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SPECIAL ARTICLE

Remote care: bidding our ICD patients a fond farewell?

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Abstract Remote follow-up has proven its safety and efficacy in the literature, and indeed in daily use. It saves the patient time and travel, allows earlier detection of events, and reduces inappropriate shocks. At the same time, it is not infallible and definitely not a universal substitute for in-office visits, as the 5 cases below demonstrate. It saves time, but also takes some time, with problems and challenges we were hitherto not familiar with. Hopes for the future include uniform definitions regarding policy and responsibilities, reimbursement, even better connectivity, better alert management and remote programmability. To end on a more utopic note, it would be a huge step forward if devices and leads were so reliable that we did not need remote care to detect malfunctions.

Keywords Remote care · ICD

If you have ever suffered from insomnia, had jetlag or stayed at a hotel in the US, late night shopping channels hold no secrets for you. You'll recognise the feeling as you watch exotic products scroll by, that these are all solutions desperately waiting for a problem. Slicing and dicing devices for coaxing vegetables into shapes they were never meant to have, exercise machines for muscle groups you never knew you had and therefore probably don't, and macabre trimming implements for hair you may be glad to have in the first place. Is remote follow-up of implantable devices just another example of "sellevision"? Having been around for 10 years, with feature after feature eagerly marketed by manufacturers but no randomised controlled trials as to its usefulness until very, very recently (and then only few), you might ask yourself: where is the problem that goes with this solution? Do I really need this? To take it even further, if remote care is designed to keep your patients away from your office, why did you spend all those years in med school and go to the trouble of refining your bedside manner?

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What's the point of remote follow-up, and when (not) to use it?

From the patient's viewpoint, the biggest advantage of remote care is that it saves travel time and expense. Even in a small country like the Netherlands, the distance to an ICD centre, or travel time given traffic conditions on major motorways, can be significant. In the South West, for example, patients travelling from parts of Zealand to our clinic in Breda are faced with a 210 km round trip taking them at least 2.5 h (without rush-hour traffic), and that is assuming they have their own transportation. Public transport sometimes means that the patient and accompanying family members spend the better part of the day coming and going for a 30-min appointment. The time, inconvenience (particularly for the employed) and expense can obviously be prohibitive, and remote follow-up a solution. The down side is that there is no physical contact or examination, while these are often patients with significant (co)morbidities which may hence go undiagnosed. A large proportion of patients (many tens of percents) actually decline remote care because they feel they would miss the one-on-one contact with the technician and cardiologist – so we must be doing something right. An additional advantage of remote follow-up from the clinic's viewpoint is a logistic one. With steadily

increasing numbers of patients and ICD follow-up visits, outpatient clinics can become clogged and overbooked. In Breda, the number of ICD follow-ups has risen from approximately 400 per quarter in 2007 to 1100 per quarter in 2011. Substitution of a portion of the live follow-ups for remote may alleviate the problem. Before addressing the issue of the evidence base for remote care, the matter of substitution of visits begs the question when not to do it and stick to live follow-up.

Brugada et al. published an interesting paper on this topic a number of years ago [1]. A total 271 patients with an ICD were followed for 12 months with routine follow-up at 3-monthly intervals. The physician reviewed remote follow-up data prior to the office visit, and gave a forecast as to whether or not that live visit could in fact be skipped. There was a 67% negative predictive value, 15% false positives at 3 months and 8% at 12 months. The bottom line: 503 of 1079, so nearly half of the routine office visits, could safely have been skipped and substituted with a remote follow-up. Secondly, a number of circumstances were identified when not to skip a live follow-up: a. never skip the first follow-up after implant, b. never skip a follow-up if the patient has previously demonstrated pacing threshold problems, c. always follow-up live after a hospital admission, d. perform live follow-up following episode detection, and e. follow-up live if the patient reports symptoms. This still seems to be a safe and sensible approach.

What is the evidence base (RCTs)?

