

Longitudinal Experience with Remote Monitoring for Automated Peritoneal Dialysis Patients

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Keywords

Remote monitoring · Automated peritoneal dialysis · Telemedicine · Inperson visit · Night alarms · Long-term peritoneal dialysis

Abstract

Background: Peritoneal dialysis (PD) is an ideal model for testing remote monitoring (RM). In this study, we evaluated the RM application longitudinally in stable patients undergoing automated PD (APD). **Methods:** This was an observational study, comparing outcomes in patients with (current patients) and without (historical data) exposure of RM. We analyzed cost-effectiveness of RM-APD measuring the number of night alarms, number of hospital visits, direct and indirect costs. **Results:** Changes in APD prescription were almost double in the case group (RM) compared to the control group ($p = 0.0005$). The need for in-person visits and nocturnal alarms was significantly less in RM-APD than in traditional APD ($p = 0.01$ and $p = 0.002$, respectively). The distance traveled by patients in the case of RM-APD was reduced by 1,134 km with a time saving of 1,554 min for patients. The overall cost reduction for the PD center in terms of time/nurse and time/physician was 2,647 and 3,673 min, respec-

tively. All these advantages were obtained in the presence of an improved technique survival with a significant reduction of dropouts. All patients found that it is easy to use the RM system and were satisfied with the high level of interaction with the care team and with the possibility of timely resolving technical problems. **Conclusion:** These data confirm the long-term benefits of RM applied to APD. RM-APD is cost-effective; it allows early detection and resolution of problems, improved treatment compliance, reduction of patient's access to hospital center for technical and clinical complications with consequent savings, and improved patient's quality of life.

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Introduction

Peritoneal dialysis (PD) is a home-based therapy that relies on patients and their caregivers for treatment delivery. PD offers greater patient independence and autonomy compared to in-center HD, with improved quality of life. However, patient's adherence to physician's prescription at home is fundamental for the success of PD [1]. In the home environment, patients may experience a

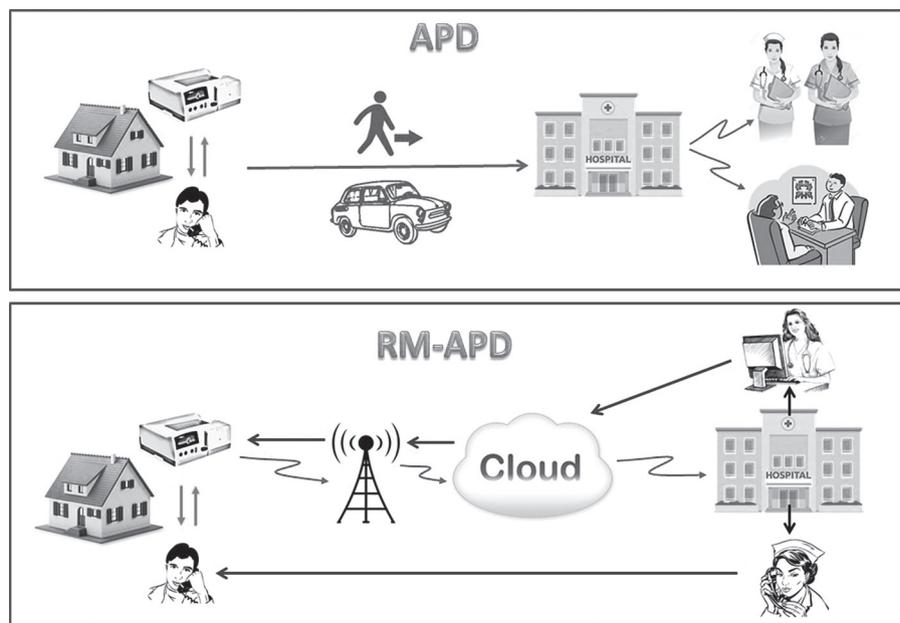


Fig. 1. The 2 APD protocols are described. In the top section the traditional APD regime encompasses the need for patient to be seen at the hospital every time there is a need for prescription change of a solution of a problem not manageable by the phone. In the lower panel the new RM-APD regime with a bidirectional cloud-based communication system is described. Data analysis and prescription modification is made possible via computer. APD, automated peritoneal dialysis; RM-APD, remote monitoring-APD.

sense of freedom and safety, but they must actively monitor their therapy with daily recording of weight, blood pressure, and fluid removal [2]. It is imperative that patients notify the care team when problems arise so that timely interventions can be applied to prevent severe complications and optimize outcomes. Patients and caregivers, however, may be uncertain on when to notify the care team, sometimes minimizing problems that in fact may go for extended periods of time before being addressed. This limitation may jeopardize the benefits of PD. Furthermore, although PD is a home-based therapy, patients still require periodic hospital visits to receive a full assessment of treatment adequacy from the medical and nursing team [3].

