is feasible

	Catheterization Laboratory (n = 44)	Recovery Room (n = 39)	P
Age (yrs)	57 ± 14	57 ± 17	0.952
Male gender, n (%)	29 (66%)	25 (64%)	0.863
BMI, (kg/m ²)	28 ± 5	29 ± 5	0.322
Hypertension, n (%)	26 (59%)	23 (59%)	0.996
Diabetes, n (%)	3 (7%)	5 (13%)	0.352
Ischemic heart disease, n (%)	3 (7%)	3 (8%)	0.875
Strokes/TIA, n (%)	2 (5%)	2 (5%)	0.812
Complications, n (%)	1 (2.2%)	1 (2.6%)	1.0
Peri-procedural antibiotics, n (%)	10 (23%)	8 (21%)	0.204

1. Harrington et al. Feasibility and safety of Reveal LINQ insertion in sterile recovery room versus cardiac catheterization laboratory environment. Heart Rhythm 2015 12 Suppl 1 (S328-S329)



ILR insertions In vs out of cath lab

- REVEAL LINQ ICM REGISTRY: BEINART, HRS ORAL 2016¹
- N=489 patients from the ongoing Reveal LINQ™ ICM Registry had device insertion:
 - In-lab (Cath/EP lab/OR) (n=304)
 - Out-of-lab (clean/procedure room or EP lab holding area) (n=185)

While significant procedure differences were observed between in-lab vs. out-of lab, this had no apparent effect on the occurrence of infections or other adverse events.

- There was no difference in procedure-related adverse events (1.3% in-lab vs 1.6% out-of-lab)
- Of 489 procedures, only one resulted in a serious infection requiring explant
 - Overall infection rate: 0.8%
 - 2 (0.7%) In-lab; 1 serious
 - 2 (1.1%) Out-of-lab: both minor
- Other adverse events: 2 erosions and 1 migration

Procedure Characteristics	In-lab (304)	Out-of Lab (185)	P Value
Local anesthesia	252 (82.9%)	184 (99.5%)	< 0.0001
Moderate IV sedation	61 (20.1%)	1 (0.5%)	< 0.0001
Pre-operative abx	121 (39.8%)	8 (4.3%)	< 0.0001
Post-operative abx	46 (15.1%)	3 (1.6%)	< 0.0001
Use incision of tool	225 (74%)	70 (37.8%)	< 0.0001
Use of insertion tool	234 (77%)	168 (90.8%)	< 0.0001
Device fixation	21 (6.9%)	1 (0.5%)	< 0.0002
Wound closure:			
Suture	10 (3.3%)	27 (14.6%)	< 0.0001
Staples	112 (36.8%)	103 (55.7%)	< 0.0001
Adhesive strips	183 (60.2%)	103 (55.7%)	< 0.0001

1. Beinart et al Real-world comparison of in-hospital Reveal LINQ insertion inside and outside of the cardiac catheterization or electrophysiology laboratory. Heart Rhythm 2016;13:S15 Suppl

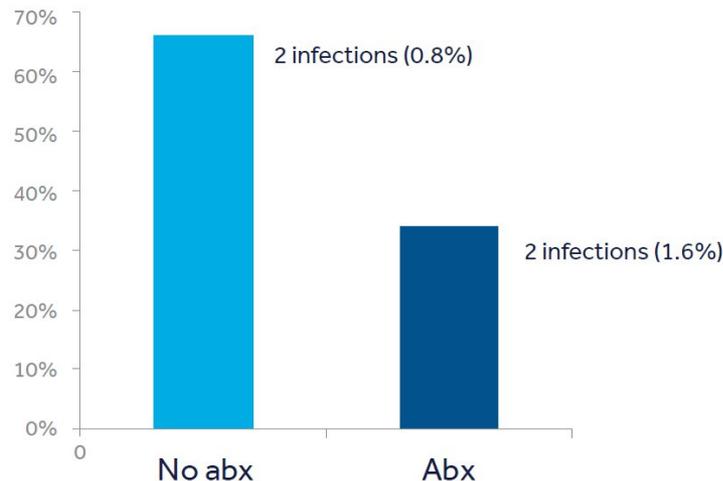


Use of antibiotics in ILR procedures

BEINART, PACE¹

- Real-world use of antibiotics (abx) in Reveal LINQ™ ICM insertion procedures (Reveal LINQ ICM Registry)
- N=375 patients from 14 US centers
- 66.4% of patients did not receive pre-procedural abx
- Overall infection rate: 1.1% (n=4)
 - Group without abx (n=249): 0.8% (n=2)
 - Group with abx (n=126): 1.6% (n=2)
- 60.5% of procedures were performed in the cath/EP lab; the rest out of the lab but within hospital

Real-world insertions of Reveal LINQ ICM in the US were mainly performed without the use of prophylactic antibiotics and are associated with a low infection rate



1. Beinart et al. Real-world use of prophylactic antibiotics in insertable cardiac monitor procedures. PACE 2016; 39:837-42



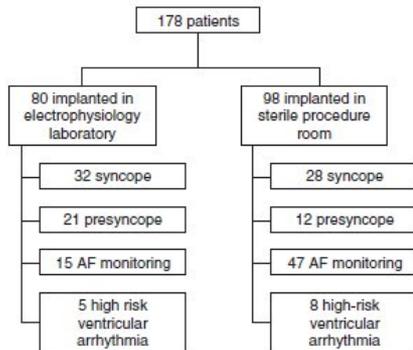
ESPERIENZA MONOCENTRICA UNIVERSITA' DI ADELAIDE

- Agosto 2016

Feasibility and safety of Reveal LINQ insertion in a sterile procedure room versus electrophysiology laboratory

