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Health Policy 2:
Status Quo & The Future of Remote Monitoring

원격 모니터링의 해외 사례

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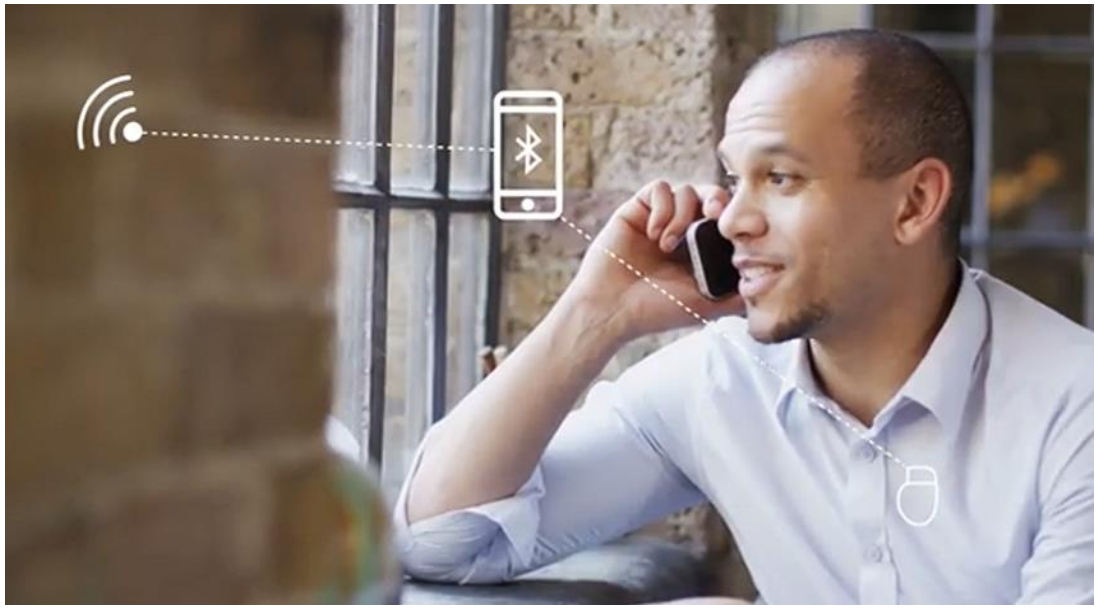
1) 미국내 원격 모니터링 현황

2002년

2015년~현재



- 2002년 미국내에서 최초로 원격 모니터링이 사용됨
- 초기에는 별도의 데이터 전송 장치 등이 필요하였으나, 2015년 이후 휴대폰의 블루투스/셀룰러 통신 기능을 활용한 원격 모니터링 기술이 도입됨

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1) 미국내 원격 모니터링 현황

Trends in utilization and spending on remote monitoring of pacemakers and implantable cardioverter–defibrillators among Medicare beneficiaries

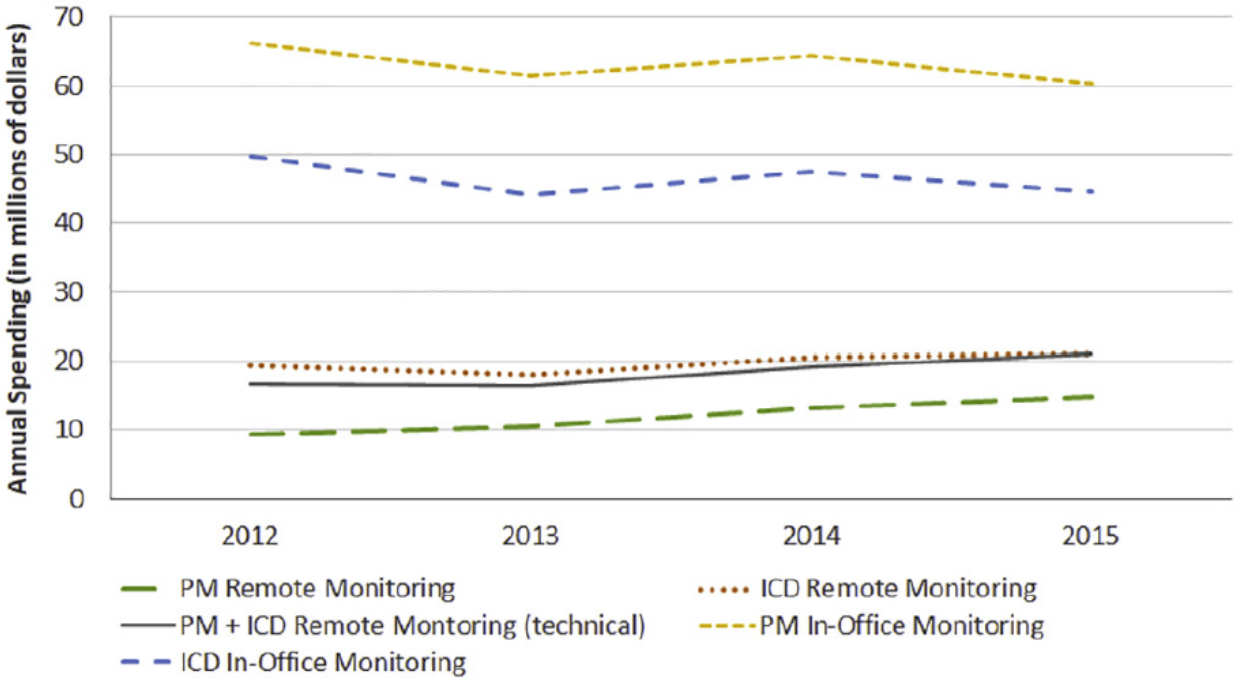

Figure 1 Trends in Medicare spending on remote and in-office interrogations of pacemakers (PMs) and implantable cardioverter–defibrillators (ICDs).

