A Prospective Multicenter Comparison Trial of Home Monitoring against Regular Follow-up in MADIT II Patients: Additional Visits and Cost Impact

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Abstract

The number of patients with primary prophylactic ICD implantation rises. Resources for a regular ICD follow-up every 3 months are not available. The REFORM Study investigated in a prospective, randomized and multicenter comparison study the effect of ICD Home Monitoring (HM) against conventional follow-up (FU) in MADIT II patients: A special focus was on different resource use and resulting costs in the two different arms. For cost measurements a model from Leipzig Graduate School of Management (HHL) was used and process times and resulting costs for human resources and equipment was calculated for the study for 115 patients. The study revealed no significant difference in hospitalisations and mortality, whilst potential cost savings and reduction of patient visits at higher effectiveness was highly significant: For a group of 100 patients a sum of 81 physician hours and 71.231 € costs could have been saved p. a. by HM in the hospital.

1. Introduction

As a consequence of landmark trials like MADIT II the number of patients with primary prophylactic ICD implantation rises. ICD implantation numbers in the U.S. rose from 3.000 in the year 2001 to 104.000 in the year 2005 [1]. Physicians struggle to provide the resources for a regular ICD follow-up every 3 months. Additionally it is known, that patients with primary prophylactic ICD implantation have a lower number of therapy episodes – lowering the need of a close meshed in-office follow-up. The technology of Home Monitoring (HM) allows remote follow ups (FUs) of the ICDs over the Internet and has the potential to replace part of the in-office follow ups (see figure 1) at the same level of patient security [2].

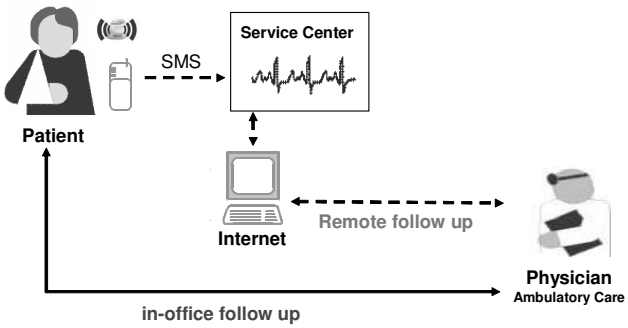

Figure 1. Illustration of the Home Monitoring Process

This potentially saves physician and patient time, lowers cost for equipment and transportation taxes and sets resources free. On the other side, the technology may also generate more efforts over additional patient visits and the additional event monitoring of the patients. To get objective data specially on the economic question of resource utilisation and overall patient visits, a part of the REFORM Trial investigated in a prospective, randomized and multicenter comparison trial the economic effect of ICD Home Monitoring (HM) against conventional follow-up in MADIT II patients. Other questions were the security of the treatment, proper function of the information transfer and the impact of the reduced patient-doctor interactions [3].

For the cost measurements a cost model from Leipzig Graduate School of Management (HHL) was used [4].

2. Methods

115 patients (86% male, 14% female; 62 +/- 8 years) with CHD, EF<30% and after MI (>1 month) received a primary prophylactic ICD implantation (110 one-chamber systems, 5 two chamber systems) with HM function. 3 months after implantation patients were randomized in two groups: 12M = "HM and just a single follow-up per year", 3M = "normal 3 month cycle for in-office follow-up and HM" (trial design see figure 2). HM was used in both groups and the reason for additional visits was tracked over the CRF. Additionally the CRFs tracked selected procedure times (see table 1). Primary endpoint was the number of unplanned visits, secondary endpoints were total costs in follow-up vs. HM, Quality of Life (SF-36) and overall mortality. For the calculation of costs in the different arms an economic model was used in combination with costs, process times and process rates from the trial and different data sources (see table 1 and figure 3). For each FU (HM or in-office) the resulting costs were derived from the process steps in the participating centers. Euro symbols in figure 2 tag the points, where costs were derived. Figure 3 graphs the single steps taken into account. Only for the 12M-group also the efforts for the continuous process of additional event monitoring were calculated.

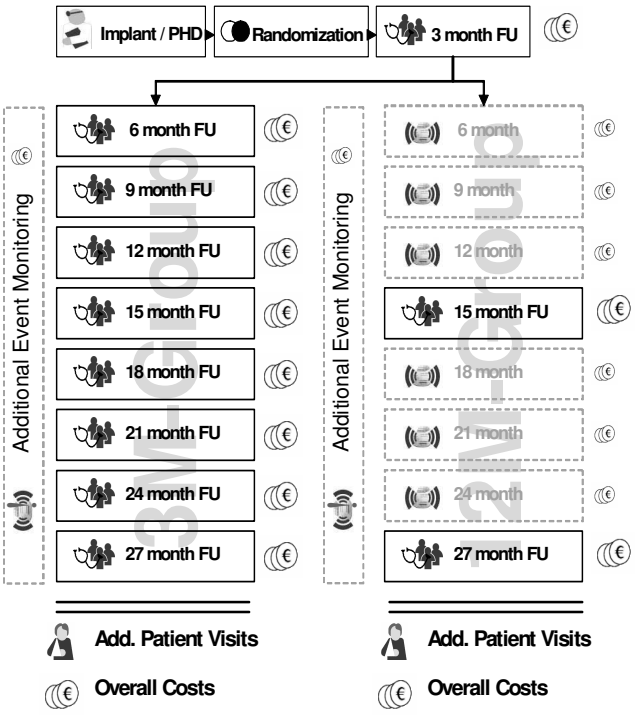

Figure 2. Basic design of the REFORM trial with special focus on cost and resource utilisation. In the study protocol the HM FUs were optional. For the economic model the HM FUs were calculated in every case.

