Original Article

TANAFFOS

Using Home Spirometry for Follow up of Lung Transplant Recipients: "A Pilot Study"

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Background: Lung transplantation is considered the ultimate treatment for some patients, but due to the specific condition of patients undergoing it, follow up is a major concern. The aim of this study was to evaluate the role of home spirometry in follow up of lung transplant recipients and early detection of complications in these patients.

Materials and Methods: A PC-based portable spirometry set was used to evaluate the well being of two lung transplant recipients on a regular daily basis for a 6-month period. Patient satisfaction and compliance, and device sensitivity in detecting complications were evaluated. Results of follow up were compared with 2 matched control patients.

Results: Patient adherence to home spirometry was 80% in one and 61% in the other patient and both patients were satisfied with the method, although this satisfaction declined towards the end of the study period. The main reason for low adherence was insufficient internet access. This method succeeded in early detection of infectious complications.

Conclusion: Home spirometry seems to be a reliable method for follow up of lung transplant recipients, but further studies in a larger group of patients is recommended.

Key words: Home spirometry, Lung transplant complications, Lung transplantation follow up, Pulmonary function tests, Telemedicine

INTRODUCTION

Lung transplantation has become the ultimate therapeutic option for some patients with advanced lung disease (1). Transplantation outcome has improved with advances in operative techniques, but optimal management of infection and rejection remains a problem, partly because these complications may be undetectable at early phases by routine clinical evaluation (2). Long-term survival for lung recipients is dependent on the number and severity of opportunistic infections and chronic rejection episodes (3,4). To improve long term survival, early intervention for earliest possible detection of the

infection or the rejection event is essential. The potential benefits of early detection of infection or rejection in lung allograft have recently been cited in several studies(5-9) . Due to the lung transplant recipients' immune system condition, they are highly prone to acquire opportunistic infections. Considering the high prevalence of contagious diseases in the hospital environment, each extra visit for close follow up can increase the risk of infection in these highly susceptible patients (10-12). In addition, most patients have several socio-economic problems preventing them from presenting to the transplant center for post-operative follow up. Home Spirometry is a useful

instrument that can measure lung function and help to monitor the progress of lung transplantation and aid in early detection of allograft dysfunction (13). Home spirometers are widely used to provide easy access to more detailed information about lung function.

Despite the fact that some researchers around the world have worked hard on this topic (14,15), due to the cultural nature of these studies, their studies may not fully eliminate the need for more information in countries like Iran which is taking the first steps on this road.

The aim of this pilot study was to evaluate the role of home spirometry for early detection of complications in lung transplant recipients with the ultimate goal of improving the outcome of lung transplantation.

MATERIALS AND METHODS

This observational study was performed between May to October 2011 as the pilot phase of a longitudinal study based on using home spirometry for lung transplant recipients. This study was approved by the Medical Research Ethics Committee of National Research Institute of Tuberculosis and Lung Disease.

The project team randomly selected two patients with recent lung transplantation as the control group and two other lung transplant recipients that matched controls in terms of age, baseline disease and type of operation as the case group. All four subjects received the same high standard care based on international guidelines for lung transplant recipients. At the time of discharge, each lung transplant recipient in the case group received a portable PC-based spirometry (Spirostik-Geratherm Respiratory) to collect and store daily spirometric data (including FVC, FEV1, forced expiratory flow after 25 to 75% of vital capacity has been expelled, and peak flow). Proper use of the device was taught to each patient and practiced in presence of a trained physician. Baseline PFT was performed with a standard spirometry device as the golden standard and another one with portable spirometry for comparison and as a reference. In addition to the routine care, each lung transplant recipient in the case

group was required to complete 2 spirometric tests per day, one in the morning and the other in the evening, for 6 months after discharge. Also, a questionnaire containing initial symptoms of infection or rejection was completed daily. Data were recorded and sent via internet to the data center every day. The patients were instructed to contact the transplant center if they had any questions about the test results or symptoms. Whenever patients reported symptoms like fever, purulent sputum production or increased dyspnea, or more than 10% decline from baseline in home spirometric values and there was a strong clinical suspicion of infection, the patients were called for an immediate visit at the hospital for more evaluation. To ensure validity we tested the portable home spirometry set by a medical professional experienced in spirometry each month. The medical professional would ask the patient to perform the spirometry test again under his/her supervision. During the study period and after that we asked patients about their satisfaction level about the use of home spirometry, the problems they encountered for sending the results, whether or not they had enough time to use it and if they were willing to continue using it after the study period. All data, related to episodes of complications in lung transplant recipients in both case and control groups were collected and we compared the efficacy of using home spirometry for early detection of respiratory complications

RESULTS

Initially, the portable spirometry set was evaluated by comparing the results of this device with a standard spirometry device for 5 working days. No difference was detected between the two devices. Patients' performance was then evaluated to make sure that the test was performed properly. In this phase of the study, both patients were asked to perform a spirometry test once with the standard device and again with the portable one. Meanwhile, the patients' performance was assessed by an expert. Both patients succeeded in performing the tests and

no difference was seen between the results of the two devices.

