The role of integrated home-based care in patient adherence to antiretroviral therapy

O papel da assistência domiciliar integrada na adesão do paciente à terapia anti-retroviral

Neil Gupta¹, Angela Caulyt Santos da Silva² and Luciana Neves Passos²

ABSTRACT
Non-adherence is one of the primary obstacles to successful antiretroviral therapy in HIV+ patients worldwide. In Brazil, the Domiciliary Therapeutic Assistance is a multidisciplinary and integrated home-based assistance program provided for HIV+ patients confined in their homes due to physical deficiency. This study investigated ADT’s ability to monitor and promote appropriate adherence to ARV therapy. Fifty-six individuals were recruited from three study groups: Group 1 - patients currently in the ADT program, Group 2 - 21 patients previously treated by the ADT program, and Group 3 - 20 patients who have always been treated using conventional ambulatory care. Using multivariable self-reporting to evaluate adherence, patients in the ADT program had significantly better adherence than patients in ambulatory care (F = 6.66, p = 0.003). This effect was independent of demographic and socioeconomic characteristics as well as medical history. Patients in the ADT program also showed a trend towards greater therapeutic success than ambulatory patients. These results suggest the incorporation of characteristics of ADT in conventional ambulatory care as a strategy to increase adherence to ARV therapy.


RESUMO
O sucesso da terapia antiretroviral depende da adesão ao tratamento. A Assistência Domiciliar Terapêutica é um programa de atendimento multidisciplinar a pacientes com HIV/AIDS e com dificuldades de se deslocar para atendimento ambulatorial. Este estudo compara a adesão de pacientes ao esquema ARV em um programa ADT com aqueles em tratamento ambulatorial convencional. Foram estudados: Grupo 1 - 15 pacientes no programa de ADT, Grupo 2 - 21 pacientes em tratamento ambulatorial convencional, Grupo 3 - 20 pacientes em tratamento ambulatorial convencional que nunca freqüentaram o programa ADT. Os pacientes inscritos no programa ADT apresentaram significativamente maior adesão ao tratamento do que pacientes ambulatoriais (F = 6.66, p= 0,003). Os resultados observados não foram influenciados pelas características demográficas, características socioeconômicas, ou histórico médico. Pacientes em programa de ADT também mostraram uma tendência a melhor resposta terapêutica do que os ambulatoriais. Este estudo sugere a utilização das características do ADT como estratégia para melhorar a adesão à terapia antiretroviral.

Palavras-chaves: Terapia antiretroviral. HIV. Adesão ao tratamento. Assistência domiciliar.

One of the main obstacles to successful antiretroviral (ARV) treatment of HIV/AIDS patients worldwide is patient non-adherence to the treatment regimen. Previous studies report that 60 to 69% of patients in Brazil comply with ARV therapy, a percentage considered insufficient to control the epidemic. Non-adherence has been found to be associated with negative clinical outcome in terms of blood viremia, CD4 cell counts, patient survival, and is largely responsible for the emergence of drug resistant forms of the virus. The predictive value of economic and sociodemographic characteristics is controversial, with some studies reporting the association of age, race, income, education, and health knowledge with adherence. Social and psychological aspects have also been implicated in determining adherence to treatment.
Other studies, however, have provided compelling evidence that the quality and characteristics of health services are a greater determinant to adherence than patient or treatment characteristics. Some authors have suggested that in order to increase adherence, health care providers should consider treatment strategies that place a greater emphasis on individual circumstances, lifestyle, social support and home life. Various HIV/AIDS programs have implemented home-based care, either within or outside the traditional health care system, to support these proposals for personalized and integrated health care settings. One such program, denominated Domiciliary Therapeutic Assistance (ADT) has been implemented in the state of Espírito Santo, Brazil.