Strangely, the first randomised controlled trial on remote follow-up for ICDs was not published until nearly 10 years after introduction of the technology. The TRUST study [2], published in 2010, describes 1339 patients with a Biotronik ICD, randomised 2:1 to home or live monitoring with a 15-month follow-up. The primary endpoint was the number of in-office visits, and a composite safety endpoint (including death, stroke and ICD-related events requiring surgical intervention); secondary endpoint was time of onset till evaluation of VF, VT and AF, and the number of patient-initiated alerts that required admission or ER assessment. The number of in-office visits was significantly lower in the remote group, 2 vs 3.5 ($p<0.001$; RR 43%). These numbers would seem to suggest that even with remote care, these patients have such morbidity that they require live medical attention several times a year. The safety endpoint did not differ significantly. The number of days earlier that VF, VT and AF were detected was 25, 34 and 26 days, respectively, allowing for faster appropriate action in the given circumstances. Finally, 88% of alerts could be dealt with at a distance; of the remaining 12% only 52% were actionable. The CONNECT study [3] is quite similar both in design and results. It describes 1997 ICD patients randomised 1:1 to either Medtronic Carelink or in-office follow-up, also with 15 months of follow-up. The primary endpoint was time to clinical decision/intervention, the secondary endpoint a composite of health care utilisation. As was the case for TRUST, CONNECT demonstrated a significant reduction in time to action from 22 to 4.6 days ($p<0.001$), 70%< 1.5 days. There was also a reduction in the number of in-office visits from 6.3 to 3.9, and a reduction in admission duration from 4 to 3.3 days ($p=0.002$). Rounding up the very short list are two abstracts presented at the 2011 ESC meeting in Paris: ECOST, by Kacet and co-workers, and EVATEL, by Mabo et al. Both studies address safety and efficacy of remote follow-up, with special attention to reduction of inappropriate shocks. ECOST demonstrated a lower incidence of inappropriate shocks in the remote group, 5% vs. 10.4% ($p=0.03$), and hospital admissions from 11% to 3% ($p=0.02$). EVATEL showed similar numbers, with 4.7% vs. 7.5% inappropriate shocks for the remote and live groups respectively ($p=0.0325$). As an interesting aside in this multicentre French study, there was only a 0.04% crossover from remote to live due to connectivity problems. Our own experience with regional telecom providers in the South West Netherlands is unfortunately substantially worse, with significant teething problems while we were starting up our remote care facilities in 2008. Our technicians enjoyed many a cup of coffee and even breakfast while trying to get a patient online in some remote rural area, crawling around on the bedroom floor looking for a phone jack. Still, these time-consuming house calls did rather defeat the idea of remote follow-up. In summary, the available evidence shows that remote follow-up is non-inferior to live (with certain caveats mentioned above), that it clearly reduces the number of in-office visits, and reduces detection time of arrhythmias and the number of inappropriate shocks.

Remote follow-up: panacea or band-aid?

Having discussed the evidence base, let's get practical. The non-believer might well say, "who needs remote features like lead integrity alert if manufacturers would just get with the programme and make better products?" Probably true, but not very likely. Device and particularly lead malfunctions are a fact of life, whether we like it or not. What would really be ideal is that all alerts in our remote care system are appropriate, timely, and actionable. Again, probably true, but no such luck. The following 5 recent examples from our own centre serve as a brief demonstration of life with remote follow-up.