In the case group, our first patient was a 23 year-old man who had been suffering from cystic fibrosis and underwent lung transplantation in March 2011. During his follow up, he faced two episodes of complications but had no hospitalization. We monitored him for 160 days during which his PFT and vital signs were normal. His adherence to the test was 61% and he was very satisfied with this new method. The reason why he did not show a high adherence to performing the test was because of not having internet access throughout the day due to local network problems. Therefore, he usually sent his test results every other day (a total of 97 times).

Our second patient was a 24 year-old man who underwent lung transplantation in April 2011 due to cystic fibrosis. We received 111 test results from him during a period of 139 days and his adherence was 80%. He also declared good satisfaction in using this method. During his follow up, he reported two episodes of post nasal discharge but with no spirometric evidence of lung problem, which was diagnosed and treated as sinusitis. He faced one episode of H1N1 flu, which according to our home spirometry he had a dramatic fall in FEV1, 2 days before his clinical manifestations. Therefore, he was hospitalized, diagnosed immediately and treated accordingly. He was discharged after one month with no complications.

Both patients in the case group declared good satisfaction, especially during the first two months and they admitted that being in contact with a medical staff and being evaluated on a daily basis was very reassuring. But after four months their compliance declined and they complained that sending 2 PFT in one day was time consuming. To cope with that we asked them to send their PFTs daily instead of two times per day but warned them not to hesitate when any sign of complications occurred. Overall, patients' compliance and adherence to the test performing decreased after four months of monitoring.

In the control group, we followed two patients for six months after their lung transplantation. The first patient was a 28 year-old woman who had been suffering from bronchiectasis. She underwent lung transplantation and during six months of her follow up, she faced five episodes of complications and was hospitalized three times. The first episode was vomiting and gastric pain, which was diagnosed to be a drug reaction and by adjusting her medications, she was discharged in good condition. In her second episode, she presented with fever, consecutive vomiting and infiltration in her chest radiography. She was hospitalized with suspicion of transplant rejection but was discharged after 2 weeks in good condition. Again, she suffered from common cold symptoms but the follow up tests were normal, therefore she was treated as an outpatient. Through the last episode, and the hardest one, she was admitted with symptoms of viral infection and during her hospitalization, due to her serious condition, open lung biopsy was performed and after work-ups, she was diagnosed with tuberculosis. Therefore, she underwent anti-tuberculosis therapy. The time between initiation of symptoms and patient referral to hospital was approximately 2 weeks.

The second patient was a 30 year-old man suffering from cystic fibrosis. During the six months of post transplantation follow up, he faced three episodes of extra pulmonary non-hospitalized complications and 3 episodes of pulmonary complications, one of which he was hospitalized and treated for fungal infection. The lag time between the early initiation of symptoms and diagnosis was not clear.

DISCUSSION

Post-operative care for lung transplant recipients is a very critical phase in transplantation process. There are two major concerns about these patients: first, acute rejection that can threaten their lives and second, their greater vulnerability to opportunistic infections. Measuring pulmonary function parameters plays a vital role in follow-up of lung transplant recipients (1,6,16). Sensitivity of

FEV1 for detection of complications of heart-lung and bilateral-lung transplant recipients has been stated to range from 60 to 75% in the previous studies (12). Furthermore, as reported by Martinez and colleagues, declines of >/= 11% in FVC or 12% in FEV1 were related to allograft dysfunction due to infection or rejection in heart-lung and bilateral-lung transplant patients (17). During the recent years, home spirometry has been considered as a practical tool in this regard (5,10,13-18) . Since the burden of using home spirometry in limited resource setting must have a logical justification (19), the present study was designed to evaluate the affordability and feasibility of home spirometry and assess its power in early detection of complications in lung transplant patients. Our study showed that home spirometry is a reliable device for measuring pulmonary function and Iranian lung transplant recipients have good adherence to this method. Our pilot study also showed that home spirometry in Iranian patients can detect lung transplantation complications earlier than routine workup and with considerable reliability and patient satisfaction. These findings illustrate that if we use home spirometry for lung transplant recipients we can reduce the total burden of lung transplantation on the health care system.