ADT is a fully integrated service that utilizes a multidisciplinary health team, consisting of a doctor, nurse, social worker, physiotherapist, and psychologist, to meet the needs of HIV+ patients confined within their homes. Patients who present physical deficiency that makes it impossible for them to seek conventional care in hospital/ambulatory care settings, are referred to the ADT program by various units in the public health system, primarily after hospital discharge. As many of these patients have previously demonstrated problems with treatment adherence and often present greater difficulties in continuing with medication, it is important to assess the effectiveness of this form of care in promoting and monitoring appropriate adherence.

The present study explores the role of the ADT program on patient adherence to ARV medications. A multivariable indicator of adherence, taking into account patient self-reports, last treatment missed, and the frequency of individual difficulties over the past year, is used to compare adherence between patients under care of the ADT program and those receiving conventional ambulatory care services.

MATERIAL AND METHODS

Sixty subjects recruited for the study were divided into three groups: Group 1 – patients currently enrolled in the ADT program (current ADT), Group 2 – patients who were previously enrolled in the ADT program but subsequently discharged to seek treatment in conventional settings after showing significant improvement in physical ability (past ADT), and Group 3 – patients who had never been enrolled in the ADT program (non-ADT) and seek treatment at the Ambulatory Care Service of the University Hospital Cassiano Antônio Moraes, a large reference hospital in Vitória, Brazil. Patients from the ADT program were admitted to the program based on physical or psychosocial requirements, rather than by voluntary inscription. Additionally, no subjects in the non-ADT group had previously qualified or been offered ADT services. All subjects were HIV+, at least 18 years of age, not pregnant, and had been prescribed ARV therapy for at least three months over the previous year. All subjects were receiving ARV medications provided free of charge by the Brazilian health services.

Subjects were interviewed in their home or at the hospital. Subjects from the non-ADT group were randomly selected from the daily agenda of consultations in the ambulatory center by a random number generator. These subjects, therefore, were selected independent of order of arrival or adherence to scheduled appointments. All were requested to participate in the study before or after their regular consultation, and signed an informed consent form approved by the Institutional Review Boards of the Centro Biomédico of the Universidade Federal do Espírito Santo (Vitória, BR) and Duke University (NC, USA).

All interviews were conducted by the same interviewer in reassuring, comfortable locations with minimal distraction. If the subject was considered incapable of completing the interview independently, care providers were requested to assist in accurately completing the interview.

The questionnaire used for the interview solicited personal data, patient self-rating of adherence (0-6 rating), recall of last dose missed (0-4 rating), reasons for failing to take medications (0-3 rating for each of 20 possible reasons), dates and reasons for abandonment, and opinions on health care services. Medical history, including diagnoses, medications, and exam results, were obtained from patient charts following the interview. The CDC Guidelines for Using Antiretroviral Agents Among HIV-Infected Adults and Adolescents assert that viral load is a more reliable indicator of therapeutic success than CD4 cell counts; therefore, this study defined successful therapy as an undetectable viral load (<400 copies/ml) in the most recent viral load test, reported at least three months after initiation of treatment.

Patient adherence to prescribed ARV medication was assessed by calculating the patient's Compliance Score. Compliance Score being the sum of the self-rating for adherence (0 a 6 = never miss à always miss/abandonment), last dose missed (0 a 4 = never à today), and frequency of missed treatment due to each of twenty possible reasons (0 a 3 = never miss à frequently miss). Using this formula, a Compliance Score of 0 indicates perfect adherence, with 70 being the highest possible non-adherence score. (Subjects who had abandoned treatment at the time were still asked for reasons why they missed treatment during the period that they were taking medications over the last year. The most compliant possible score for these subjects was 10).

Statistical analysis was completed by k-way ANOVA with Tukey HSD and Bonferroni post-hoc tests for numerical comparisons and Kruskal-Wallis test for nonparametric comparisons.

RESULTS

Demographic and socioeconomic characteristics. A total of 56 subjects participated in the study (three selected subjects were unable to be interviewed, one subject was pregnant and excluded from the study). The mean age was 41.5 years and 62.5% were male and 37.5% female (Table 1).