Telemedicine (TM) is an innovative tool to provide remote transmission, interpretation, and storage of clinical parameters and useful diagnostic images. A subset of TM is remote monitoring (RM) where physiological variables or images can be sent to a central monitoring center for review and intervention of the care team. It allows for accurate home monitoring of patients enabling the team to improve care through prevention and early identification of problems, with consequent timely interventions. In this view, TM and RM may have important reflections on prognosis, outcomes, and quality of life [4]. RM has proved to be useful in chronic diseases where frequent controls are particularly useful such as heart failure, diabetes, and hypertension [5, 6]. The possibility to keep patient's out-of-hospital supporting their home care by RM may con-

tribute not only to prevent complications but also to reduce direct and indirect costs [7–9]. In the dialysis setting, RM has been sporadically utilized, and single center reports have demonstrated patient satisfaction and effective utility with effective timely interventions [10].

Recently, a novel automated cyclor for automated PD (APD), connected with a modem to a cloud-based network, has been introduced in clinical practice (Claria™, Baxter Healthcare, Deerfield, Illinois). This APD equipment with a built-in RM capability enables patients to receive and transmit data through a TM platform from and to a PD center (RM-APD). RM of patients on APD with this platform offers the potential benefits of accurate monitoring of the therapy, improved patient safety through surveillance of critical stages of the treatment, early detection of problems, or limited compliance to prescription. Furthermore, the 2-way communication system with interactive interface allows a fast trouble shooting: the physicians can change the prescription using the remote connection, reducing the need for frequent in-person visits to the PD center (Fig. 1) [11].

In the PD center at San Bortolo Hospital, in Vicenza, we recently used RM for APD treatments. In the first months of adoption, we initially observed a benefit in the personalization of APD prescription more strictly than the traditional recording system [12].

The aim of the present study was to evaluate the utility of this novel RM-APD system for 1 year. In particular, we compared RM-APD with specific remote intervention

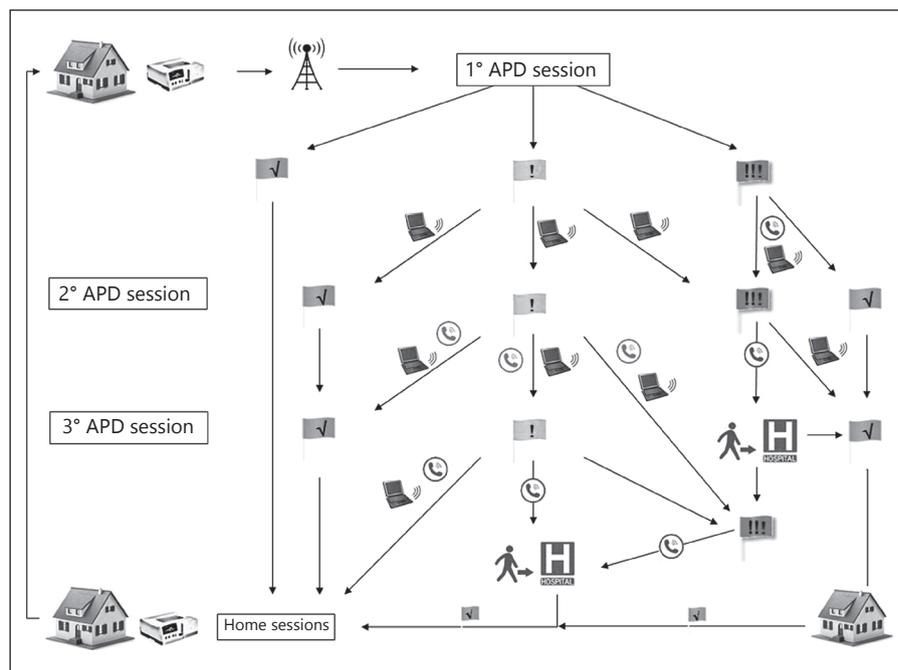


Fig. 2. Algorithm for RM-APD patients to describe different type of alarms and consequent actions prompted by the alarm codes. APD, automated peritoneal dialysis.

protocol to a traditional APD management. Outcome measures studied included the frequency of personalized prescription changes, in-person visits to the PD center, and number of nocturnal alarms.