Geoffrey R. Wong¹, Dennis H. Lau¹, Melissa E. Middeldorp, Judith A. Harrington, Simon Stolzman, Lauren Wilson, Darragh J. Twomey, Sharath Kumar, Dian A. Munawar, Kashif B. Khokhar, Rajiv Mahajan, Prashanthan Sanders*

International Journal of Cardiology 223 (2016) 13-17



- 80 vs 98 pazienti NON Randomizzati, ma con caratteristiche di base non diverse in modo statisticamente significativo
- Stessa tecnica di impianto eseguita da EP

Risultati:

Follow-up: 8.9±5.5 mesi (EP) vs. 9.8±6.9 (fuori sala)

Comparison of procedural characteristics and complications between the electrophysiology lab and procedure room groups.

	Electrophysiology laboratory (N = 80)	Procedure room (N = 98)	p-Value
Antibiotics Intravenous cephazolin	11 (14)	1 (1)	0.007
Closure method			
• Sutures	1	0	0.27
• Steri-strips	80	98	
Total complications (%)	2 (3)	1 (1)	0.45
Device extrusion	1	0	0.27
Superficial infection	0	1	0.36
Pocket infection requiring explant	1	0	0.28
Follow-up (days)	268 ± 164	296 ± 206	0.35
Diagnosis and pacemaker implantation	8 (10)	4 (4)	0.11

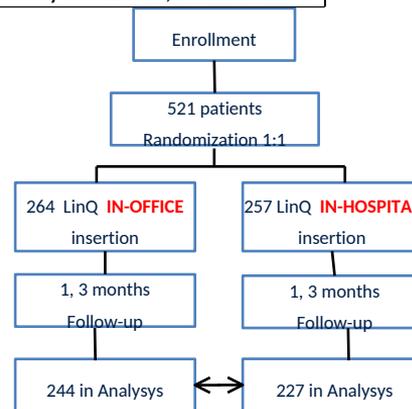
In-office insertion of a miniaturized insertable cardiac monitor: Results from the Reveal LINQ In-Office 2 randomized study

Heart Rhythm 2017;14:218-224



- Randomized, multicenter, prospective, parallel group clinical study SPONSORED BY MEDTRONIC conducted in the 26 centers in United States, comparing **IN-HOSPITAL vs OUT OF HOSPITAL** procedures
- **Primary endpoint:** untoward events (unsuccessful ICM insertion OR severe complication* related to ICM system or procedure)
- STRICT SAFETY PROTOCOL FROM THE BEGINNING OF THE STUDY: requirements for sterility standard
- Wound closure: adhesive strips, surgical glue, sutures, staples, or a combination depending on physician practice (similar in the 2 groups).

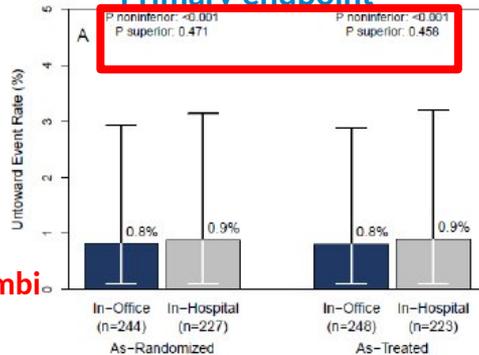
*Severe Complication: AEs that result in death, termination of significant device function, or required invasive intervention including the administration of intravenous medications.



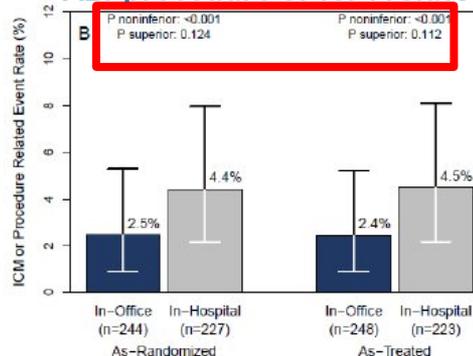
NON INFERIORITA' nel successo all'impianto o eventi avversi seri -

<1% di Complicanze, 0% infezioni in entrambi i gruppi

Primary endpoint



AEs procedure or ICM related





STUDIO RIO 2 US:

In-office insertion of a miniaturized insertable cardiac monitor: Results from the Reveal LINQ In-Office 2 randomized study [®]

RISULTATI DEL QUESTIONARIO MEDICO:

- ✓ Le procedure eseguite in ambulatorio avevano una **probabilità significativamente minore di essere ritardate di oltre 15 minuti** rispetto a quelle eseguite in ospedale (16% vs 35%, $P < 0,001$).
- ✓ I medici hanno anche indicato che i loro **pazienti hanno risposto in modo più favorevole all'inserimento dell'ICM in ambulatorio** rispetto alle procedure ospedaliere.
- ✓ Allo stesso modo, **l'85% degli intervistati ha valutato l'ubicazione della procedura in ambulatorio come "molto conveniente"**, mentre solo il 29% degli intervistati ha valutato gli inserimenti in ospedale "molto conveniente" ($P < 0,001$).
- ✓ Infine, dopo aver inserito l'ICM in ambulatorio, il **91% degli intervistati ha dichiarato che preferirebbe eseguire procedure in un setting ambulatoriale se il rimborso fosse disponibile.**

IMPIANTO FUORI SALA: EVIDENZE CLINICHE

Am Heart J, 2019

Real-world comparison of in-hospital Reveal LINQ insertable cardiac monitor insertion inside and outside of the cardiac catheterization or electrophysiology laboratory