Type	2012	2015	Change
RM – IPM	414,218	668,130	+61.3%
RM - ICD	433,202	457,282	+5.6%
Office – IPM	1,816,915	1,767,547	-2.7%
Office – ICD	942,600	897,946	-4.7%

Conclusion

Remote monitoring of pacemakers and ICDs has the potential to improve patient access to care while decreasing the need for in-clinic visits and lowering health care costs. We observed increased uptake of this technology and slight re-

Holtzman, Jessica N., et al. "Trends in utilization and spending on remote monitoring of pacemakers and implantable cardioverter–defibrillators among Medicare beneficiaries." *Heart Rhythm* 17.11 (2020): 1917-1921.

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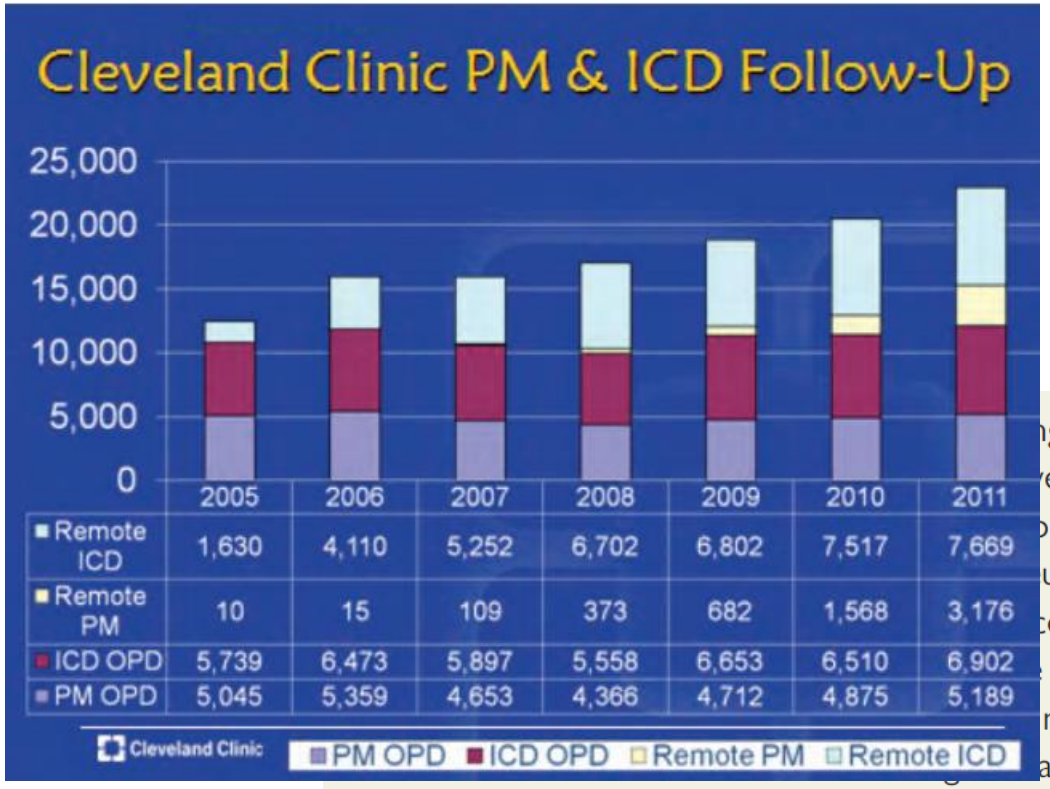
1) 미국내 원격 모니터링 현황

Cost efficiency and reimbursement of remote monitoring: a US perspective



ng increased utilization of cardiac implantable electronic devices (CIEDs) remote monitoring. In very, services rendered are valued based upon time, intensity, and technical or practice expense o contain spending, Medicare has grouped physician services into families. Spending within each utral. Cardiac implantable electronic devices monitoring services, remote and in-person, are es within this family increases, the individual encounters are destined to be discounted into of remote monitoring is demonstrated to extend beyond the previous boundaries of in- made to reconsider the relative value of remote monitoring. Outcome data supporting the apidly accumulating, including (i) patient convenience, with reduced use of office services, (ii) equal safety compared with in-person evaluation, (iii) shorter detection time to actionable events (arrhythmias, cardiovascular disease progression, and device malfunction), (iv) reduced length of stay for hospitalizations, (v) reduced inappropriate shocks, (vi) increased battery longevity, and (vii) a relative reduction in the risk of death. Fully automatic wireless technology, only recently widely implemented, will add considerable clinical efficiencies and further increase the value of remote monitoring. The U.S. challenge will be to appropriately define the relative value of CIEDs remote monitoring now that outcome data have demonstrated its value extends beyond in-person interrogation.

Slotwiner, David, and Bruce Wilkoff. "Cost efficiency and reimbursement of remote monitoring: a US perspective." *Europace* 15.suppl_1 (2013): i54-i58.

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1) 미국내 원격 모니터링 보험적용 현황

가이드라인	싱글 챔버 Pacemakers	듀얼 챔버 Pacemaker/CRT-P	ICD/CRT-D	ILR
CPT Code Guidance[1]	90일에 한번 이상			30일에 1번 이상
Heart Rhythm Society[2]	매 3-12 개월마다		매3-6개월 마다	-

- 원격 모니터링 횟수와 관련된 가이드라인은 US FDA의 허가사항을 기반한 것이 아니며, 정보 제공 차원의 권고사항임
- 의료진이 환자의 상태 및 이식된 기기의 상황에 따라 원격 모니터링의 실시주기를 결정함

1 CMS Website (https://www.cms.gov/medicare/physician-fee-schedule/search)
2 Slotwiner, David, et al. "HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices." Heart rhythm 12.7 (2015): e69-e100.

