Exploring the potential of self-monitoring kidney function after transplantation : from patient acceptance to replacing outpatient care

Lint, C.L. van

SUMMARY

After kidney transplantation, patients have to visit the outpatient clinic frequently to monitor their kidney function. The high frequency of these appointments is burdensome to both the recovering patient and to healthcare resources. Experiences that have been gathered in other conditions requiring chronic care show that self-monitoring important clinical parameters at home has the potential to increase patient satisfaction and accelerate the detection of complications while reducing healthcare consumption at the same time. The general objective of this thesis was to investigate whether self-monitoring kidney function after transplantation supported by an online self-management support system (SMSS) can replace part of regular care safely and without loss of quality of care.

In **chapter 2**, the results of a prospective pilot study that was performed to investigate kidney transplant patients' experiences and satisfaction with self-monitoring kidney function after transplantation are described. Thirty patients self-monitored their level of creatinine and blood pressure and registered the measurement results in an online SMSS, where both patients and doctors had access to. The results showed that patients were highly motivated to self-monitor kidney function and reported high levels of general satisfaction. The receipt of an automatic warning when creatinine level was increased was considered the most important benefit of the SMSS. The use of both the creatinine and blood pressure meters was considered pleasant and useful, despite levels of trust in the accuracy of the creatinine device being relatively low. Trust in the accuracy of the creatinine device appeared to be related to level of variation in subsequent measurement results, with more variation accompanying lower levels of trust. Some patients expressed disappointment about their physicians paying little attention to the recorded measurement values. Average adherence to the monitoring protocol was good, but large individual differences between patients were found that increased over time. Based on these findings we concluded that at-home monitoring of creatinine and blood pressure after transplantation offers a promising strategy. However, important prerequisites for a successful implementation of self-monitoring in transplant care seem to be confidence in the accuracy of the devices that are used and patients experiencing support from their physicians.

For the design and implementation of SMSS, it is important to understand the factors that influence patients' acceptance of such systems. The results of a study in which we aimed to identify these key factors is described in **chapter 3**. Level of acceptance of the SMSS that was used throughout the randomized controlled trial (RCT, see chapter 5), expressed as behavioural intention to start or continue using the system, was investigated using a self-developed questionnaire based on two models that have been used before to explain people's acceptance of technology. Fifty kidney

transplant patients completed the questionnaire before and after having used the SMSS for 4 months. Patients were found to be on average positive towards using the SMSS, both in advance of use and after having used the SMSS for 4 months. Behavioural intention could mostly be explained by patients' affect towards the SMSS (26% explained variance), with affect referring to whether patients liked to use the system. This is different than what is usually found, with the degree of ease associated with using the system (effort expectancy) traditionally being one of the most important factor explaining behavioural intention. However, as patients were 'free' to choose whether they used the SMSS or not, it makes sense that their appreciation of using the system was a crucial factor. This finding suggests that the emotional experience of using a SMSS should be taken into account when designing and implementing a system to be used in healthcare.

In **chapter 4** we describe the results of a study investigating the analytical performance of the creatinine device that was used throughout our studies, the StatSensor® Xpress-i™, for both detecting current renal function with a single measurement and monitoring renal (dys)function with subsequent measurements in kidney transplant patients. Concerning single measurements, the total allowable error criterion of 6.9% was not met. Further, the average overall coefficient of variation (CV) for the StatSensor® was 10.4% using capillary whole blood results while this was < 1.5% for the central laboratory serum creatinine method. Based on these findings, we concluded that the StatSensor® at that time was not suitable for detecting kidney (dys)function of kidney transplant patients in case of single capillary blood measurements. During kidney transplant follow-up, however, creatinine values are usually interpreted by comparing subsequent measurements, reflecting a monitoring purpose in which the uncertainty of a single creatinine test results is less critical. Our results showed a reasonable correlation (R=.77) between the percentages change that were detected by the central laboratory and the StatSensor® device. A sudden increase in creatinine of >10% is of special interest, as this suggests further analysis or intensified follow-up is needed. The StatSensor® correctly identified a difference of > 10% (true positive) in 70% and a difference of ≤ 10% (true negative) in 67% of all cases (total agreement 68%). We concluded that although StatSensors'® ability to detect changes in kidney function needs improvement, it does have potential for monitoring creatinine in case StatSensor® measurements are performed in a higher frequency than laboratory creatinine analyses. This will result in a more reliable trend, as the confidence interval decreases proportionally to the square root of the number of performed measurements, given a normal distribution. As such, the chances of detecting rejection are increased and theoretically, the number of outpatient visits can be safely reduced.