Methods

Study Design

This study is an observational cohort study, comparing outcomes in patients with and without exposure of RM. The cohort of patients without RM is a historical cohort. It is a single center study performed in the PD center at San Bortolo Hospital, in Vicenza, Italy.

In this center, all patients included in the present study were treated with “traditional” APD using the Claria Cyler Equipment (Baxter, Deerfield Illinois) and standard embedded software from May 31, 2015, to November 31, 2016. Patients were then switched to RM Automated PD (RM-APD) from December 1, 2016, using the same cyler but the new Sharesource cloud-based software (Baxter, Deerfield, Illinois). Furthermore, since December 1, 2016, incident APD patients started directly with the RM-APD. All patients treated with RM-APD for more than 3 months and with ≥ 18 years old were then included in the study.

The historical control APD group included 42 patients, while the RM-APD group (period between December 1, 2016, and May 30, 2018, included 43 patients. Every patient was longitudinally followed for at least 12 months.

In the APD group, sessions were reviewed during the routinely planned hospital visits, or in case of unplanned hospital visits due to complications experienced by the patients, or identified by the care team in a phone conversation.

In the RM-APD, every session was analyzed by the software and transmitted to the center where the PD nurse surveyed the results. Exploratory phone calls or direct changes in APD prescription via software were made by nurse/physician.

In the control group, prescription changes were only made after telephone calls of the patient or in-hospital visits (patient’s visits beyond regular scheduled controls in hospital were either requested by the patient or scheduled by the physician/nurse after a telephone conversation in which the problem was reported by the patient but it could not be resolved on the phone).

In the RM-APD group, these changes and telephone calls were prompted by the Sharesource program results. In particular, in the RM-APD group, we followed the algorithm reported in Figure 2. Every specific intervention was prompted by an orange (warning) or red (problem) flag as reported in the figure. In case of repeated or unresolved problems, the in-hospital visit was scheduled. In particular, when the red flag was not corrected after 2 remote (telephone + software-driven) intervention, a patient visit was scheduled. We recorded the number of changes in APD prescription and of in-person hospital visits during the entire observation period and the number of machine/treatment alarms for 1 month of treatment for every patient.

We calculated the time and money saving for personnel based on the minutes of activity (visits and treatment control) and on logistics points of view. We extrapolated travel time and distance and costs based on the number of visits for all the patients.

Patients were kindly requested to fill out a simple for internal use questionnaire about the usability and satisfaction regarding the RM-APD.

In all studied patients, clinical characteristics, laboratory data, and dialysis-related parameters were recorded for all patients. Total renal + peritoneal clearance was utilized to calculate weekly Kt/V_{urea} and weekly creatinine clearance as PD adequacy parameters [1].

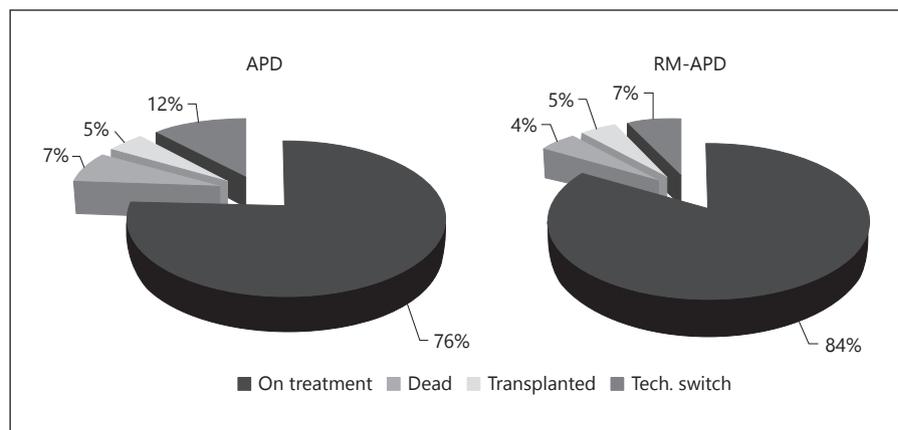


Fig. 3. Conditions and outcomes for RM-APD and APD groups after 1 year of observation. APD, automated peritoneal dialysis; RM-APD, remote monitoring-APD.