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1) 미국내 원격 모니터링 보험적용 현황

- Pacemaker의 경우 (CRT-P 포함)

구분	코드	항목	수가	비고
방문	93288	PC	$28	의사 수가
	93288	TC	$21	의사 수가
원격 모니터링	93294	PC	$31	의사 수가
	93296	TC	$25	의사 수가
-	5741	-	$36	병원수가 (방문 및 원격 모니터링에 모두 적용)

- **'방문 모니터링' 수가에 비해 '원격 모니터링' 수가 비용이 더 높음**
- **PC (Professional Component): 의료인이 실시하는 원격 모니터링 판독 및 일련의 업무에 대한 수가**
- **TC (Technical Component): 비의료인이 행하는 원격 모니터링 관련 행정업무 및 데이터 처리 등과 같은 기술적인 업무에 대한 수가**
- **원격 모니터링 시행 시 청구되는 총 수가는 $31(PC) + $25(TC) + $36(병원수가) = $92 (주마다 비용 소폭 상이)**

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1) 미국내 원격 모니터링 보험적용 현황

- ICD/CRT의 경우

구분	코드	항목	수가	비고
방문	93289	PC	$38	의사 수가
	93289	TC	$28	의사 수가
원격 모니터링	93295	PC	$39	의사 수가
	93296	TC	$25	의사 수가
-	5741	-	$36	병원수가 (방문 및 원격 모니터링에 모두 적용)

- **‘방문 모니터링’ 수가에 비해 ‘원격 모니터링’ 수가 비용이 더 높음**
- **원격 모니터링 시행 시 청구되는 총 수가는 $39(PC) + $25(TC) + $36(병원수가) = $100**

  (주마다 비용 소폭 상이)

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1) 미국내 원격 모니터링 보험적용 현황

- ILR의 경우

구분	코드	항목	수가	비고
방문	93288	PC	$19	의사 수가
	93288	TC	$24	의사 수가
원격 모니터링	93294	PC	$28	의사 수가
	93296	TC	보험사와 계약에 의해 결정	의사 수가
-	5741	-	$36	병원수가 (방문 및 원격 모니터링에 모두 적용)

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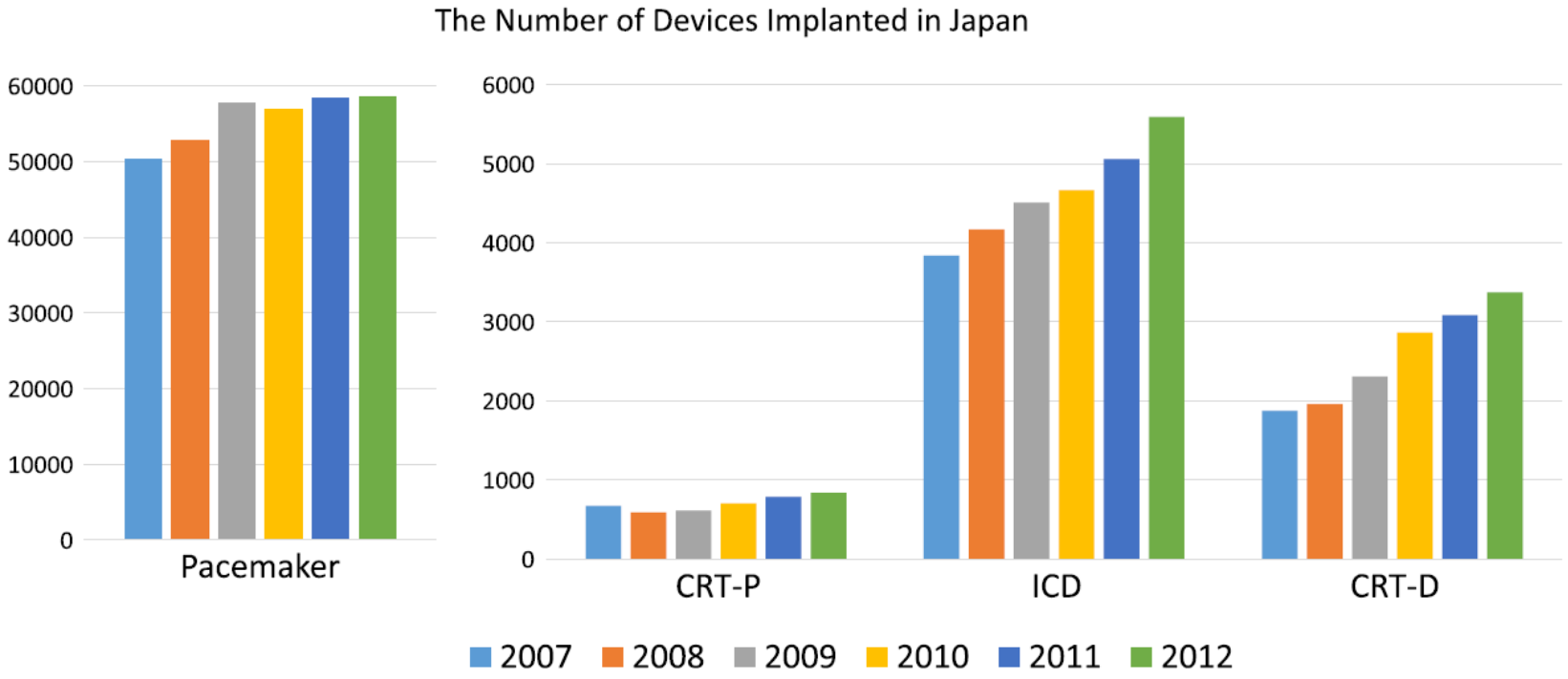
2) 일본내 원격 모니터링 현황

Remote monitoring of cardiovascular implantable electronic devices in Japan



- 2000년대 일본은 노령 인구 증가에 따라 CIED 누적 이식 환자수가 급격하게 증가하는 추세였음
- 이에 따라, 효율적인 의료자원 활용을 위한 Remote monitoring 도입 결정은 필수적 이었음

Okamura, Hideo. "Remote monitoring of cardiovascular implantable electronic devices in Japan." *Journal of Arrhythmia* 30.6 (2014): 421-427.