Sean C. Beinart, MD, FACC, FHRS,^a Andrea Natale, MD, FACC, FHRS, FESC,^b Anul Verma, MD, FRCP,^c Alpeh Amin, MD, MBA, MACP, SFHM, FACC,^d Scott Kasner, MD, MSCE, FAHA, FAAN,^e Hans-Cristoph Diener, MD, PhD,^f Maurizio Del Greco, MD,^g Bruce L. Wilkoff, MD,^h Erika Poulriot, MS,ⁱ Noreli Franco, PhD,^j and Sumec Mittal, MD, FACC,^k Rockville, MD; Austin, TX; Ontario, Canada; Irvine, CA; Philadelphia, PA; Essen, Germany; Piazza S. Maria, Rovereto, Italy; Cleveland, OH; 8200 Coral Sea St. Mounds View, MN; and Paramus, NJ



- Multi center prospective observational “Real world” study of **1222 LINQ** implanted in 18 centers in the US, 17 centers in Middle East/Asia, and 15 centers in Europe.
- 2 cohorts according to the location of the procedure: **IN-LAB** (CATH lab, EP lab, or operating room) (n = 820, 67.1%) and **OUT OF LAB** (clean/procedure rooms or non-invasive laboratory) (n = 402, 32.9%).

Patient characteristics	Total (N = 1222)	In-lab (n = 820)	Out-of-lab (n = 402)	P
Age, mean (range)	61.0 ± 17.1 (11-92)	59.4 ± 17.9 (11-92)	64.2 ± 14.6 (13-90)	<.0001
Male, n (%)	710 (58.1%)	463 (56.5%)	247 (61.4%)	.11
BMI, mean (range) [number of patients with available BMI]	27.9 ± 6.5 (10-61) [n = 1100]	27.7 ± 6.6 (10-57) [n = 743]	28.2 ± 6.2 (16-61) [n = 357]	.25
Primary indication for ICM, n (%)				<.0001
Syncope	370 (30.3%)	295 (36.0%)	75 (18.7%)	
Cryptogenic stroke	224 (18.3%)	144 (17.6%)	80 (19.9%)	
Suspected AF	149 (12.2%)	103 (12.6%)	46 (11.4%)	
Palpitations	140 (11.5%)	101 (12.3%)	39 (9.7%)	
AF management	139 (11.4%)	65 (7.9%)	74 (18.4%)	
Post-AF ablation monitoring	56 (4.6%)	24 (2.9%)	32 (8.0%)	
Ventricular tachycardia	47 (3.8%)	17 (2.1%)	30 (7.5%)	
Pre-AF ablation monitoring	26 (2.1%)	22 (2.7%)	4 (1.0%)	
Transient ischemic attack (TIA)	19 (1.6%)	14 (1.7%)	5 (1.2%)	
Seizures	2 (0.2%)	1 (0.1%)	1 (0.3%)	
Other	50 (4.1%)	34 (4.2%)	16 (4.0%)	
History of COPD, n (%)	55 (4.5%)	40 (4.9%)	15 (3.7%)	.46
History of Cancer, n (%)	119 (9.7%)	83 (10.1%)	36 (9.0%)	.54
Diabetes, n (%)	181 (14.8%)	122 (14.9%)	59 (14.7%)	1.00
Congestive heart failure, n (%)	69 (5.6%)	42 (5.1%)	27 (6.7%)	.29
Peripheral vascular disease, n (%)	44 (3.6%)	25 (3.1%)	19 (4.7%)	.14
History of TIA/stroke, n (%)	380 (31.1%)	255 (31.1%)	125 (31.1%)	1.00
Baseline OAC, n (%)	363/1211 (30.0%)	224/812 (27.6%)	139/399 (34.8%)	.01
Baseline antiplatelets, n (%)	474/1208 (39.2%)	318/808 (39.4%)	156/400 (39.0%)	.95

Statistical tests used were: t test to compare numeric averages between the 2 groups (age and BMI) and Fisher exact test to compare categorical variables between the 2 groups. Abbreviations: COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack; OAC, oral anti-coagulation.

Device setting distribution:

- 33 centers solely performed in-lab procedures, (n = 688),
- 3 centers solely performed out-of-lab procedures (n = 60),
- 14 centers had a mix of service sites (n = 474).

Implanters:

- electrophysiologists (90.5%)
- interventional cardiologists (5.2%) -
- general cardiologists (3.9%)

IMPIANTO FUORI SALA: EVIDENZE CLINICHE

Real-world comparison of in-hospital Reveal LINQ insertable cardiac monitor insertion inside and outside of the cardiac catheterization or electrophysiology laboratory

Am Heart J, 2019



Difference in the procedures:

- **Intravenous moderate sedation** was **more** commonly used **in-lab** (13.2% vs. 0.5% out-of-lab, P b .0001).
- **Pre-procedural antibiotics** were used **more often in the in-lab** group (47.5% compared with 11.4% in the out-of-lab group, P <=.0001).
- Fixation with sutures was performed more often in-lab than out-of-lab (18.6% vs 6.8%, P<=.0001).
- Wound closure: **sutures** was performed **more often in-lab** than out-of-lab (18.6% vs 6.8%, P <=.0001).

ICM/procedure-related adverse events (FU: 10.4 months (0.0-35.6)):

- **Low total event rate (1.4% AEs, 0.8% Serious AEs, and 0.6% infections)**
- **No statistically significant difference in AEs rate per subject**
 € 1.3% in-lab (n = 11) and 1.5% out-of-lab group (n = 6).