All procedures were in accordance with the Helsinki Declaration. The protocol and consent form were approved by the Ethics Committee of San Bortolo Hospital. All patients were informed about the experimental protocol and the objectives of the study, and they all gave written informed consent.

Statistical Analysis

Statistical analysis was performed using the SPSS Software package. Categorical variables were expressed as percentages; continuous variables were expressed as means \pm SD (parametric variables) or median and interquartile range (IQR) (nonparametric variables). The Mann-Whitney U test or *t* test was used for comparison of 2 groups, as appropriate. Correlation coefficients were calculated with the Spearman's rank or Pearson's correlation coefficient test, as appropriate. A *p* value of < 0.05 was considered statistically significant.

Results

RM-APD group included 43 patients, while the APD control group included 42 patients that performed traditional APD without RM. The PDycler was the same in each group with the same catheter connection, lines, and bags. The median length of observation for the RM-APD group ($n = 43$) was 13.28 months (IQR 6.65–14.65) while for the APD control group the period of observation was retrospectively set at 12 months. The time for initial training was the same in the 2 groups. Patients who switched from traditional APD to RM-APD needed 4.0 ± 0.5 h of retraining.

In the RM-APD group, 7 patients dropped out during the study period (16.27%): 2 patients died, 2 had a kidney transplant, and 3 changed dialysis modality (2 patients lost the ultrafiltration and one had omental wrapping). In the APD control group, 3 patients died, 2 were transplanted, and 5 required a technique switch (2 patients lost

ultrafiltration, one had omental wrapping and 2 relapsing peritonitis). A reduction in patient's dropout was observed with RM-APD compared to 1 year observation in the APD control group (23.8%). In particular, the lower dropout was due to a reduced rate of technique failure and change of dialysis modality (Fig. 3). However, there was no significant difference in terms of patient's dropouts; in fact, this difference is based on only 5 patients changing modality in APD group versus 3 in the RM-APD group. Table 1 summarizes the clinical data of the 2 groups (Table 1). Table 2 reports the comparison between the studied groups in terms of analyzed parameters, program changes, and treatment optimization (Table 2).

In Figure 4, we report the most common problems and the relevant interventions prompted by orange or red flag alarms in the RM-APD group (Fig. 4). These were observed and practically actuated in real time with maximum 1 day delay, while in traditional APD, they would have been recognized weeks or months later.

We considered the number of night alarms in a complete month of APD treatment for every patient, excluding the first 3 months. The number of alarms was statistically lower in the RM-APD group compared to the control APD group (1.3; IQR 0.6–1.5 vs. 2.0; IQR 1.3–3.7; $p = 0.002$). There was no significant difference in terms of PD adequacy (total weekly Kt/V, total weekly creatinine clearance) between the 2 groups ($p = 0.94$ and $p = 0.61$, respectively; Table 2).

The patients who underwent traditional APD needed 5.14 (IQR 4.25–5.75) in-person visits in the year of observation. Considering the median distance from the San Bortolo Hospital and the median travel time, they traveled for 5,670 km with a time consumption of 7,770 min in total. Given the results, using the RM-APD tool, they would made a median of 3.56 in-person visits (one in-

Table 1. Characteristics of patients in case (RM-APD) and traditional APD group

	RM-APD	APD
Patients, <i>n</i>	43	42
Gender, men, %	75	76
Age, years, means ± SD	56±17	57±14
Diabetes, %	26	28.5
Residual diuresis >500 mL, %	72	69
BMI, kg/m ²	26.9±4.3	24.6±4.4
Travel distance, km, median (IQR)	19 (10–40)	27 (12–42)
Travel time, min, median (IQR)	30 (20–50)	37 (20–50)

RM, remote monitoring; APD, automated peritoneal dialysis; BMI, body mass index; IQR, interquartile range.