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2) 일본내 원격 모니터링 보험 적용 현황

厚生労働省
Ministry of Health, Labour and Welfare

12　心臓ペースメーカー指導管理料
イ　遠隔モニタリングによる場合　460点
ロ　イ以外の場合　320点
注１　体内埋込式心臓ペースメーカー等を使用している患者であって入院中の患者以外のものに対して、療養上必要な指導を行った場合に、イにあっては４月に１回に限り、ロにあっては１月に１回に限り算定する。ただし、イを算定する患者について、算定した月以外の月において、当該患者の急性増悪により必要な指導を行った場合には、１月に１回に限りロを算定する。
２　区分番号Ｋ５９７に掲げるペースメーカー移植術、区分番号Ｋ５９８に掲げる両心室ペースメーカー移植術、区分番号Ｋ５９９に掲げる埋込型除細動器移植術又は区分番号Ｋ５９９－３に掲げる両室ペーシング機能付き埋込型除細動器移植術を行った日から起算して３月以内の期間に行った場合には、導入期加算として、所定点数に140点を加算する。

- **2010년 4월 일본 후생노동성에서는 원격 모니터링에 대한 건강보험을 고시함**

Reference: Notification No. 69, 2010 of the Ministry of Health, Labor and Welfare. (http://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken12/dl/index-011.pdf)

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2) 일본내 원격 모니터링 보험 적용 현황

- 心臓ペースメーカー指導管理料(심박동기의 지도관리료)

행위 코드	항목	수가	비고
B001-12-나	• ペースメーカーの場合(**심박동기의 경우**)	• 300점 (3,000엔)	
B001-12-다	• 植込型除細動器又は両室ペーシング機能付き植込型除細動器の場合 (**이식형 제세동기 또는 양실 페이싱 기능이 있는 이식형 제세동기의 경우**)	• 520점 (5,200엔)	
주5	• 前回受診月の翌月から今回受診月の前日までの期間、遠隔モニタリングを用いて療養上必要な指導を行った場合は、遠隔モニタリング加算として、それぞれ260点又は480点に当該期間の月数（当該指導を行った月に限り、11月を限度とする。）を乗じて得た点数を、所定点数に加算する。(이전 진료월의 다음 달부터 이번 진찰월의 전날까지의 기간, 원격 모니터링을 이용하여 요양상 필요한 지도를 한 경우에는 원격 모니터링 가산으로서 각각 **260점 또는 480점에 해당 기간의 월수(해당 지도를 한 달에 한하여 11월을 한도로 한다)를 곱하여** 얻은 점수를 소정점수에 가산한다)	• Pacemaker의 경우: 260점 x 개월수 • ICD의 경우: 480점 x 개월수 • 환자가 병원을 방문한 달은 청구 불가 • 청구 가능한 최대 개월 수는 11개월로 제한	• 예) ICD 환자가 1년에 총 5번 원격 모니터링을 통한 관리를 받을 경우 수가 산정방식 • : 520점(지도관리료) + 480점 x 5번 = 2,920점 (29,200엔)

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3) 호주내 원격 모니터링 현황

2015년 9월 원격 모니터링에 대한 Medicare Benefit Schedule(MBS)를 발표함

- 호주 HTA 평가 결과 임상적 안전성·유효성 외에 비용효과성까지 입증되어 급여 결정으로 이어짐
- 보험이 적용되지 않던 FY13-14에 연간 987건 시행되던 원격 모니터링이 MBS 수가 적용 다음해에는 그 사용이 2,269건으로 증가함
- 같은 해 11월 호주 정부는 원격 모니터링용 치료재료인 트랜스미터 기기에 대한 보험 적용을 발표함

https://insightplus.mja.com.au/2017/6/remote-monitoring-of-medical-devices-in-australia/

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3) 호주내 원격 모니터링 보험 적용 현황

- Pacemaker의 경우 (CRT-P 포함)

코드	구분	MBS Code	수가	비고
Pacemaker	Review	11719	AU $ 67.9	• CRT-P 포함 • 12개월에 1번 청구 가능
Pacemaker	Test	11720	AU $ 67.9	• CRT-P 포함 • 이상반응 확인후 실시 및 청구 가능
ICD	Review	11725	AU $ 192.55	• CRT-D 포함 • 12개월에 1번 청구 가능
ICD	Test	11726	AU $ 96.25	• CRT-D 포함 • 이상반응 확인후 실시 및 청구 가능
ILR	-	11736	AU $ 36.75	• 1년에 최대 4번까지 청구 가능
Implantable ElectroCardiogram	-	11737	AU $ 36.75	• 4주당 1번 청구 가능

MBS Online (http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home)

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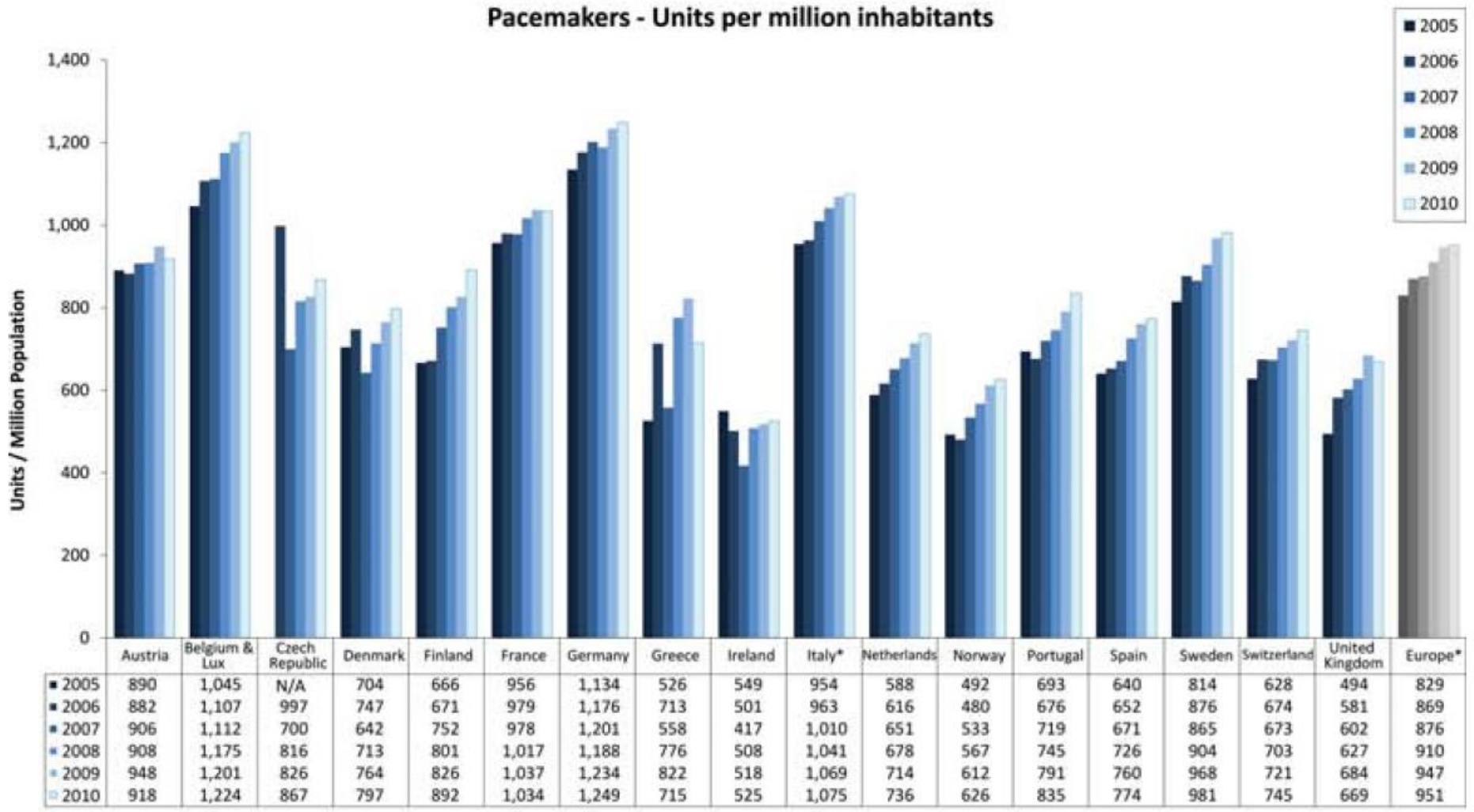
4) 유럽내 원격 모니터링 현황