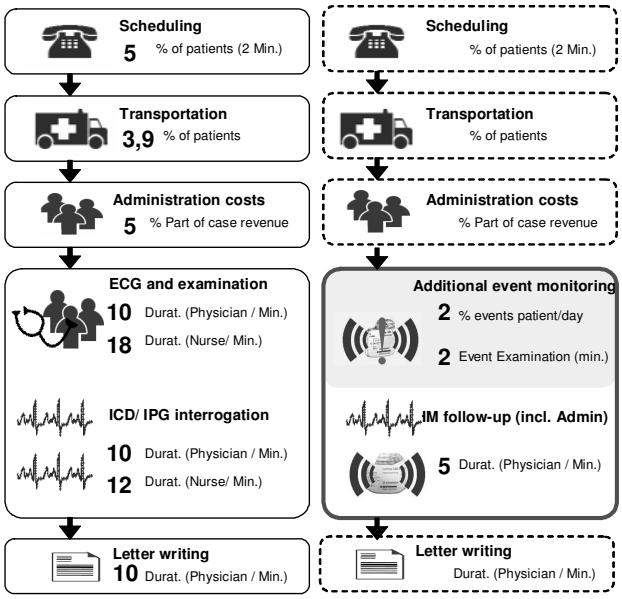

Figure 3. Single steps with process times and rates taken into account in the economic model for the participating centers. Left: in-office, right: HM. The grey area shows the additional and continuous process of event monitoring, dotted lines show eliminated process steps.

Table 1. Values used and corresponding sources

Name	Source	Values
Process times in-office FU	REFORM CRFs and HHL Database [5]	See figure 3
Process times HM FU	Clinical Benchmarks and HHL Database [5]	See figure 3
Revenues per average Case in the centers	German INEK Database [6], DRG Catalogue [7]	4.000 € per case
Average Cost Administration Overhead	German INEK Database [6], Calculation of additional fees	5% of Revenues
Cost for Infrastructure	German INEK Database [6], Common Price Lists [7]	20.000 € p.a.
Cost for Workforce	German INEK Database [6], Common Salary Lists [7]	60 €/h (Doctors) 25 €/h (others)
Transportation taxes and quote	Common Catalogue for Patient Transportation [8] and CRFs	65€ one way 3,9% of pts.
Patient time and costs for transportation	REFORM CRFs and common tax deductibles catalogue [9]	20€ one way

3. Results

The mean observation time was 117 days (23-513 days). The LV-EF was at 24+/-6%, NYHA spread NYHA I = 3%; NYHA II = 50%; NYHA III = 47%; NYHA IV = 0% over the population. The study revealed no significant dif-ference in hospitalisations and mortality of the patients. After the 3M FU the additional FUs were categorized: 15,7% of the overall visits in the 12M group were HM induced, in the 3M group only 0,75% of the additional visits were HM induced. Patient-induced visits accounted in the 12M group for 31,6% additional visits and in the 3M group for 1,5% (see figure 4). The effectiveness of the visits was shifted from 36% high or medium necessity in the 3M group to 47% high or medium necessity. Over 80% of the HM-induced visits had a "high" necessity evaluation and all were classified high or medium.

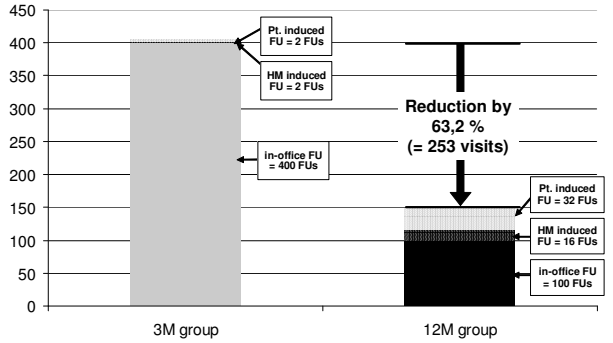

Figure 4. Overall Patient visits (n = 115 Patients, observation time 117 days mean): Interpolation for 1 year and 100 patients in each arm. Black / Grey area = protocol-initiated visits, cross-hedged area = HM-initiated visits, Dotted area = patient-initiated visits. Definition of "HM induced in 3M group": FU visit was scheduled at least 4 weeks earlier than regular because of HM event

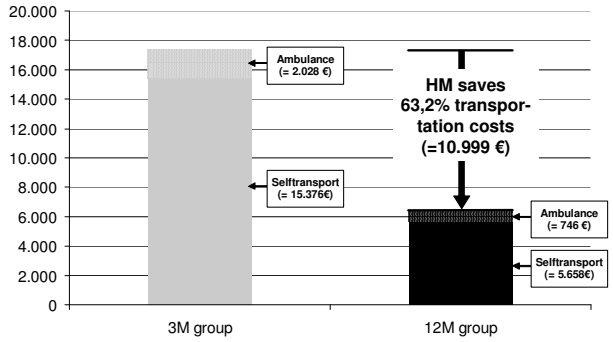

Figure 5. Transportation Costs (n = 115 Patients, obser-vation time 117 days mean). Cross-hedged areas = ambulance transportation, normal areas = self-transport. Interpolated for 1 year for 100 patients in each arm.