Initially, pulmonary function data from the portable spirometer were compared with those obtained from an office-based spirometer. Our study showed a good correlation between the results of home spirometry and office-based spirometry, which is comparable with other studies. Morlion and colleagues found only a slight difference (114 ml) between home values and hospital values of FEV1 (12). Lindgren and coworkers also reported a tiny (120 ml) difference among spirometry measurements at home and clinic (14). Meanwhile, similar to the findings of the latter study (14) and another research conducted by Finkelstein and coworkers (20), our participants also proved that they have the ability of learning and performing spirometry properly by themselves at home. These findings suggest that we can trust home spirometry as a reliable tool for assessing pulmonary function in lung transplant recipients.

The next step was to evaluate adherence of patients to the home spirometry in the first 6 months after discharge from hospital. One of our cases used home spirometry on a regular daily basis and sent the results to the research group as predicted and an adherence of 80% was calculated for him. In the second case, which was not as punctual as the first one, we also observed % 61 adherences to home spirometry. Although if he had not have problem with internet connection, he might have shown a higher rate of adherence. These findings are comparable with other studies. In Belgium, Morlion and coworkers achieved average adherence of 55% for two measurement sessions a day and 84% for one measurement session daily (12). Finkelstein SM and colleagues reported 82% adherence for sending spirometry data once a week (21). Another noticeable point in this regard which was completely similar to the results of above-mentioned studies was the decreasing trend of patient adherence with the passing of time. While Sabati and colleagues indicated poor health status, laziness and time conflict as barriers to adherence in their research (11), being time consuming and problem in internet access were the major setbacks for patient adherence in our study. One bright aspect of using home spirometry and daily check of its result is that the care givers can have a close observation of the patients and if the lung transplant recipients do not send the routine results they can contact them and follow any possible unexpected events. This kind of close contact is also stated to be a beneficial factor in promoting adherence by Chlan and coworkers (22).

As the main goal of this study, we determined the power of home spirometry in early detection of complications. In our study, one episode of H1N1 flu was detected by evaluating a drop in FEV1 (around 10%) 3 days before beginning of symptoms and routine workup in one of our cases. It has been stated by Bjørtuft and colleagues (23) that FEV1 and FVC in home spirometry decrease significantly during rejection and help in early detection of rejection episodes. Similarly, Otulana et al. reported FEV1 and FVC decline during episodes of lung

rejection and opportunistic infections (10.4%, 9.3%, and 12.8%, 12.5%, respectively) (24). Since, for lung transplant recipients early intervention is an important part of treatment, detecting such life threatening conditions is priceless. Considering the potential life threatening menaces of each episode of infectious disease for lung transplant recipients, the role of such device, that can detect complications, becomes obvious.

Our study also showed that the lung transplant recipients who used home spirometry faced significantly less complications and were diagnosed earlier than other lung transplant recipients who had recurrent check-ups in the hospital. We compared the follow up results of two matched control patients and found that one of our patients was diagnosed with tuberculosis and the other had experienced several episodes of pulmonary infection during the first 6 months of follow up. In the first patient, the most important point was that several follow up visits to the hospital must have been the major cause of contracting tuberculosis and that it would have been prevented by reducing the in-hospital visits. The other point was that the time lost between onset of symptoms and patient referring to the hospital was about two weeks, as expressed by the patient, which might have been shortened if home monitoring had been implemented. Regarding the other patient, it was obvious that if home monitoring had been used, recurrent episodes of pulmonary infection would have been diagnosed earlier, patient might have been treated as out-patient and therefore, exposure to other contagious diseases in the hospital environment would have been prevented.

Eventually we evaluated the satisfaction of patients in working with home spirometry. All patients were eager to use such system in the future and felt safer while being in close contact and under direct supervision of the transplant team. In addition, the patients indicated that it was important for them to know that their results could be reviewed in the medical center by a professional staff on a regular basis.

This pilot study was designed to provide a basic ground for implementing home spirometry for the follow-up of lung transplantation. However, there were some limitations. As the number of lung transplant recipients in Iran is limited, results of the small sample size of this study may not be generalizable to all the patients in this category. Furthermore, based on the nature of lung transplantation, consequences in each patient are unique; therefore, finding the actual underlying cause of each complication needs further studies. Additionally, it is apparent that application of this method to a broader number of patients is a costly process; and precise estimation of cost-effectiveness of this technology and also determining the role of government and insurance in funding is crucial. Much work also remains to be done to evaluate the problems of internet connection between patients and health professionals and to strategize some plans so as to improve the present status.

In conclusion, our study showed that home spirometry monitoring is feasible and reliable for lung transplant recipients. Pulmonary function parameters collected by this portable spirometry device and without professional supervision were valid and comparable to those collected by the standard device at the spirometry laboratory of the hospital. In addition, the patients were satisfied with the method and were willing to cooperate in the future. But in order to include this method in lung transplantation follow up protocol of our country, future studies with a larger number of patients and using better communication methods are essential.

Acknowledgements

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