Table 2. Comparison between RM-APD and traditional APD

	RM-APD (<i>n</i> = 43)	Traditional APD (<i>n</i> = 42)	<i>p</i> values
Program changes per patient/year, median (IQR)	2 (1–3)	1 (0–2)	0.005
In-person visits per patient/year, median (IQR)	4.0 (3.0–5.0)	5.0 (4.25–5.75)	<0.01
Night alarms per patient/months, median (IQR)	1.3 (0.6–1.5)	2.0 (1.3–3.7)	0.002
Total wKt/V	1.8 (1.5–2.2)	1.79 (1.55–2.0)	0.94
Total wCreatinine clearance	58.5 (44.5–86.5)	68 (48.2–84.7)	0.61

wKt/V, total (renal and peritoneal) weekly Kt/V_{urea}; wCreatinine clearance; total (renal and peritoneal) weekly creatinine clearance; IQR, interquartile range; RM, remote monitoring; APD, automated peritoneal dialysis.

person visit less) to the PD center in 1 year. In this case, the kilometers traveled and the time spent would have been 4,536 km and 6,216 min, respectively (Fig. 4). The time needed by physicians and nurses for in-person visit was 60 min (50–70) and 40 min (38–42) for both systems, respectively. The time needed for card evaluation during in-person visit was 20 min (15–25) for physicians and 30 min (25–35) for nurses. The time needed for daily RM platform was 8.5 min (5–11) for physicians and 15 min (10–20) for nurses.

During the observation time (all patients were prevalent and started observation at least after 3 months from beginning of therapy), the physicians performed 2.02 program changes per patient of the APD prescriptions in the RM-APD group, almost double compared to the control group (1.07 program change/patient; *p* = 0.0005; Table 2; Fig. 4). The frequency of in-person hospital visits in the 2 groups during the study period was 3.56/year for RM-APD group and 5.14/year for APD control group: this reduction was statistically significant (4; IQR 3–5 vs. 5; IQR 4.25–5.75; *p* = 0.01; Table 2; Fig. 4).

The reduction of time/physician and time/nurse for in-person visits for each patient was statistically significant (*p* = 0.005 and < 0.001, respectively). The time saving for 4 vs. 5 in-person visits for all patients per year was 2,520 min for the physicians and 1,680 min for the nurses. Furthermore, the additional reduction of time/physician and time/nurse was, respectively, 1,153 and 967 min in 1 year due to reading of the cloud-based information versus the traditional patient card analysis. Thus, the overall cost reduction for the PD center in terms of time/physician and time/nurse was 3,673 and 2,647 min, respectively (Fig. 5).

In addition, we submitted to the case group a simple test evaluating the satisfaction about the RM system. Based on the results extracted from this questionnaire, all patients (100%) found the new system easy to use; they were satisfied with the high level of interaction from the care-team, and with the possibility to resolve some technical problems timely (Fig. 2). As a drawback, we may report occasional and temporary problems due to Internet connection that however occurred in 3% of the patients.

	Type of alarms	First action	Second action
	Treatment time lost >30 min	Call the patient, verify compliance	<ul style="list-style-type: none"> • Remotely change the APD prescription • In-person visit
	Delivery volume lost >10%		
	Bypass drain >2 times	Call the patient, exclude overfilling	
	Bypass dwell/fill >2	Call the patient, verify compliance	<ul style="list-style-type: none"> • Remote reduction of tidal % or UF • In-person visit
	Numbers of events >2	Suggest to avoid constipation/use heparin	
	Numbers of events >10		

Fig. 4. Type of alarms and feedback from care team. Vicenza Center alarms default settings: if treatment time lost is more than 30 min alarm's code is yellow. The alarm's code is red if the volume lost is more than 10% of prescribed. In both case, if alarms are frequent, the nurse calls the patient to verify compliance and, if persistent, patient is invited to come to the center to verify dialysis adequacy. Patients are allowed to bypass drainage not more than 3 times; otherwise, a yellow flag appears. In this case, abdomen overfill needs to be excluded. The nurse calls the patient and invites him/her to make a manual drainage. If the bypass happened during a fill or dwell more than 2 times, the flag appears in red and if it happens often, the nurse calls the patients to identify the problem. If such alarms are still persistent, the patient needs to come to the center to verify dialysis adequacy. Each alarm is considered an

event. If events are more than 5, alarm's code is yellow, if more than 10, the code is red. Line alarms are usually related to kinking of catheter or obstruction by fibrin. In some case, if catheter performance is considered to be low, tidal percentage can be modified directly by remote, so that lower volume drainage is required during the night. Alarms, such as UF insufficient, negative UF or insufficient drain volume, happen when drainage is over and drained volume is inferior to set. In this case, the same suggestion of line alarms are given by the nurse and if alarms are persistent, the patient needs to come to the center to exclude volume overload and perform a manual drainage. If it happens during the first home treatments, when the standard volume of ultrafiltrate is still to be established, it can be directly changed by remote. APD, automated peritoneal dialysis; UF, ultrafiltration.