	Austria	Belgium & Lux	Czech Republic	Denmark	Finland	France	Germany	Greece	Ireland	Italy*	Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom	Europe*
2005	890	1,045	N/A	704	666	956	1,134	526	549	954	588	492	693	640	814	628	494	829
2006	882	1,107	997	747	671	979	1,176	713	501	963	616	480	676	652	876	674	581	869
2007	906	1,112	700	642	752	978	1,201	558	417	1,010	651	533	719	671	865	673	602	876
2008	908	1,175	816	713	801	1,017	1,188	776	508	1,041	678	567	745	726	904	703	627	910
2009	948	1,201	826	764	826	1,037	1,234	822	518	1,069	714	612	791	760	968	721	684	947
2010	918	1,224	867	797	892	1,034	1,249	715	525	1,075	736	626	835	774	981	745	669	951

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4) 유럽내 원격 모니터링 보험 적용 현황

Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe

Table 2 Reimbursement of in-clinic and remote CIED device checks and for HF disease management in different European countries

Country	Reimbursement tariff for in-clinic device check	Reimbursement tariff for remote CIED management	Reimbursement specific for hardware and services for remote monitoring	Reimbursement tariff for HF disease management
Austria	Yes	No	No	Yes, from 2022
Belgium	Yes	No	No	No
Bulgaria	No	No	No	No
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	No	No
Finland	Yes	Yes	Yes	No
France	Yes	Yes[a]	Yes[b]	No
Germany	Yes	Yes[c]	Yes for some health insurance	No
Hungary	Yes	Yes	No	No
Italy	Yes	Yes (in 10 of 20 regional health services)	No	No
Norway	Yes	Yes	No	No
Poland	No	No	No	No
Portugal	Yes	Yes	No	Yes
Russia	No	No	No	No
Slovakia	No	No	No	No
Spain	Funded, no tariff	Funded, no tariff	N/A	No
Sweden	Yes	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	No	Yes[d]
UK	Yes	Not at a national level, it is dependent on Clinical Commissioning Groups and NHS Trusts	Ordered by NHS Trusts	No

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Boriani, Giuseppe, et al. "Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe." Europace 24.12 (2022): 1875-1880.

4) 유럽내 원격 모니터링 보험 적용 현황

	국가	행위수가	수가 산정 방법
	독일	• 원격 모니터링당 $25-65 수가 청구	• 1년에 최대 5회 산정
	스위스	• 원격 모니터링당 $130-330 수가 청구	• 1년에 최대 4회 산정
	프랑스	• 환자당 1년에 총 $150 수가 청구	• 횟수에 상관 없이 1년 총 청구 가능한 금액은 $150로 제한 (ICD 환자는 제외)
	덴마크	• 원격 모니터링당 $170 수가 청구	
	영국	• 지역별 별도 수가 협상	• NHS에서 원격 모니터링에 대한 National tariff를 결정하는 대신, 해당 병원과 지방 정부간 협상을 통해 결정함

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Expert Consensus Statement

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2015 HRS Expert Consensus Statement

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

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Heart Rhythm Society SM

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Slotwiner, David, et al. "HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices." Heart rhythm 12.7 (2015): e69-e100.

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2015 HRS Expert Consensus Statement

HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E

Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A

2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement

ESC European Society of Cardiology

Europace (2023) **25**, 1–44
https://doi.org/10.1093/europace/euad123

EHRA DOCUMENT

2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic

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Ferrick, Aileen M., et al. "2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic." Europace 25.5 (2023): euad123.

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2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement

Recommendations for RM considerations

COR	LOE	Recommendations	References
1	A	1. In patients with CIEDs, RM is recommended as part of the standard of care.	1,11,30–38
1	B-R	2. In patients with CIEDs on RM, routine surveillance of lead function and battery status is recommended to ensure device integrity.	30,39,40
1	C-EO	3. In patients with CIEDs on RM with a device capable of continuous connectivity, connectivity should be maintained.	