Regarding educational level, 16.1% had a secondary school education, 19.6% elementary school education, 44.6% had an incomplete elementary school education, and 16.1% no...
formal education. Average household income was 532 reais per month (approximately US$169). On average, the subjects lived with 3.7 other family members, and 44.1% reported having a primary care provider that helps them with their ARV treatment. These care-providers were most often mothers and spouses, but also siblings, in-laws, children or hired workers. No demographic or socioeconomic characteristic showed significant association with Compliance Score or clinical outcomes. Only percentage of subjects reporting having a primary care provider was significantly associated with study group (p = 0.031).

Medical histories. Of all subjects, 30.4% had lived less than two years with a positive diagnosis for HIV, 60.7% for less than 4 years, and 91.1% for less than six years (Table 1). The most common opportunistic and co-infections among these subjects were toxoplasmosis (35.7%), tuberculosis (30.4%), candidiasis (23.2%), cytomegalovirus (12.5%), herpes virus (12.5%) and hepatitis C (12.5%). Half of all subjects were undergoing a treatment regimen of nucleoside analogue reverse transcriptase inhibitors (NRTIs) in combination with protease inhibitors (PIs), 29.6% of subjects NRTIs with non-nucleoside reverse transcriptase inhibitors (NNRTIs), 5.6% NNRTIs with PIs, 1.9% of subjects NRTIs only, and 13% triple-therapy consisting of all three categories of medications. None of these medical factors were significantly associated with Compliance Score or clinical outcomes.

Clinical outcomes. Overall, 49.9% of subjects exhibited successful therapy (also referred to as successful clinical outcome) as demonstrated by undetectable viral load results (Figure 1). Successful clinical outcome was seen in 57.1% of current ADT patients, 47.6% of previous ADT patients and 45% of non-ADT subjects. There was no significant association between study group and clinical outcome.

Adherence to ARV treatment. The overall mean Compliance Score was 8.27, with values ranging from 0 (perfect adherence) to 39. The mean Compliance Score for current ADT patients was 4.0, for previous ADT patients 6.76, and for non-ADT patients 13.05 (Figure 1). Compliance Score differed significantly between current ADT and non-ADT subjects (F = 6.66, p = 0.003) and between previous ADT and non-ADT subjects (p = 0.029). Compliance Score was not significantly correlated with clinical outcome.

Adherence difficulties/abandonment. Of the subjects interviewed, 23.2% had previously or currently abandoned ARV therapy - 20% of ADT patients, 20% of previous ADT patients, and 30% of non-ADT patients (Table 1). There was no significant difference among these groups. The most frequently reported reasons for missing treatment were away from home (46%), forgetting (32%), medications ran out (32%), side-effects/ sick (29%), and sleeping (27%). These reasons were reported evenly across the three study groups.

Patient preferences/opinions. The approval rating of ADT services by current and previous ADT patients was 97% compared to 83% for ambulatory care. Among 33 subjects who had experienced both ADT and ambulatory care services, 69.7% preferred the ADT service, 15.2% preferred ambulatory care, and 15.2% had no preference.

DISCUSSION

Home-based care has been used to personalize care in a wide variety of health fields, including HIV/AIDS care, not only to provide improved assistance for patients but also to reduce burdens on overcrowded and under resourced health systems. However, the effect of these programs on treatment adherence has yet to be established. According to the ADT Guide for Procedures in HIV/AIDS, one of the principle objectives of the ADT program is to promote the improvement of treatment
adherence of HIV/AIDS patients\(^2\). The present study is the first to confirm the success of ADT in achieving this objective.

Adherence among patients in the ADT program was significantly better than patients who were treated with conventional ambulatory care and had never been under the care of the program (\(F = 6.66, p = 0.003\)). Adherence among subjects who had previously been in the ADT program but were now under conventional care was between these two groups and also significantly better than non-ADT subjects (\(p = 0.029\)). These effects were independent of demographic, socioeconomic, and treatment characteristics, all of which were found not to be significantly associated with adherence.