Case 1. This patient was admitted due to a lead integrity alert (Fig. 1). The Sprint Fidelis lead was replaced,

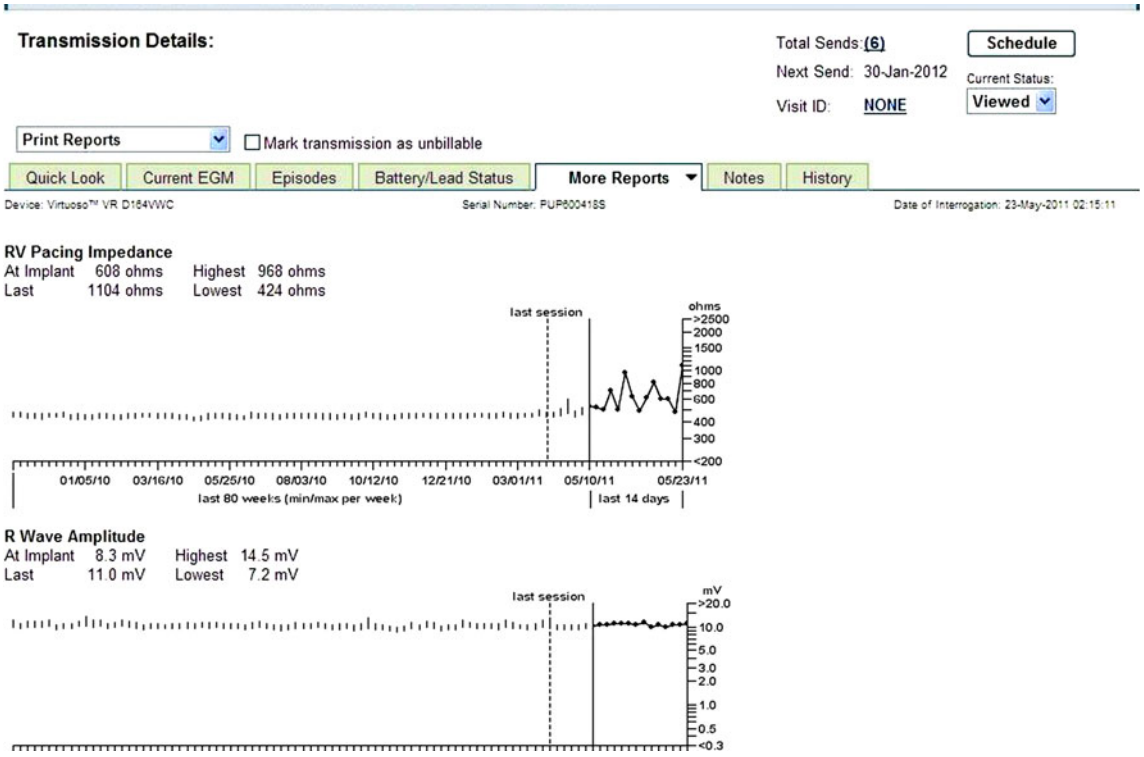

Fig. 1 A lead integrity alert was transmitted due to sudden fluctuations in impedance, caused by impending lead fracture

and the patient escaped inappropriate shocks. This is obviously remote follow-up at its best.

Case 2. This patient was not as lucky – he was admitted to our clinic in February following 3 inappropriate shocks. There had been no previous alert, despite a sudden change in both amplitude of the ventricular electrogram and impedance a month earlier (Fig. 2). This only became apparent on device interrogation, due to the fact that changes were within system tolerance. The cause was immediately obvious on the admission chest X-ray: twiddler syndrome (Fig. 3). This resulted in double