Recommendations for RM payment/reimbursement models

COR	LOE	Recommendations	References
1	B-NR	1. For the care of patients with CIEDs on RM, it is recommended that health care payers adopt adequate reimbursement for RM that is tailored to regional health system care patterns and facilitates sustainable and cost-effective CIED follow-up care.	35,57–60,62,66, 79–89

Recommendations for staffing requirements for RM

COR	LOE	Recommendations	References
1	B-NR	1. For the care of patients with CIEDs on RM, a team-based organizational model with formal policies, procedures, and clear definitions of the roles and responsibilities of qualified staff is recommended to optimize all related RM tasks.	1,25,28,29,53,90,102–109
1	B-NR	2. For the care of patients with CIEDs on RM, it is recommended that there is adequate dedicated time to perform all RM tasks, including scheduled and nonscheduled transmissions, patient follow-up, and administrative tasks.	25,28,57,104,106,110

Continued

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2013 Canadian Cardiovascular Society/Canadian Heart Rhythm Society Joint Position Statement

Canadian Journal of Cardiology 29 (2013) 644–651

Society Position Statement

Canadian Cardiovascular Society/Canadian Heart Rhythm Society Joint Position Statement on the Use of Remote Monitoring for Cardiovascular Implantable Electronic Device Follow-up

Primary Writing Panel: Raymond Yee, MD, (Chair),[a] Atul Verma, MD,[b] Marianne Beardsall, RN,[b] Jennifer Fraser, RN,[c] Francois Philippon, MD,[d] and Derek V. Exner, MD[e]

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Domain	Canadian Cardiovascular Society [49]	
	Recommendation	Strength
Eligibility and application of RM for patients with a CIED	Integrate RM into routine care functions of patients with CIED	Strong recommendation and moderate-quality evidence
	Routine follow-up of CIED patients (after 3 months post-implant) should include alternating RM and in-clinic in 1:1 ratio	Conditional recommendation and low-quality evidence
	RM should be used to supplement in-person monitoring in clinical circumstances warranting more intensive surveillance	Strong recommendation and low-quality evidence
Patient education	RM should only be implemented after explicit consent and proper patient education including medico-legal implications and effects on patient privacy and confidentiality	Strong recommendation and very low-quality evidence
Frequency and initiation of RM	Follow-up of patients with CIED should be done in person until 3 months post-implantation	Conditional recommendation and low-quality evidence
Role of allied healthcare professionals	Health professionals responsible for RM interpretation and subsequent patient management decisions have the same qualifications, training, and experience as those performing in-clinic assessments	Strong recommendation and low-quality evidence
RM program management	Develop infrastructure, resources, policies, and procedures to optimally support an RM program analogous to in-clinic assessment	Strong recommendation and very low-quality evidence

Yee, Raymond, et al. "Canadian Cardiovascular Society/Canadian Heart Rhythm Society joint position statement on the use of remote monitoring for cardiovascular implantable electronic device follow-up." Canadian Journal of Cardiology 29.6 (2013): 644-651.

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2012 ISHNE/EHRA Expert Consensus

Europace (2012) **14**, 278–293
doi:10.1093/europace/eur303

ISHNE/EHRA CONSENSUS PAPER

ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)

Sergio Dubner[1]*, Angelo Auricchio[2], Jonathan S. Steinberg[3], Panos Vardas[4], Peter Stone[5], Josep Brugada[6], Ryszard Piotrowicz[7], David L. Hayes[8], Paulus Kirchhof[9,10], Günter Breithardt[10], Wojciech Zareba[11], Claudio Schuger[12], Mehmet K. Aktas[11], Michal Chudzik[13], Suneet Mittal[3], and Niraj Varma[14]

Document reviewers: Carsten Israel (Germany), Luigi Padeletti (Italy), and Michele Brignole (Italy)

Benefits of remote monitoring

There are many potential benefits of remote patient monitoring (RPM) for the patient and their caregivers, the follow-up centres, the health care infrastructure, the manufacturer, and the discipline of cardiac implantable electronic device (CIEDs) management.[4]

Several recent studies [COMPAS, CONNECT, OEDIPE, PREFER, REFORM, and TRUST[10,13,39,41,48,64,65] in addition to important registry data (ALTITUDE[13])] today constitute a strong evidence base for RM. In the very early days of RM, there was

Remote monitoring provides timely detection of clinical events

Another important benefit is that RM detects clinical abnormalities that would be either completely missed by less frequent in-office visits, or detected significantly later in the absence of close to continuous RM data assessment. Clinical data demonstrate earlier detection of clinical events of up to 148 days.[10,37,41,48,61] The TRUST trial[48] reports that median time from onset to physician evaluation of combined first AF, VT, and VF events was significantly reduced from 35.5 days to only 1 day in the remote follow-up arm.

Dubner, Sergio, et al. "ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)." Europace 14.2 (2012): 278-293.

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원격 모니터링 관련 주요 임상연구

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주요 RCT 임상 연구 목록

연구명	연도	CIED	연구유형	환자수	결과(평가) 변수	결론
PREFER	2009	PM	RCT, Multicenter	897	• Mean time to first diagnosis of CAE, comparing the RM arm and the control Arm	• Mean **time to first diagnosis of CAE was shorter** in the RM Arm
COMPAS	2011	PM	RCT, multicenter	538	• MAE: hospitalization for PM-related complications, CV events, and death	• RM was safe and **reduced the number of in-office visits** • RM enabled **earlier detection of clinical and device-related adverse events**
TRUST	2010	ICD	RCT, prospective, multicenter	1,339	• Total in-hospital device evaluations • Overall adverse event rate	• RM was safe in supplanting “routine” in-office visits, **enabling early event detection** in ICD recipients
CONNECT	2011	ICD, CRT-D	RCT, prospective, multicenter	1,997	• Time from a clinical event to a clinical decision	• RM **reduced the time to a clinical decision** • RM **reduced the mean LOS**
ECOST	2012	ICD	RCT, prospective, multicenter	433	• Incidence of MAE (all- cause and CV death)	• RM **was as safe as standard FU** • RM **reduces appropriate and inappropriate shocks**
EVOLVO	2012	ICD, CRT-D	RCT, prospective, multicenter	200	• Rate of the emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events	• RM **reduced the number of emergency department or urgent in-office visits** and health care use • RM **increased the efficiency of health care**
REFORM	2013	ICD	RCT, parallel	155	• Scheduled and unscheduled ICD visits • Difference in quality-of-life scores at baseline and after 27 mo	• RM safely **reduces the ICD FU burden** for 27 mo after implantation • Favorable impact of RM on the **quality of life**
IN-TIME	2014	ICD, CRT-D	RCT, parallel.	716	• Primary outcome measure was a composite clinical score combining all- cause mortality, overnight hospital admission for heart failure, change in NYHA class, and change in patient global self- assessment	• Patients on HM **had lower mortality**

Slotwiner, David, et al. "HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices." Heart rhythm 12.7 (2015): e69-e100.