Studies have traditionally used self-report as the primary tool to assess patient adherence, using measures such as self-report, recall of last-dose missed, or report of pills missed in past three days. Self-report, although thought to overestimate true adherence, has been demonstrated to be a reliable measure of adherence and is more readily available than alternative techniques such as pill counts, electronic monitoring, and prescription refill logs\(^10\). All existing studies establish a cut-off point, such as 80% of pills taken in past three days or self-ratings of 80% adherence, to categorize subjects as adherent or non-adherent\(^5\). Such measurements, however, greatly oversimplify the definition of adherence, establish an arbitrary threshold for adherence, and rely on very little data to determine adherence. The Compliance Score used in this study is unique as it includes responses to all traditionally used self-report measures, as well as incorporating the frequency of missing treatment due to specific adherence obstacles, to create a continuous measure of adherence rather than dividing subjects into discrete adherence categories.

Patients in the ADT program also displayed a higher rate of therapeutic success (57.1%) against non-ADT patients (45%). Whereas this difference was not statistically significant, the trend towards therapeutic success reflects ADT’s effect on adherence (Figure 1). Although this trend is apparent as an overall effect, clinical outcome was not directly correlated to adherence within individual patients. This suggests that therapeutic success is not a one-dimensional or highly predictable outcome purely dependent on patient adherence. In addition to patient adherence, the rate at which viral load declines toward undetectable levels is affected by the baseline CD4\(^+\) T cell count, initial viral load, potency of drug regimen, previous exposure to ARV agents, opportunistic infections, drug resistance, and malabsorption\(^4\).

The most frequently reported reasons for failing to adhere to treatment regimen were away from home, forgetting out of medications, side effects/ feeling ill and sleeping. The success of the ADT program in promoting patient adherence to ARV therapy, as compared to conventional ambulatory care, can be attributed in part to the service’s ability to assist patients to overcome such obstacles to adherence. Therapeutic and integrated home-based care promotes an extended relationship established between health care team and patient. Furthermore, it offers greater attention for family and community members, allowing for closer monitoring of patient needs, in terms of medical attention, medications, physiotherapeutic equipment/ rehabilitation, and social and psychological support. Additionally, in concentrating therapy and rehabilitation within the home, this form of assistance establishes primary care providers within the home or community, fortifying the patient’s immediate social support network and greatly increasing personal attention received by the patient in the daily adherence to ARV therapy. This fact is apparent in the high percentage of ADT patients (73%) reporting being cared for by a primary care provider as compared to non-ADT patients (30%). The advantages of the ADT program are apparent in patient opinions as well, since 97% of patients approved of its services and 69% preferred the service over ambulatory care.

The Brazilian Ministry of Health reports that in the year 2000, the Brazilian government spent approximately $332 million on the provision of high-cost ARV medications, or $4,137 per patient. In light of the success of ADT to monitor and promote patient adherence, the costs of the extended resources of integrated home-based care would likely be justified as a cost-effective measure via the more effective allocation and use of these medications. This preliminary study justifies larger, more comprehensive adherence studies in the future, which would include in-depth analysis of unsuccessful therapy (infections, death and total non-adherence), confirmation of self-report methods with an alternative measure of adherence (i.e., pill counts), examination of further HIV care settings in Brazil (reference centers, day hospitals, non-profit homes), and extensive cost-benefit analyses.

Considering both therapeutic and public health advantages, we recommend that home-based care for physically deficient HIV/AIDS patients by multidisciplinary teams be considered as an important and valuable alternative to conventional ambulatory and hospital care. Furthermore, characteristics of the ADT program, such as increased attention and support by health care professionals, integrated health care services, and strengthened social network for the patient, should be incorporated into the practice of conventional HIV care as a means to increase all patients’ adherence to ARV therapy.

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REFERENCES