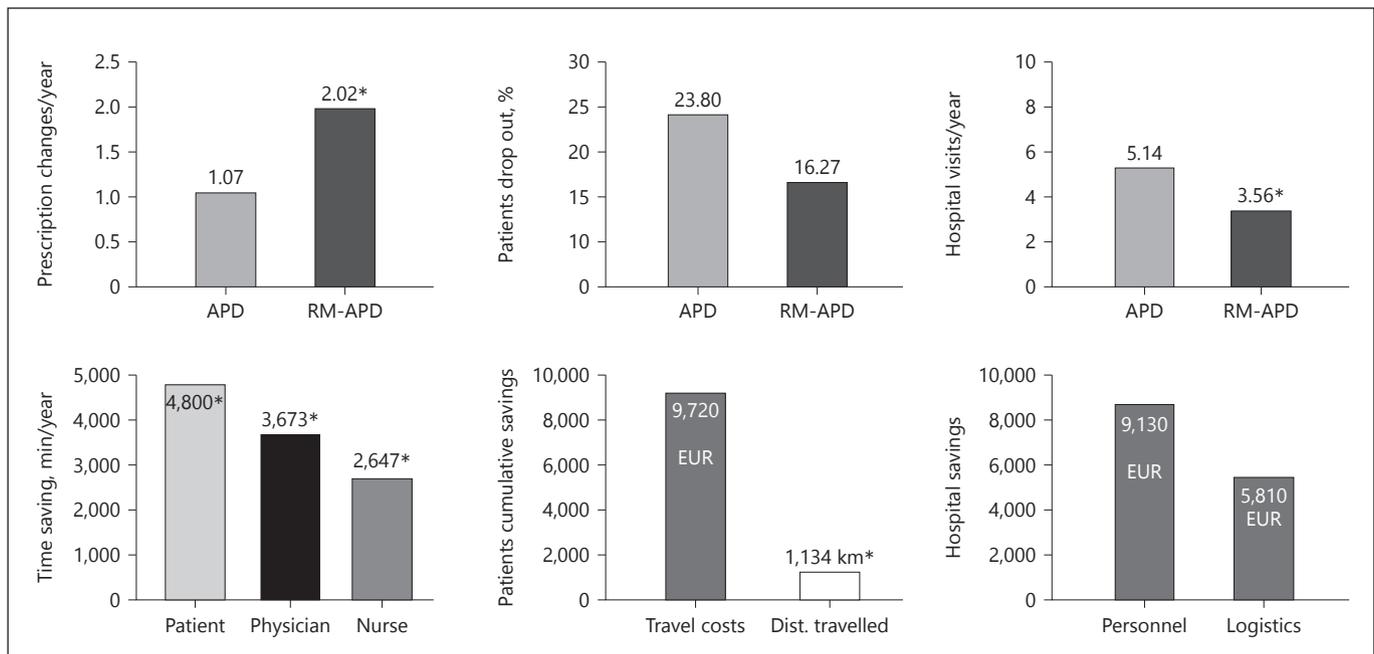
Discussion

Previous studies have underlined the potential of TM and RM for chronic kidney disease patients in improving the quality of life, decrease of hospital readmission and emergency room visits, and potentially decreasing costs [13–15]. In patients undergoing APD, the surveillance of device-transmitted outpatient treatment data is now possible through a new cyler with 2-way cloud-based RM. Very few studies described the role of RM applied to APD in the long term, and we feel that our paper may contribute to future practice offering some important experience matured on the field in a quite large population on PD and for a significant amount of time.

The present study investigates the prolonged use of RM-APD. In particular, we report the benefits of RM-

APD and the possibility to make changes of the prescription based on the observation of data from the TM platform. In our experience, this new tool of monitoring leads to a reduction of night alarms as well as extra visits to the PD center.