The objective of the study that is described in **chapter 5**, was to investigate whether self-monitoring kidney function supported by an online Self-Management Support System (SMSS), where both patient and doctor had access to, can lead to a reduction in number of outpatient visits in the first year post-transplantation without compromising on quality of care. 119 patients were randomized to the intervention group, with patients self-monitoring creatinine and blood pressure and face to face and telephonic consults being alternated, or the control group, who received standard post-transplantational care. Number of outpatient contacts and clinical outcomes (eGFR, blood pressure, satisfaction and quality of life) were compared between the two groups. For the intervention group specifically, we looked at the extent to which creatinine trends measured at home were comparable to laboratory-based creatinine trends. Further, twenty intervention patients were interviewed on their self-monitoring experiences. The results showed that self-monitoring can lead to a significant decrease in number of outpatient visits (16.02 and 18.35 face to face visits for the intervention and control group, respectively, p .007) without compromising on quality of care, as was indicated by the absence of differences between intervention and control patients for eGFR, blood pressure, quality of life and general satisfaction at one year follow-up. Remarkably, the medical staff poorly adhered to the protocol of replacing physical visits with telephonic consults, leading to an underestimation of the true effect of self-monitoring on number of outpatient visits.

In 78% of relevant creatinine increases (>10%), a similar trend for home-based and laboratory-based measurements was observed, which is 10% higher than what was found in the study reported in chapter 3. Interview data showed that satisfaction was high: 95% of the interviewed patients would recommend self-monitoring to others and 75% would have liked to continue self-monitoring beyond one year. These results led to the conclusion that self-monitoring creatinine after transplantation is highly appreciated by patients and enables the number of outpatient visits to be reduced without having to compromise on quality of care. Improving the implementation of self-monitoring into post-transplantational care is expected to lead to even greater reductions in number of outpatient visits.

Chapter 6 describes a study in which we investigated the level of adherence to the self-monitoring protocol used during the RCT, the reliability of patient-reported test results and whether patients took appropriate actions based on their measurements. Level of adherence to the self-monitoring protocol was generally good, with well above 90% of all patients performing the requested number of measurements during month 2-4 after transplantation. Adherence was lower during the first month and during months 5-12 after transplantation. Approximately 90% of both creatinine and blood

pressure measurements were correctly registered in the SMSS. In cases of non-correspondence between measured and registered values, the values that were registered in the SMSS appeared to be significantly lower than those actually measured. This suggests that patients select, alter or add values in such a way that their creatinine profile looks more positive. The percentage of patients following the advice that was shown automatically when a new creatinine value was registered in the SMSS ranged from 53-85%, depending on the specific feedback. The advice to contact the hospital, which was given in case level of creatinine had increased by >15%, was followed in only 58%. This is alarming as taking immediate action in case of early signs of graft failure is vital to prevent or diminish damage to the kidney transplant. Many patients had saved up their measurements over several days or weeks to register them all at once. With registering measurements retrospectively, the advice given by the SMSS was no longer up to date, which was probably the main reason why patients did not follow it.
Patients' tendency to postpone registration and to select lower creatinine values for registration and the suboptimal adherence to the automatic advice might challenge the safety of self-monitoring. This should be well considered when designing self-monitoring care systems, for example by ensuring that self-measured data is transferred automatically to an SMSS.

CONCLUSION

The studies that were performed and are described in this thesis show that self-monitoring kidney function after transplantation is an attractive option to kidney transplant patients and can lead to a significant decrease in number of outpatient visits without compromising on quality of care. Further, self-monitoring could offer a relatively cheap way to increase monitoring frequency, which could lead to earlier detection and treatment of complications and, consequently, improved clinical outcomes. But the results of these studies also show there is room for improvement. To unravel the full potential of self-monitoring kidney function after transplantation, it is recommended to use accurate measurement devices that both patients and healthcare professionals have confidence in, design a protocol with the involvement of a multidisciplinary group that is truly representative of all stakeholders (including patients and physicians that are more critical of self-monitoring) and choose a study design that includes formative evaluations instead of summative evaluations alone.