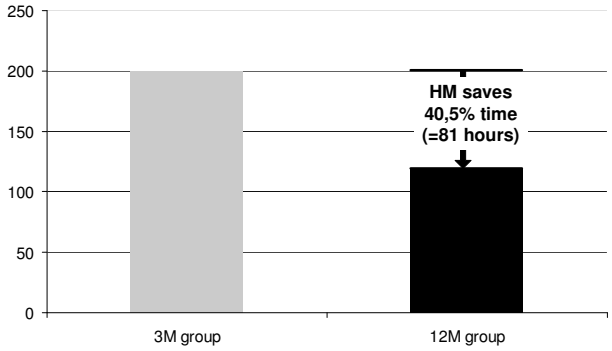

Figure 6. Physician Time with n = 115 Patients over an observation time of 117 days (mean). Numbers interpolated from mean observation time for 1 year, arms normalized to 100 patients each.

Additionally an average of 109,99 € transportation costs could have been saved per patient and year (see Figure 5). These costs split 11,6% on ambulance transportation costs and 88,4% on travel-expenses for patients (calculated according to common tax deductible catalogue [9]). Approximately 50 minutes of physician time could be saved per patient and year in the 3M group against the 12M group (see Figure 6).

Under the assumption, that savings derived immediately due to resource reallocation or reduction the overall savings per patient and year could have been at 712,31 € for the hospital in the 12M group against the 3M group (see Figure 7).

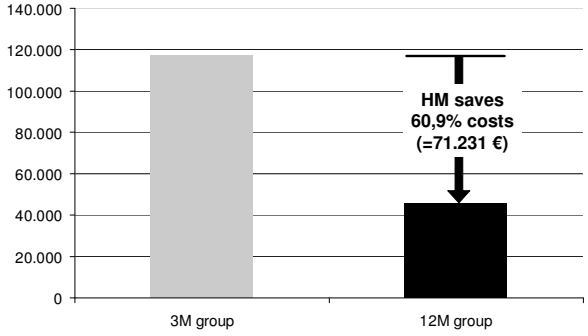

Figure 7. Hospital Costs with n = 115 Patients over an observation time of 117 days (mean). Numbers interpolated from mean observation time for 1 year, arms normalized to 100 patients each.

Without administration costs (in the model 5% of average patient revenue and cost for scheduling) the cost-savings spread with 54% for facilities utilisation, 32,5% for physicians work and 13,5% for nursing.

4. Discussion and conclusions

The REFORM trial preliminary results with n = 115 Patients over a mean observation time of 117 days prove, that the simplified ICD follow-up scheme with additional HM in MADIT II patients can reduce the number of visits significantly by 63,2% - reflecting a reduction by 75% through protocol-related effects and an increase of 3,9% through HM-induced effects and 7,9% through patient-initiated visits.

Under the assumption, that savings derived immediately due to resource reallocation or reduction for a hospital the savings per patient and year were at 712,31€ in the 12M group against the 3M group. Overall HM could have saved 81 hours physician working time with 100 patients over 1 year. How much of these effects can be realized in a hospital may depend on the individual configuration: How intensively are resources used and how effective is the reallocation?

For the "real" realization of the savings one may overall argue, that the probability for a short term realization in an average clinic may be quite low with 10 – 30% as a short term reallocation of resources is difficult to realize. But a long-term effect with e.g. avoided new facilities and other new resources may realize up to 100% of the savings for every new patient starting with the HM therapy regime.

Having a look at the patients´ hospitalisations and mortality [3], no significant difference can be seen between the arms. The overall results can therefore be interpreted as a preliminary proof of a high cost-effectiveness of HM at equal or even higher quality of care in the REFORM setting. Slight proof of this mentioned higher effectiveness and quality of the FUs can be interpreted from the shift in the "evaluation of necessity" by the physician: All HM-induced FUs were highly effective. As all HM FUs were calculated in the economic model – but not necessarily done by the physician – and the quotes for the additional visits in the 12M group are interpolated from a very early observation period, overall effects may be underestimated at this point of time, as it is known, that most HM-induced FUs occur in the early follow-up period.

Newer data from the REFORM Trial supports this argumentation and proves that savings may be even higher, as additional visits are significantly reduced over time. Additionally an even lower necessity for HM FUs can be assumed, as patients´ safety is increased by the additional event monitoring.

References

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[9] Reference in http://www.wikipedia.de for „mileage allowance = Entfernungspauschale" according to German tax deductible catalogue

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