In a previous study on RM-APD incident population, we compared 37 RM-APD patients, 16 incident patients (naïve to APD), and 21 prevalent patients who switched from traditional APD to RM-APD system. The length of observation for every patient was 6 months. We observed that the APD prescriptions were modified more frequently in RM-APD versus traditional APD in incident and prevalent patients. In-person visits were significantly less in RM-APD than in traditional APD for incident patients. The results demonstrated that RM improves personalization of APD prescription in incident and preva-



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Fig. 5. Different benefits were observed from the utilization of the RM-APD regime. In particular, a significant difference of prescription changes was observed demonstrating that even in a stabilized prevalent population, prescription change is more frequent in case of RM-APD leading to a more personalized therapy regime. Pa-

tient drop out decreased significantly mostly due to a lower rate of technique failure. The number of in person hospital visits was reduced with consequent savings for the patient, the care team, and the hospital. * $p < 0.01$. APD, automated peritoneal dialysis; RM-APD, remote monitoring-APD.

lent population and increases patient independence from PD center [12]. Until now, very few studies have focused on the acceptance and outcomes during the long-term use of TM and RM in PD patients.

In this paper, we have studied the long-term effects of RM applied to APD in stable prevalent patients. During the period of the study, we found that the number of adjustments of the APD program in patients treated by RM-APD was almost double compared to the older system. Consequently, we observed less night alarms in RM-APD patients. In particular, we evaluated night alarms (excluding the first 3 months) to establish that the tailoring of treatment continues to be useful not only at the beginning but also during the time.

Based on our results, we reported a reduction of in-person visits in 1 year of treatment per patient. The number of clinical checks in center decreased, and we establish to perform 4 visits for year reflecting our management policy for stable patients. In this context, we speculated that the travel distance would have been reduced by 1,134 km and the time saved by 1,554 min for all traditional APD patients, if they had been treated by the RM system. Our results confirm the data described by Wallace et al. [16] who reported that replacing the face-to-face encoun-

ter with a telehealth monitor can reduce patient driving time, time spent in waiting rooms, and travel costs. In this context, Makhija et al. [17] performed a study based on a simulated environment and estimated the reduction of health-care resource utilization and associated costs by early intervention using RM on APD patients.

From the patients' questionnaire, we extrapolated that all patients had high satisfaction with the new monitoring system. Importantly, patients perceived a virtual reduction of the distance between them and the clinical staff. Our experience findings where RM can improve collaborative care between patients and the team and improve patient compliance [18].

The study is limited by the single center design of the study, the small number of patients in relation with low statistical power, and the impossibility to have a concurrent control group. The 1-year duration could be potentially adequate to reflect long-term effects of the RM through the ongoing management of APD. Unfortunately, the study was too short to detect difference in outcome measures such as peritonitis rates, hospitalizations, and mortality.

An important observation was the significant savings achieved by the hospital care team in terms of time and money. The savings on the distance traveled by patients

were limited, but one should consider that in Italy the distance between hospital and patient's home seldom exceeds the 10 km range. Such aspects would become of greater importance in remote rural areas or in vast and disseminated territories.

In conclusion, these data confirm the long-term benefits of a 2-way communication system: an early detection of problems permits a close follow-up of outpatients and a knowledge-based handling of complications, avoiding extra visits for technical problems. Time- and cost-savings in transport are particularly useful, both for the patients affected by end-stage renal disease and for their caregivers. Based on these results, we conclude that RM-APD has an important role in home dialysis care over time. RM permits a tailoring of dialysis treatments and a saving time and costs both for PD patients and PD team.

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Ethics Statement

This study was approved by the Ethics Committee of San Bortolo Hospital in Vicenza (Del. n.67/17.), and the procedures were in accordance with the Helsinki Declaration. All the patients or their relatives were informed about the experimental protocol and the objectives of the study before providing informed consent and blood samples.

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Disclosure Statement

The authors declare that they have no competing interests. This manuscript has not been published and is not under consideration elsewhere; the results presented in this paper have not been published previously, except in abstract form. All persons listed have contributed sufficiently to the project to be included as authors, and all those who are qualified to be authors are listed in the author byline. Consent for use of deidentified images contained in this article was given by the individuals involved.

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Author Contributions

S.M.M. conceived of and designed the study, collected data, interpretation, and drafting of the manuscript; M.H.R. prepared the manuscript and final approval of the draft.; G.M.V. conceived of and designed the study, performed statistical analysis, and prepared manuscript; A.G. and C.C. assisted with study design, enrolled patients, and collected data; S.B. enrolled patients and collected data; C.R. provided intellectual content of critical importance to this work, conceived of the study and final approval of the draft. All authors drafted and reviewed the manuscript. All authors read and approved the final manuscript.

Availability of Data Materials

The datasets generated and analyzed during this study are available on reasonable request.

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