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RCT 문헌 9건으로 수행된 체계적문헌고찰

Remote Monitoring of Implantable Cardioverter-Defibrillators

A Systematic Review and Meta-Analysis of Clinical Outcomes

Nirmalatiban Parthiban,*† Adrian Esterman, PhD,‡ Rajiv Mahajan, MD, PhD,* Darragh J. Twomey, MBBS,* Rajeev K. Pathak, MBBS,* Dennis H. Lau, MBBS, PhD,* Kurt C. Roberts-Thomson, MBBS, PhD,* Glenn D. Young, MBBS,* Prashanthan Sanders, MBBS, PhD,* Anand N. Ganesan, MBBS PhD*

ABSTRACT

BACKGROUND Remote monitoring (RM) of implantable cardioverter-defibrillators (ICD) is an established technology integrated into clinical practice. One recent randomized controlled trial (RCT) and several large device database studies have demonstrated a powerful survival advantage for ICD patients undergoing RM compared with those receiving conventional in-office (IO) follow-up.

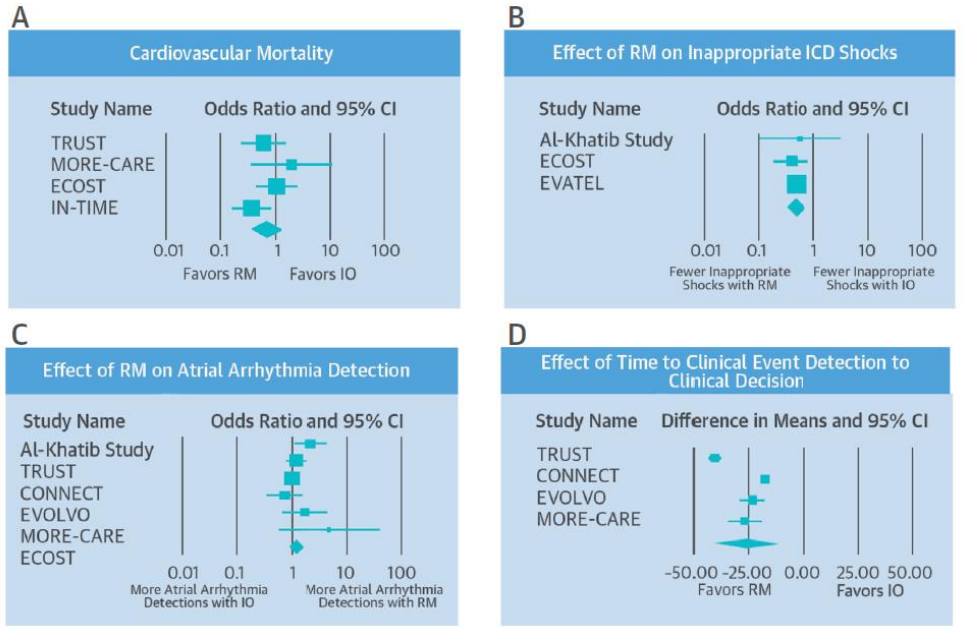
OBJECTIVES This study sought to conduct a systematic published data review and meta-analysis of RCTs comparing RM with IO follow-up.

METHODS Electronic databases and reference lists were searched for RCTs reporting clinical outcomes in ICD patients who did or did not undergo RM. Data were extracted from 9 RCTs, including 6,469 patients, 3,496 of whom were randomized to RM and 2,973 to IO follow-up.

RESULTS In the RCT setting, RM demonstrated clinical outcomes comparable with office follow-up in terms of all-cause mortality (odds ratio [OR]: 0.83; p = 0.285), cardiovascular mortality (OR: 0.66; p = 0.103), and hospitalization (OR: 0.83; p = 0.196). However, a reduction in all-cause mortality was noted in the 3 trials using home monitoring (OR: 0.65; p = 0.021) with daily verification of transmission. Although the odds of receiving any ICD shock were similar in RM and IO patients (OR: 1.05; p = 0.86), the odds of inappropriate shock were reduced in RM patients (OR: 0.55; p = 0.002).

CONCLUSIONS Meta-analysis of RCTs demonstrates that RM and IO follow-up showed comparable overall outcomes related to patient safety and survival, with a potential survival benefit in RCTs using daily transmission verification. RM benefits include more rapid clinical event detection and a reduction in inappropriate shocks. (J Am Coll Cardiol 2015;65:2591-600) © 2015 by the American College of Cardiology Foundation.

CENTRAL ILLUSTRATION Effect of RM on Patient Safety and Survival



Parthiban, Nirmalatiban, et al. "Remote monitoring of implantable cardioverter-defibrillators: a systematic review and meta-analysis of clinical outcomes." Journal of the American College of Cardiology 65.24 (2015): 2591-2600.

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주요 레지스트리/코호트 연구 목록

연구명	연도	CIED	연구유형	환자수	결과(평가) 변수	결론
AWARE	2007	PM, ICD, CRT	Retrospective analysis	11,624	• Time to detection of events and impact on physician workload, comparing the RM arm vs the standard care arm	• RM **improved safety and optimized the allocation of health resources**.
ALTITUDE	2010	ICD, CRT-D	Non-randomized network patients	185,778	• Patient survival	• RM **improves survival**
MERLIN	2015	PM, ICD, CRT	Non-randomized network patients	269,471	• Survival according to the level of adherence to RM and device type	• RM-mediated **survival is dose dependent on the degree of adherence** but not on CIED complexity