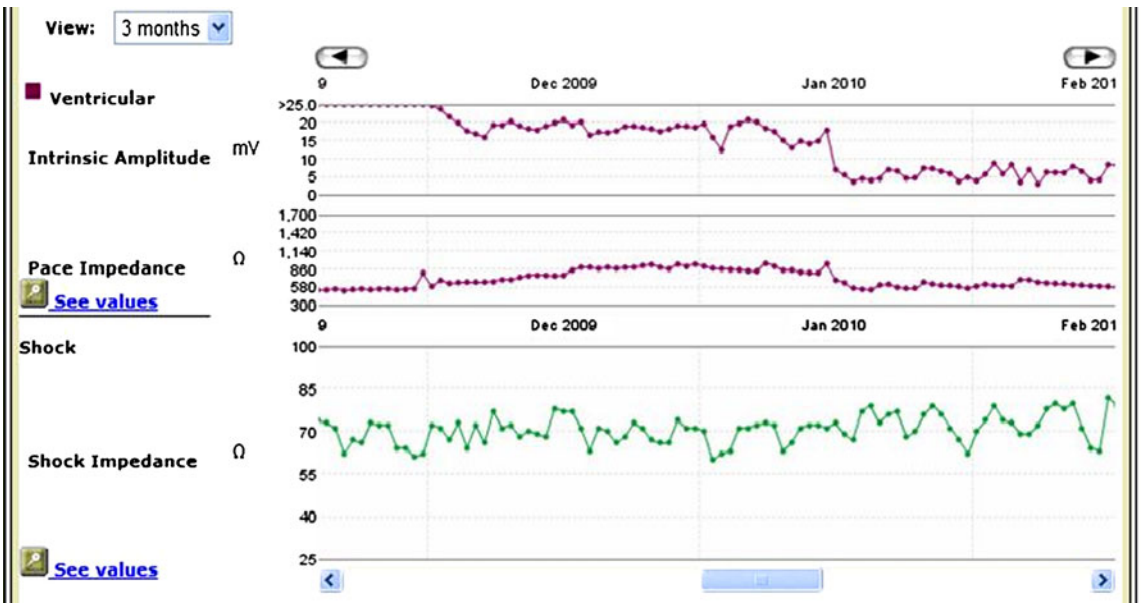

Fig. 2 A sudden drop in both pacing impedance and amplitude of the ventricular electrogram had occurred a month prior to admission with inappropriate shocks

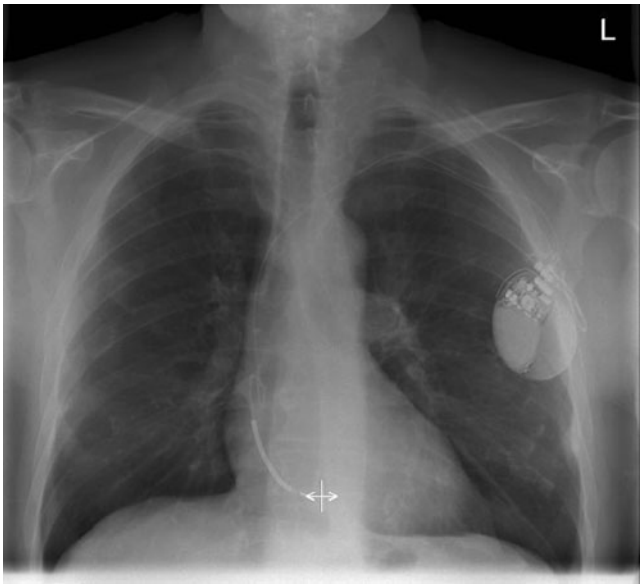

Fig. 3 The cause of inappropriate shocks in this patient was double counting (atrial and ventricular EGMs) due to lead dislocation resulting from twiddler syndrome

counting (both atrial and ventricular signal due to the proximity of the dislocated lead to the tricuspid annulus) and hence inappropriate shocks.

Case 3. This is an unusual case. We received an alert of a shock, opened on Monday morning at the start of office hours, transmitted the day before. Figure 4 shows the accompanying electrogram. At first glance it seems that VF has occurred, been detected, and terminated with a single shock followed by AV sequential pacing. Closer examination raises the suspicion that this may in fact be noise, and the shock therefore inappropriate. Strangely, the patient had not contacted the clinic over the weekend, so we called his home number. His daughter answered, and informed us that her father had died in his sleep on Saturday. Wait a minute, the shock alert was on Sunday…shades of Edgar Alan Poe? No. The solution: the undertaker removed the deceased's ICD on Sunday. While cutting through the lead he created noise and a shock, pacing artefacts were due to the lack of intrinsic electrical activity for obvious reasons. The patient undoubtedly died the day before in asystole, not VT or VF.

