Remote Management of Pacemaker Patients with Biennial In-Clinic Evaluation: Continuous Home Monitoring in the Japanese at Home Study – A Randomized Clinical Trial

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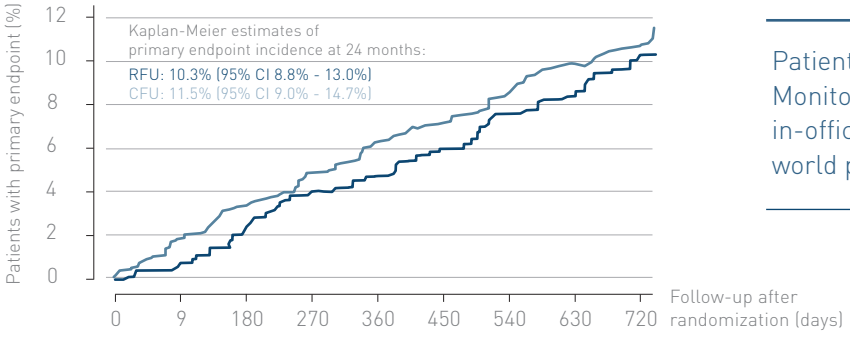
Study Design

- Large, prospective, randomized, controlled, multicenter study
- 1274 consecutive pacemaker patients at 85 centers in Japan
- BIOTRONIK Evia devices with Home Monitoring (HM)
- 1:1 randomization to HM + remote follow-up or HM + in-office follow-up
- Regular biannual follow-ups in both arms, unscheduled additional in-office follow-ups, if needed
- 24 months follow-up duration*
- To study safety and resource consumption of exclusive remote follow-up in pacemaker patients for a prolonged period of two years without scheduled in-office follow-ups in between

Main Result

The at Home study demonstrated the non-inferiority of exclusive remote follow-up over 2 years in comparison to continuous remote monitoring associated with in-office follow-ups for real-world pacemaker patients*.



Patients at risk

• RFU:	636	624	608	594	587	575	549	513	403
• CFU:	638	618	600	579	564	548	525	495	374

Cumulative percentage of pacemaker patients suffering from a composite of death, stroke or cardiovascular surgery
RFU: Home Monitoring only; CFU: Home Monitoring plus in-office follow-ups (control)

Patient surveillance purely based on Home Monitoring for 24 months (no scheduled in-office visits in between) was safe for real-world pacemaker patients*.

*Remote only follow-up for 24 months is not yet approved by product labeling and at this point cannot be recommended by BIOTRONIK.

Clinical Relevance

- The at Home study is the largest randomized trial to investigate pacemaker patient follow-up exclusively with Home Monitoring for 2 years.
- The main concern about extending the time between in-office follow-ups was that safety could be compromised. The at Home results indicate that surveillance of a real-world pacemaker patient population exclusively based on Home Monitoring for 2 years is safe.
- Follow-up of cardiac implantable electronic devices is the most frequent activity reported by cardiac electrophysiologists. By exclusively using Home Monitoring, the proportion of in-office follow-ups can be significantly reduced for pacemaker patients, thus significantly reducing the resource consumption related to management of pacemaker patients.

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Exclusive Home Monitoring–Based Follow-Up of Pacemaker Patients for Two Years Reduces the Need for Clinical Visits and Helps Save Follow-Up Related Cost

Significant Reduction of In-Office Follow-Ups

	Home Monitoring only	Home Monitoring + in-office follow-ups	Reduction (n (%))
Total follow-up duration [patient-years]	1324	1296	
Total follow-ups [n (ppy)]	2448 (1.85)	2275 (1.76)	
Total remote follow-ups [n]	1738	0	
Regular in-office follow-ups [n]	509*	2172	
Additional in-office follow-ups** [n]	201	103	
Total in-office follow-ups [n (ppy)]	**710 (0.54)**	**2275 (1.76)**	**1565 (69%)**
Median in-office follow-ups per patient/year [n; (IQR)]	**0.50 (0.50-0.63)**	**2.01 (1.93-2.05)**	**1.51 P<0.0001**

69% Less In-Office Visits
Exclusive Home Monitoring for 2 years significantly reduced in-office follow-ups by 69% for pacemaker patients*

Remote and in-office follow-ups in the Home Monitoring only group versus control after 24 months.
* Mandatory in-office follow-ups at the end of the study according to the study protocol.
** Additional unscheduled visits needed due to patients and/or physician request or due to alerts notified by HM.

Significant Reduction of Follow-up Related Cost

	Home Monitoring only	Home Monitoring + in-office follow-ups	Cost Reduction ($ (%))
Patients [n]	635	634	
Individual insurance claims per patient-year [Yen(= $)]			
Cost for follow-up [Median (IQR)]	15,500 (14,700 - 16,600)	15,200 (13,700 - 15,800)	
Cost for related diagnostics [Median (IQR)]	3,100 (1,300 - 4,200)	7,000 (2,500 - 10,400)	
Total cost for follow-up and related diagnostics [Median (IQR)]	18,800 (16,500 - 20,700)	21,400 (16,700 - 25,900)	**2,600 (12%) P<0.0001**

12% Less Cost
Exclusive Home Monitoring for 2 years significantly reduced cost for follow-up by 12% for pacemaker patients*

Comparison of follow-up cost in the Home Monitoring only group versus control.
The analysis represents a conservative estimate as it concentrated on payer costs only and did not account for nursing and physician time, which was considerably reduced with remote management and patient costs (entailing time away from work, travel time, etc.).

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Source: Watanabe E et al. Remote management of pacemaker patients with biennial In-clinic evaluation: Continuous Home Monitoring in the Japanese at Home study. A randomized clinical trial Circulation. Arrhythmia and electrophysiology, 10.1161/CIRCEP.119.007734. 28 Apr. 2020, doi:10.1161/CIRCEP.119.007734

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