AEs	All Adverse Events			Serious Adverse Events		
	In-lab (820)	Out-of-Lab (402)	P	In-lab (820)	Out-of-Lab (402)	P
Infection	4 (0.5%)	3 (0.7%)	.69	2 (0.2%)	0 (0.0%)	1.00
Device Extrusion	2 (0.2%)	0 (0.0%)	1.00	2 (0.2%)	0 (0.0%)	1.00
Implant Site Bleeding	1 (0.1%)	0 (0.0%)	1.00	1 (0.1%)	0 (0.0%)	1.00
Implant Site Pain	2 (0.2%)	1 (0.2%)	1.00	1 (0.1%)	1 (0.2%)	.55
Pocket Erosion	2 (0.2%)	1 (0.2%)	1.00	2 (0.2%)	1 (0.2%)	1.00
Migration	1 (0.1%)	0 (0.0%)	1.00	1 (0.1%)	0 (0.0%)	1.00
Skin Abrasion	0 (0.0%)	1 (0.2%)	.33	0 (0.0%)	0 (0.0%)	-
TOTAL	11 (1.3%)	6 (1.5%)	.80	8 (1.0%)	2 (0.5%)	.51

- **no statistically significant difference in the number of infections (P = .69).**



BioMonitor 2 in-office setting insertion safety and feasibility evaluation with device functionality assessment: results from the prospective cohort BioInsight study

Khaled Awad^{1*}, Raul Weiss², Asim Yunus³, Jon M. Bittrick⁴, Rajasekhar Nekkanti⁵, Mahmoud Houmsse², Toshimasa Okabe², Teagan Adamson⁶, Crystal Miller⁶ and Abdul K. Alawwa⁷

Awad et al. *BMC Cardiovascular Disorders* (2020) 20:171
<https://doi.org/10.1186/s12872-020-01439-8>

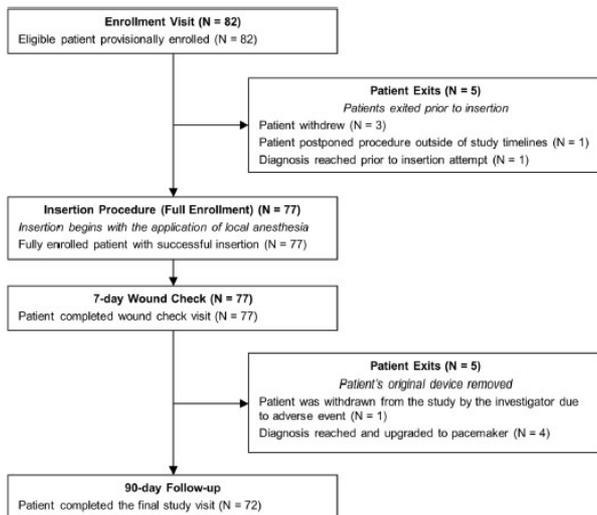
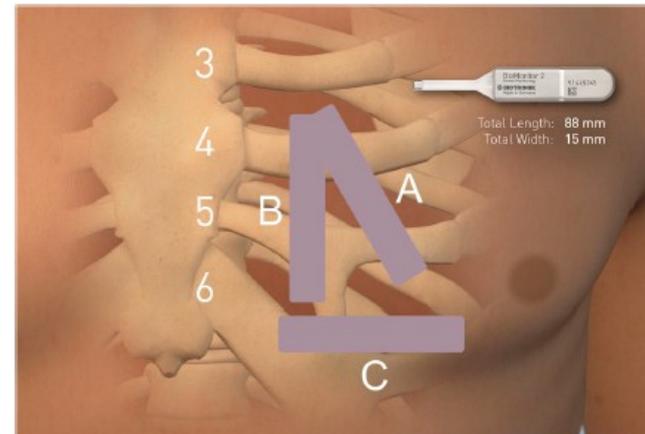


Table 2 Insertion procedure characteristics for fully enrolled patients

Characteristic	Patients N = 77
Device Orientation	
Position A	35 (45.5%)
Position B	38 (49.4%)
Position C	1 (1.3%)
Other	3 (3.9%)
Final Incision Size (mm ± SD) ^a	14.9 ± 3.7
Total Procedure Duration (min ± SD)	8.4 ± 3.7
Prophylactic Antibiotic Use	
After the procedure ^b	29 (37.7%)
Before the procedure	3 (3.9%)
Oral Anticoagulant Use	
Non-vitamin-K OAC	34 (44.2%)
OACs not held prior to procedure	30 (39.0%)
Closure Material^b	
Deep tissue (subcutaneous) sutures	50 (64.9%)
Superficial (dermal) sutures	23 (29.9%)
Barbed sutures	13 (16.9%)
Topical adhesive	48 (62.3%)
Skin closure strips	5 (6.5%)



No complication related to the insertion procedure



IMPIANTO DI LOOP RECORDER IN UN SETTING AMBULATORIALE

STUDY	PATIENTS	OUT-OF-LAB PROCEDURES (% OF TOTAL)	OVERALL INFECTION RATE	OUT-OF-LAB INFECTION RATE	OVERALL USE OF ANTIBIOTICS
Reveal LINQ™ Usability ¹	151	19 (12.6%)	2 (1.3%)	0 (0.0%)	48.3%
Reveal LINQ™ Registry ²	489	185 (37.8%)	4 (0.8%)	2 (1.1%)	33.6%
RIO 2 OUS ³	191	191 (100%)	0 (0.0%)	0 (0.0%)	44.0%
LOOP ⁴	1420	753 (53%)	13 (0.9%)	12 (1.6%)	100%*
Wong, et al. ⁵	178	98 (55.0%)	2 (1.1%)	1 (1.0%)	7.0%
Di Odoardo, et al. ⁶	16	8 (50.0%)	0 (0.0%)	0 (0.0%)	100%*
Kipp, et al. ⁷	125	125 (100%)	1 (0.8%)	1 (0.8%)	100%*
Maines, et al. ⁸	154	154 (100%)	0 (0.0%)	0 (0.0%)	0.0%
RIO 2 ^{9**}	451	224 (49.7%)	0 (0.0%)	0 (0.0%)	45.2%