Case 4. A 74-year-old man presented to our emergency department at the end of the morning on a Saturday following numerous ICD shocks. Interrogation of the device showed multiple appropriate therapies. So why hadn't he called an ambulance hours before? Because he thought we would send one when we saw he had "pressed the button on his box". Although we spend considerable time and effort repeatedly informing patients how remote care works, mainly that it is not a 24/7 watchdog, this gentleman probably forgot in the distress and panic of his electrical storm. It later turned out that the patient's GP had halved the dose of his beta-blocker several days before because he found his resting heart rate so low.

Case 5. This case is so horrible that it's almost funny. We received an alert regarding a 59-year-old lady, due to tachy events eliciting antitachycardia pacing. It was immediately apparent that this was caused by atrial fibrillation with rapid ventricular response. Luckily, therapies had not progressed to shocks, so we called her with the request to come straight in to treat her AF. Nervous as she is, the call gave her such a fright that her ventricular rate in AF accelerated into the VF detection zone and caused 3 inappropriate shocks. So much for bedside manner.

What do these cases teach us? Firstly, that remote follow-up is not infallible. Secondly, that there can be discrepancies between what may be "appropriate" behaviour from a programming point of view, but inappropriate from a clinical perspective. Thirdly, that remote care does not always cut out the human error factor. Fourthly, that it is not a 100% substitute for live follow-up, and finally what you see is not always what you get. Case 1, the Sprint Fidelis lead failure: appropriate alert with timely action. Case 2, the twiddler: from a clinical point of view, inappropriate lack of an alert. Case 3, the shocked undertaker. First an inappropriate lack of alert when the patient died, then an inappropriate alert when the ICD was removed; again, both from a clinical point of view. Case 4, the electrical storm. Appropriate alert, but inappropriate action by the patient. Case 5, the lady with AF. Appropriate alert, with dramatic consequences.

Logistic consequences for the outpatient clinic

Since our first patients were put onto some form of remote care late 2008, numbers have risen sharply: 280 early 2010, 500 early 2011, currently 750, or just over half of our population. The number of remote follow-ups has obviously increased accordingly to more than 1500 projected for 2011. At the same time, the number of live follow-ups has slowed. While this has won us time, remote follow-ups also take time, alerts in particular. In order to perform this number of "virtual visits", hitherto non-reimbursed, we have to reschedule a technician or ICD nurse for 1.5 days a week. While some "non-alerts" can be dealt with quickly, a "real" alert requiring (medical) attention, contact with the patient etc. takes approximately 30 min to wrap up. As an indication of how many alerts we receive: with about 750 patients

Fig. 4 Electrogram and marker channel of a shock alert. See text for discussion

on remote care, we had 120 alerts in August this year alone. Biggest annoyances are obviously the alerts that are not really alerts from a clinical point of view; our top 3: inappropriate patient initiated (pushed the button to check if we were still on-line, forgot to ask something last time they were here and so on), Optivol, and lead alerts in devices with unused channels (i.e. a biventricular device with a plugged LV port, or a DDD device without atrial lead) which keep sending impedance out of range alerts for non-existent leads.

Conclusions

Remote follow-up has proven its safety and efficacy in the literature, and indeed in daily use. It saves the patient time and travel, allows earlier detection of events, and reduces inappropriate shocks. At the same time, it is not infallible and definitely not a universal substitute for in-office visits, as the 5 cases above demonstrate. It saves time, but also takes some time, with problems and challenges we were hitherto not familiar with. Hopes for the future include uniform definitions regarding policy and responsibilities, reimbursement, even better connectivity, better alert management and remote programmability. To end on a more utopic note, it would be a huge step forward if devices and leads were so reliable the we didn't need remote care to detect malfunctions.

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