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주요 비용-효과 연구 목록

연구명	연도	CIED	연구유형	비용분석 결과	결론
ECOST	2014	ICD	비용-효과	• Non-hospital costs: - RM: €1,695 ± 1,131 - Conventional: €1,952±1,023 • Hospital costs: - RM: €2829 6382 - Conventional: €3549 9714 p = .46 • Savings were increased to €494 by adding the ICD to non-hospital costs or to €315 per patient per year by adding the monitoring system	• **RM reduced mean nonhospital** costs per patient per year
EVOLVO	2013	ICD, CRT-D	비용-효과	• Costs: €1962 vs €2130 p = 0.8 • Costs for patients: €291 vs €381 po0.01 • Cost utility: patients in the RM arm had a cost saving of €888 per patient and gained 0.065QALYs more over16months	• **Significant reduction in the annual cost for patients and gained QALYs** in the RM arm
EFFECT	2017	ICD, CRT-D	비용-효과	• The rate of hospitalizations was 0.27/year in the SM group and 0.16/year in the RM group (risk reduction =0.59; P = 0.0004). • Annual cost for each patient was 817 in the SM group and 604 in the RM group (P = 0.014).	• **Reduction in direct healthcare costs** of RM for HF patients with ICDs, particularly CRT-D, compared with standard monitoring.
PREDICT RM	2019	ICD	비용-효과	• RM was associated with reduced mortality; average life expectancy and average quality-adjusted life years increased by 0.77 years and 0.64 • RM patients experienced an average of 0.64 additional subsequent rehospitalizations with increased average lifetime hospitalization costs of $2784 • Base-case **incremental cost-effectiveness ratio was $10,752 per quality-adjusted life year**	• Remote monitoring is a **cost-effective approach for the lifetime management** of patients with ICDs
***Burri* et al.**	2013	CIED	비용-효과	• Over 10 years, HM is predicted to be cost neutral at about GBP 11 500 per patient in either treatment arm, with all costs for the initial investment into HM and fees for ongoing remote monitoring included. Fewer inappropriate shocks (251%) reduce the need for replacing devices for battery exhaustion (27%); the number of FU visits is predicted to be halved by HM	• HM is **cost neutral over 10 years**. This is mainly accomplished by reducing the number of battery charges and inappropriate shocks, resulting in fewer device replacements, and by reducing the number of in-clinic FU visits.

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비용 분석 연구 사례

Europace (2013) **15**, 1601–1608
doi:10.1093/europace/eut070

CLINICAL RESEARCH
Sudden death and ICDs

Cost–consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK

Haran Burri[1*†], Christian Sticherling[2†], David Wright[3], Koji Makino[4], Antje Smala[5], and Dominic Tilden[4]

Aims The need for ongoing and lifelong follow-up (FU) of patients with cardiac implantable electric devices (CIED) requires significant resources. Remote CIED management has been established as a safe alternative to conventional periodical in-office FU (CFU). An economic model compares the long-term cost and consequences of using daily Home Monitoring® (HM) instead of CFU.

Methods and results A cost–consequence evaluation comparing HM vs. CFU was performed using a Markov cohort model and data relating to events and costs identified via a systematic review of the literature. The model is conservative, without assuming a reduction of cardiovascular events by HM such as decompensated heart failure or mortality, or considering cost savings such as for transportation. Also cost savings due to an improved timing of elective device replacement, and fewer FU visits needed in patients near device replacement are not considered. Over 10 years, HM is predicted to be cost neutral at about GBP 11 500 per patient in either treatment arm, with all costs for the initial investment into HM and fees for ongoing remote monitoring included. Fewer inappropriate shocks (−51%) reduce the need for replacing devices for battery exhaustion (−7%); the number of FU visits is predicted to be halved by HM.

Conclusion From a UK National Health Service perspective, HM is cost neutral over 10 years. This is mainly accomplished by reducing the number of battery charges and inappropriate shocks, resulting in fewer device replacements, and by reducing the number of in-clinic FU visits.

Table 3 Costs results

	Cost per patient over 10 years (GBP)		
	Undiscounted		
	HM	CFU	Difference (%)
Costs			
Total	13 608	13 660	−52 (−0.4)
Device and patient management	10 091	10 143	−52 (−0.5)
CV events	3517	3517	–

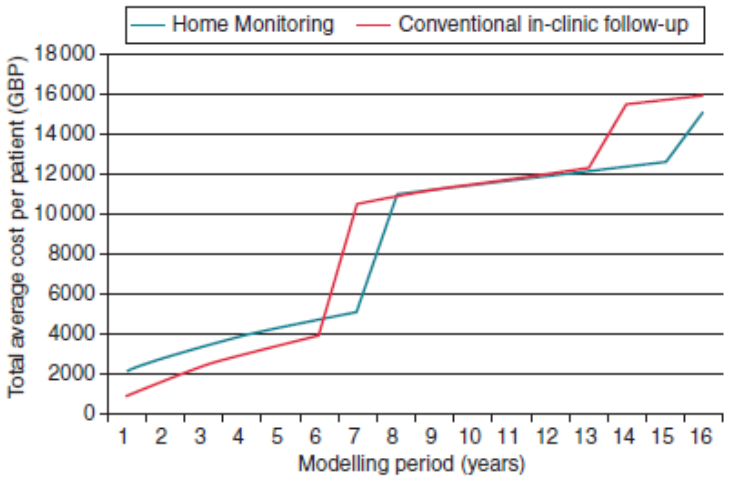

Figure 3 Univariate sensitivity analysis for modelling period: Discounted total costs per patient on HM vs. conventional in-clinic FU.

결어

CIED 환자에 대한 표준적 치료법

외국에서 CIED 환자에게 원격 모니터링 사용을 통한 예후관찰은 이미 **표준적 치료법**으로 그 활용이 강력히 권고되고 있음

근거 중심 의사결정

원격 모니터링을 활용한 예후관찰의 임상 도입은 다수의 임상적 안전성, 유효성 및 비용효과성에 대한 **임상 근거 및 체계적 문헌고찰**을 통한 결과임

원격 모니터링 특화 의료기기

CIED 환자에 대한 원격 모니터링은 단순 전화 및 화상통신이 아닌 각 CIED 제조사 별로 제공되는 **전용 데이터 전송기기 또는 앱을 통해서만 구현 가능**한 의료기술임

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