*Use of antibiotics was required per protocol

**Rio2 was undertaken outside of hospital walls

1. Mittal S, et al. PACE. 2015; 38:1464-1469. - <https://www.ncbi.nlm.nih.gov/pubmed/26412309>

2. Beinart SC, et al. Heart Rhythm. 2016;13:5 SUPPL 1 (S15).
<https://www.ncbi.nlm.nih.gov/pubmed/30487072>

3. Sanders P, et al. JACC. 2017;69:354.
<https://bmccardiovascdisord.biomedcentral.com/articles/10.1186/s12872-019-1106-3>

4. Diederichsen SZ, et al. Int J Cardiol. 2017;241:229-234.
<https://www.ncbi.nlm.nih.gov/pubmed/28457562>

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6. Di Odoardo LAF, et al. J Cardiovasc Med. 2017;18:550-552.

<https://www.ncbi.nlm.nih.gov/pubmed/27322402>

7. Kipp R, et al. PACE. 2017;40:982-985. <https://www.ncbi.nlm.nih.gov/pubmed/28691385>

8. Maines M et al. Europace. 2017;doi:10.1093/europace/eux187.

<https://europepmc.org/article/med/29016753>

9. Rogers JD, et al. Heart Rhythm. 2017;14:218-224. <https://www.ncbi.nlm.nih.gov/pubmed/32207636>



COST comparison: Procedure ROOM vs. EP/Cath LAB

- KANTERS, *EUROPACE*¹
- Cost comparison of Reveal LINQ™ ICM insertion in a procedure room vs. Reveal™ XT in cath or EP lab
- Bottom-up costing analysis using data from Netherlands, France and the UK
- Reveal LINQ ICM procedure:
 - Shorter waiting time between decision and implant
 - Shorter room occupancy (55 min)
 - Shorter procedure time (9.4 min; 5-10 min shorter)
 - May be performed by less qualified personnel
 - No antibiotics needed
 - Decrease of disposable materials due to insertion kit
- Procedure room savings in the UK: €662

Miniaturization of technology saves hospital resources and improves patient care pathway

Table 3: Costs associated with the Reveal XT and Reveal LINQ procedures in cath lab and procedure room, respectively

	Reveal XT in cath lab	Reveal LINQ in procedure room	Difference
Procedure-related costs			
Labor	€104	€42	-€63
Medication	€6	€2	-€4
Materials	€23	€20	-€3
Room-related costs			
Labor	€8	€7	-€1
Instruments/equipment	€100	€5	-€95
Cleaning	€57	€4	-€53
Overhead costs			
Overhead costs	€197	€30	-€167
Hospital admission costs			
Hospital admission	€276	€0	-€276
Total costs difference			-€662

The net cost impact for hospital depends on the cost difference between the two devices.

1. Kanters et al. Cost comparison of two implantable cardiac monitors in two different settings: Reveal XT in a catheterization laboratory vs. Reveal LINQ in a procedure room. *Europace* 2016; 18:919-24



ICMs can be routinely implanted in a non-theatre environment by a cardiac physiologist

Br J Cardiol 2019; 26 (1)

Varun Shamam, Stelios Iacovides, Luisa Cleverdon, Wasing Taggu, Philip Keeling

ESPERIENZA MONOCENTRICA: TORBAY HOSPITAL (TORQUAY, UK)

- A cardiac- physiologist (non-physician) received a specific training to implant ICM devices autonomously in the screening room of the coronary care unit
- A standard operating procedure (SOP) was written to guide LINQ implant
- Two educational video for the patients were developed to avoid pre-admission visit
- A dedicated LINQ implant list (monthly) was set up

RESULTS

- Trained cardiac-physiologist performed **116 ICM implant procedures** (113 LINQ and 3 St Jude Confirm) in the screening room of the coronary care unit

Low rate of Complications

- 2 patients developed **minor bleeding**
- **No patient developed early or late infection or erosion of the device**
- A small apical pneumothorax related to deep anaesthetic infiltration in a patient with very low body mass index. The patient was discharged the next day

**New procedure allowed
a net saving amount of 241.27 € per implant**

Table 2. Costs comparison between old and new system (GBP-2017)

Old system	Cost	New system	Cost
Pre-administration visit (cardiac technician 30 minutes)	£11.55	NA	
MRSA screening	£15.00	NA	
Admission to cath lab recovery unit			
Day-case bed, 3 hours	£36.00	NA	
Gown/bracelet/food and drink	£2.30		
Implant procedure (30 minutes)		Implant procedure (20 minutes)	
Surgical instruments, pacing pack (+ disposables)	£64.30	LINQ pack (including disposables*)	£16.43
Skin suture	£2.29	Steri-strip	£0.12
Cardiologist	£28.08	Technician x3 (Band 6)	£23.10
Nurses x2 (Band 5)	£18.12		
Radiographer (Band 6)	£11.55		
Technician (Band 6)	£11.55		
Recovery (2 hours)	£72.48	NA	
Clinic visit at 4 weeks (Technician Band 6, 30 minutes)	£11.55	Remote monitoring (Technician Band 6, 10 minutes)	£3.85
Total	£284.77	Total	£43.50

* Gown/gloves/skin prep/antiseptic local anaesthetic/gel/antiseptic/sterile drapes x2, needles x2



	TOTALE (N=157)		Pazienti impiantati da elettrofisiologo (N=74; 47%)		Pazienti impiantati da infermieri (N=83; 53%)		p-value
	N	%	N	%	N	%	
Età all'impianto (anni), Media \pm DS	56 \pm 15		58 \pm 15		55 \pm 15		0.213
Genere (Femmine)	42	27	22	30	20	24	0.426
BMI, Media \pm DS	25 + 4		26 + 4		25 + 3		0.076
Terapia antibiotica preimpianto	113	72	72	97	41	49	<0.001
Chiusura dell'incisione con steri-strip	89	140	80	59	98	81	<0.001
Indicazione all'impianto di ICM							
Sincope	30	47	31	23	29	24	0.767
Fibrillazione atriale	35	55	31	23	39	32	0.327
Tachicardia ventricolare	19	30	18	13	21	17	0.643
Bradycardia ventricolare	2	3	1	1	2	2	0.629
Sindrome di Brugada	6	10	7	5	6	5	0.851
Ictus	4	6	5	4	2	2	0.328
Pause	4	6	7	5	1	1	0.070
Eventi avversi							
Sanguinamenti entro le 24 ore	1	2	1	1	1	1	0.935



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: £6661.55						
Total staff cost saved—£3851.58						
Associated cost						
Based on Kanters et al¹³						
	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		



Standards for insertion, follow up and explant of implantable loop recorders [ILRs] by non-medical staff

August 2020

4.5 Competency

- Trainees should be observed a minimum of 20 times by a competent practitioner in ILR insertion. Competence to be assessed against a standard competency assessment tool for ILR insertion (see BHRS website for guidance). The assessor must sign to demonstrate competence has been achieved.
- Nurses or physiologists trained to implant ILR's, should perform a minimum of 20 new implants per year. This may differ according to the centre but is suggested as a guide.

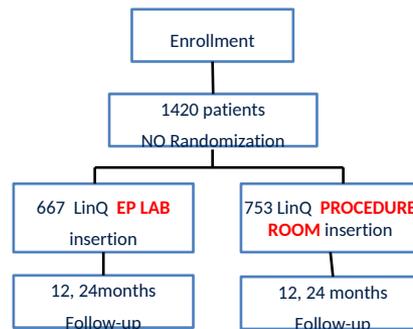
Complications after implantation of a new-generation insertable cardiac monitor: Results from the LOOP study

International Journal of Cardiology 241 (2017) 229–234



LOOP STUDY - Aprile 2017

- Observational analysis of the ICM branch of the LOOP study on **1420 pts** from 4 Danish centers (*large multi-centre randomized NON SPONSORED clinical trial investigating stroke prevention in individuals at risk using ICM to detect AF comparing EP LAB vs OUT OF EP LAB (Outpatient procedure room) at the discretion of the local centre (Non Randomized)*)
- No pre-defined Primary endpoint: procedure or ICM related AEs (bleeding from the incision, haematoma related to the device, pocket, pain, infection, or pocket erosion) in a median FU of 499 days
- SAFETY PROTOCOL TO REDUCE INFECTIONS WAS INTRODUCED IN THE SECOND PART OF THE STUDY



AE type	Surgical environment		
	EP Lab (n = 667)	PR (n = 753)	p
AEs not requiring explantation	5 (0.7%)	10 (1.3%)	0.31
Post-implant pain	2 (0.3%)	1 (0.1%)	0.60
Minor bleeding	2 (0.3%)	2 (0.3%)	1.00
Superficial infection	1 (0.1%)	7 (0.9%)	0.07
AEs requiring explantation	2 (0.3%)	7 (0.9%)	0.19
Post-implant pain	1 (0.1%)	0 (0.0%)	0.47
Infection	0 (0.0%)	5 (0.7%)	0.06
Pocket erosion	1 (0.1%)	2 (0.3%)	1.00

Rate of AE without explantation 1.1%

Rate of AE with explantation 0.6%

Difference in Total Infections 1 (0.1%) 12 (1.6%) 0.004

- **Very low risk of complications**
- **Larger risk of infections among implants performed by physicians in training**
- **And among patients undergoing implantation outside the EP Lab**

RIO2 vs LOOP STUDY



Infection Rate of Reveal LINQ implantation performed in a Procedure Room	
LOOP Study	RIO2 Study
Complications after implantation of a new-generation insertable cardiac monitor . Results from LOOP Study.	In-Office Insertion of a miniaturized insertable cardiac monitor: results from Reveal LINQ In-Office 2 randomized study
<u>International Journal of Cardiology</u>	<u>Heart Rhythm Journal</u>
April 2017	February 2017
Study 1420 patients received LINQ ICM <ul style="list-style-type: none"> 753 (53%) Procedure Room 667 (47%) EP Lab 	Study 482 patients received LINQ ICM <ul style="list-style-type: none"> 251 office outside of the hospital 231 hospital
Results Patient undergoing implantatio in a Procedure Room had more infections (12 (1.6%) vs 1 (0.1%) , p=000.4)	Results No infections were reported in either arm of the study
Conclusion: Reveal LINQ can be inserted with a very low risk of complications in both traditional EP lab and in an outpatient procedure room.	Conclusion: The safety profile for the insertion of reveal LINQ ICM is excellent irrespective of the insertion environment.
Key messages: <ul style="list-style-type: none"> Both studies concluded that is safe to perform the implantation of Reveal LINQ outside traditional EP/Cath Labs. RIO2 showed a lower infection rate due to a strict safety protocol from the beginning of the study (Medtronic sponsored) LOOP study experienced a learning curve at the beginning of the study; a safety protocol was introduced in the second part of the study to minimize infection risk (Physician initiated study) It is important to implement a safety protocol for the implantation of LINQ outside of the Cath lab. (Steffel et. al) 	
Materials: <ul style="list-style-type: none"> Publication: Insertion of miniaturized cardiac monitor outside of the catheter operating room: experience and practical advice. Steffel et al. Publication: LOOP Study Publication: RIO2 Publication Marketing: Reveal Out of the Cath Lab Starter Kit 	



Insertion of miniaturized cardiac monitors outside the catheter operating room: experience and practical advice

Marzo 2017

Jan Steffel^{1*}, David Jay Wright², Harald Schäfer³, Tabinda Rashid-Fadel⁴, and Thorsten Lewalter⁵

Table 1 Key points of consideration for office-based ICM insertion procedures

Facilities and resources

- Ensure there is sufficient space for staff movement in and out of sterile areas
- Provide a space for patient recovery after the procedure
- Install emergency equipment (including medication) in an accessible location on the same floor as the treatment room
- Provide sufficient personnel training and maintain high operator skills
- Ensure that a programmer from the manufacturer is available

Procedures

- Screen and select for eligible patients
- Ensure sterility at all times
- After closure, ensure the wound is clean, dry, and haemostatic
- Allow time for patient recovery after the procedure
- Review and assess the procedure and patients' satisfaction

Table 2 Necessary equipment for insertion of the Reveal LINQ miniaturized ICM when performed outside the catheter operating room

Equipment	Details
Local anaesthesia	Syringe, sufficiently long needle for insertion length, anaesthetics
Incision site preparation	Antiseptic solution (i.e. chlorhexidine, betadine)
Personal protective equipment ^a	Sterile gloves, gown, hat, mask
Surgical instruments	Trolley with sterile disposable drapes Sterile drape with a chest hole Manufacturer's implantation kit Surgical marker pen
Device programmer and sterile wand cover	
Emergency equipment	within close proximity
Reclining couch	
Material for skin closure	Surgical glue, surgical tape, stitches, or staples

^aWhen available, the selection of personal protective equipment and anaesthesia should follow institutional recommendations.

ESPERIENZA MONOCENTRICA OSPEDALE DI ROVERETO

- Single center NON SPONSORED observational study of 154 LINQ implanted in a procedure room **OUT OF EP LAB**. No control group.
- No pre-defined Primary endpoint: ICM or procedure related AEs in a median FU of 1 year
- The implanting physician, assisted by a specialist nurse, washed his/her hands with antiseptic solution, wore surgical cap and mask, sterile gloves and gown. No antibiotics or sedatives were administered. The skin incision was closed with sterile strips or skin glue and a dressing was applied.

Device related adverse events occurred in 1 patient (0.6%) due to skin erosion requiring ILR explantation.

0% Infections



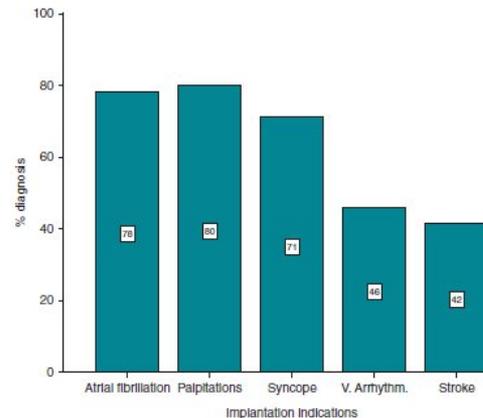
Europace (2017) 0, 1-8
doi:10.1093/europace/eux187

Luglio 2017

CLINICAL RESEARCH

Clinical impact, safety, and accuracy of the remotely monitored implantable loop recorder Medtronic Reveal LINQ™

Massimiliano Maines, Alessandro Zorzi[†], Giancarlo Tomasi, Carlo Angheben, Domenico Catanzariti, Lucio Piffer, and Maurizio Del Greco*



LOOP IMPIANTATI



DITTA	2014	2015	2016	2017	2018	2019	2020	2021	2022	TOTALE
ST JUDE	0	0	0	0	1	0	0	0	0	1
BIOTRONIK	0	0	2	6	1	22	73	30	7	141
BOSTON	0	0	0	0	0	0	0	0	0	0
MEDTRONIC	35	73	93	114	113	158	122	115	98	921
TOTALE	35	73	95	120	115	180	195	145	105	1063



IMPIANTO DEL LOOP REORDER IN AMBULATORIO



PROVINCIA AUTONOMA DI TRENTO

Reg. delib. n. 780

Prot. n.

VERBALE DI DELIBERAZIONE DELLA GIUNTA PROVINCIALE

OGGETTO:

Integrazione del Nomenclatore delle prestazioni di assistenza specialistica ambulatoriale, di diagnostica per immagini e di laboratorio erogabili nell'ambito del Servizio sanitario Provinciale e altre disposizioni.

IAH	33.79.1	IMPIANTO DI LOOP RECORDER	3.047,00	CARDIOLOGIA	Prestazione trasferita di setting (da ricovero diurno ad ambulatoriale)
					Prestazione erogabile esclusivamente presso le UU.OO. dell'APSS
IAH	86.05.2	REVISIONE O RIMOZIONE DI LOOP RECORDER	147,00	CARDIOLOGIA	Prestazione presente in dPCM LEA 12 gennaio 2017
					Prestazione erogabile esclusivamente presso le UU.OO. dell'APSS



IMPIANTO LOOP REORDER ESEGUITO DALL'INFERMIERE

Area Sviluppo Organizzativo

Servizio Formazione – Comitato tecnico scientifico provider

Referente: *dott.ssa Cristina Moletta / ac*

[Via Paolo Orsi, 1 – 38122 Trento](#)

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Rep int. n. 10364

Trento, 16/06/2017

Class.: XVI.6.7

Allegati: 4

dott. Lucio Piffer

U.O. Cardiologia

Struttura Ospedaliera di Rovereto

Oggetto: progetto di formazione sul campo stage/tirocinio: “Gestione ed applicazione mediante iniezione di Loop Recorder LINQ® (o analoghi) da parte di Personale Infermieristico esperto in elettrofisiologia” – esito valutazione ed indicazioni per la gestione

Si comunica che il progetto di formazione sul campo in oggetto è stato sottoposto alla valutazione del Comitato Tecnico Scientifico Provider Aziendale che lo ha approvato. Lo stesso potrà come da calendario.

Il Provider ECM assegna 25 crediti ai partecipanti e 12 crediti ai Tutor del progetto.



IMPIANTO LOOP REORDER ROVERETO



Impianti ed espunti loop recorder in ambulatorio

- Impianto eseguito dall'infermiere
- Espianto eseguito dal medico

- No monitoraggio ECG
- No accesso venoso
- No antibiotiprofilassi
- Punto di sutura riassorbibile

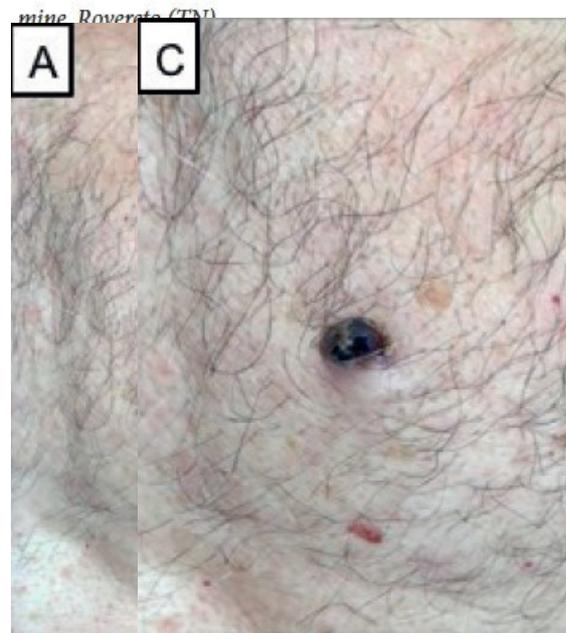
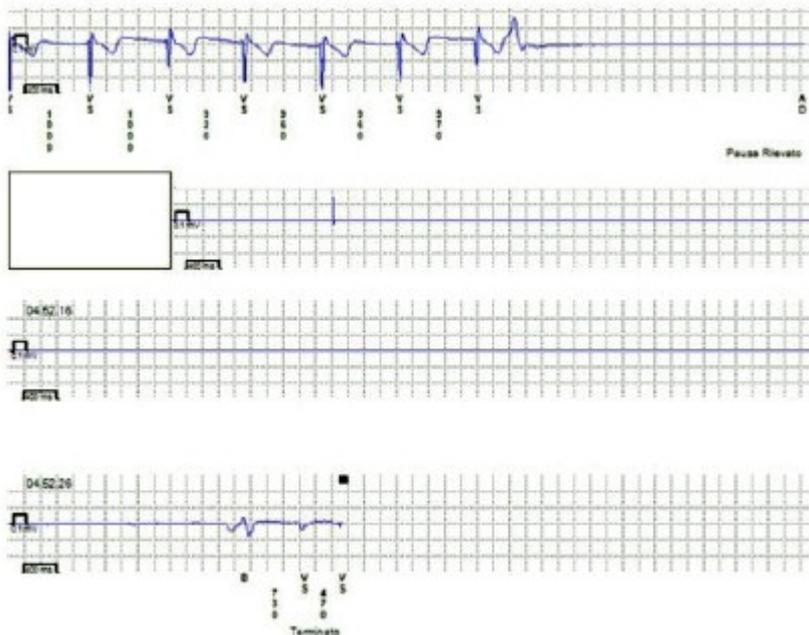




Complicanze : 0.3-0.7%

Falsa asistolia prolungata: un caso di deiscenza di tasca in portatore di loop recorder

Francesco Peruzzi, Massimiliano Maines, Domenico Catanzariti, Giancarlo Tomasi, Carlo Ansheben. Maurizio Del Greco





CONCLUSIONI

- ✓ L'Impianto di loop recorder in un setting ambulatoriale è fattibile
- ✓ L'impinto di loop recorder può essere effettuato anche da personale non medico adeguatamente formato
- ✓ Incidenza di complicanze bassa (1%) e non statisticamente diversa rispetto a impianto in sala
- ✓ Dati preliminari su consumo di risorse: Risparmio di circa 400€ - 800€



EFFICIENCY IMPROVES SERVICE OVERALL

- Frees up time to perform more complex procedures^{7,8,9}
- Improved patient flow/wait time^{1-3,9}



TIME SAVINGS UP TO 45 MINUTES SHORTER INSERTION VS. IN-LAB³

- Frees up clinical and non clinical staff time^{1,3,4,5,6,9}



COST-SAVING €400-€800 SAVED PER PATIENT VS. IN-LAB³

- No hospital admission cost^{1,4}
- Savings in materials, room and staff time^{1,3}