

EFFICACY OF A COUNSELLING INTERVENTION ON ADHERENCE TO HAART : RESULTS OF A FRENCH PROSPECTIVE CONTROLLED STUDY

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INTRODUCTION

HIV-infected patients' inadequate adherence can have profound negative implications for the individual and public health effectiveness of Highly Active Antiretroviral Therapies (HAART). Because physicians, even those with the greatest experience of HIV care, may have diverse ways of communicating with patients regarding adherence, formalised educational interventions to improve patients' adherence to HAART have been highly recommended. Attempts to evaluate such interventions have however been limited. In a prospective, controlled, randomised study carried out in a sample of

HAART-treated patients from a French hospital, we tried to evaluate the impact of a counseling intervention, provided by specially trained nurses, on both measurement of adherence and virological outcomes. We hypothesized that a HIV medication adherence counseling intervention addressing the determinant factors affecting adherence would impact on the psychological processes of participants which in turn will lead to improvements or renewals in their self care management strategies and adherence to HAART.

MATERIALS AND METHODS

✓ The counselling programme

The study population consisted of HIV-infected patients who had a medical follow-up consultation at the Nice University Hospital (South-Eastern France) between September and December 1999 and who fulfilled the following eligibility criteria at enrolment : being treated, since at least one month, by a combination of at least one Protease Inhibitor (PI) or one Non Nucleoside Retrovirus Transcriptase Inhibitor (NNRTI) or Abacavir with two Nucleoside Retrovirus Transcriptase Inhibitors (NRTI), being 18 years of age or more, not requiring an hospitalisation and not being included in another protocol. Patients were randomised in an intervention group (IG) and a control group (CG) who both received the usual clinical follow-up, and were offered similar questionnaires at enrolment (M0) and 6 months later (M6). In addition, the intervention group benefited from an educational program including three counseling sessions, one immediately following enrolment (M0) and every 2 months (M2, M4).

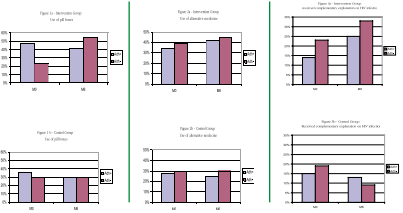
✓ Design and implementation of the intervention

As the randomised research framework necessitated standardization of the counseling intervention, we prepared a manual for nurses and wrote intervention scripts for five individually-delivered sessions organized into modules with components targeting cognitive, emotional, social and behavioural determinants affecting adherence. For each session we described its purpose, its goals and edited a guidelines built as a step-by-step guide designed to help nurses in delivering the counseling sessions. Questionnaires and other materials were also designed to help the nurses to record the key features of the sessions, including evaluation of the participant's needs, referrals made and follow-up on prior referrals and keep track of the tasks they were to perform during the sessions.

Before the implementation of the intervention the four nurses, attended a five day intensive training focused on adherence theories and on the learning of basic counseling skills followed by a monthly supervision session where issues and difficulties encountered by the nurses were identified, discussed and followed by proposed potential solutions.

RESULTS

- ✓ 123 patients in the Intervention and 121 in the Control group were compared.
- ✓ Table 1 shows that no significant difference was found between both groups at M0 for socio-demographic, biological and clinical as well as treatment characteristics.
- ✓ In the Intervention group, 67 (54%) patients had followed all three counseling sessions, while 56 (45%) had only partly followed the program.
- ✓ The proportion of those who were adherent was similar in both groups at M0 (58% vs 63%, p=0.59), while it became significantly higher in the intervention group at M6 (75% vs 61%, p=0.04), the increase in the proportion of adherent patients being significant in the intervention group (Mc-Nemar test, p=0.02). It must be noted that among the 122 patients who were initially adherent at M0, the proportion who remained adherent at M6 was higher in the intervention group (88% vs 69%, p=0.02), while among the 80 initially non-adherent patients, the proportion of those who became adherent at M6 was not significantly different (57% vs 47%, p= 0.52). It must also be noted that in the intervention group, the proportion of adherent patients at M6 was significantly higher among the 59 patients who had received all three counseling sessions (83% vs 63%, p= 0.05).
- ✓ The analysis of the determinants affecting adherence found that patients received more information on HIV regimen in the IG (p=0.04), developed specific skills in their daily routines, were more likely to use pill boxes (p=0.05). The IG followed dietary regimen (p=0.06) and got more involved in health care holistic approaches (complementary medicine services, relaxation, massages,...) (p=0.05). No difference was found between IG and CG regarding scores of depression, use of family networks, negative emotional effects of adverse events such as lipodystrophies.



DISCUSSION

- ✓ The study brings evidence of the efficacy of a structured counseling intervention to enhance adherence to HAART, and illustrates that a counseling intervention has an impact on the abilities of HIV people to develop self-care management skills. Our results correspond to the "real life" situation that most clinical settings delivering HIV care would encounter if they introduce formalised educational interventions about adherence.
- ✓ The intervention was more effective in the subgroup of patients who completed the three planned counseling sessions and in helping initially adherent patients to maintain this behaviour during follow-up rather than in modifying non adherent behaviours. Moreover, no difference was found between IG and CG regarding scores of depression, use of family networks, negative emotional

In order to assure the quality of the intervention, a clinical supervisor was assigned to review regularly sample of the counseling sessions and the psychologists trainers also assisted nurses on an individual basis by summarizing observation of several counseling sessions documenting nurse-counselor's communication, counseling skills and completion of the required activities.

✓ Counseling Approach

The counseling approach was founded on principles of motivational psychology client-centered therapy and the use of an empathic therapeutic style and of strategies to enhance strategies to enhance participants self-efficacy and skills. The contents of the counseling scripts were based on the consistent findings about the identification of cognitive, emotional, social and behavioural determinants affecting adherence.

✓ Evaluation

The endpoints of the study were: proportion of patients achieving an adherence level of 100% at M6, evolution in viral load (VL) between M0 and M6 and percentage of patients achieving plasma HIV-1 RNA levels < 40 copies/ml at M6.

✓ Data collection

At M0 and M6, in-depth data about patients' characteristics and self-reported adherence to HAART were collected by means of a self-administered questionnaire, which was filled out by the patient apart from any member of medical staff. Adherence measurement was based on five different questions accordingly to the methodology established by the AIDS Clinical Trial Group, which has already been validated in the French context.

✓ Data analysis

The intervention and the control groups were compared at M0 and M6 using a Chi-square test for categorical variables including adherence measurement. A Student t-test or a Mann-Whitney test was used when comparing continuous variables such as VL. Evolutions of adherence and VL between M0 and M6 in each group were assessed by a Wilcoxon rank sum test or a Mc-Nemar test. Statistical analyses were performed using SPSS (Carry, Inc. 9.0).

Table 1: Baseline characteristics of HAART-treated patients included in a prospective, controlled study for evaluation of a counseling intervention to increase adherence (n=244, South – Eastern France)

	Intervention group (n=123)	Control group (n=121)	p
Median age [IQR]	39.8 [35-49]	38 [36-45]	0.26 ¹
Gender			
Male	87 (71%)	91 (75%)	
Female	36 (29%)	30 (25%)	0.52 ²
HIV-infected by injecting drug use			
Yes	40 (33%)	35 (29%)	
No	83 (67%)	86 (70%)	0.64 ²
High school certificate			
Yes	41 (32%)	36 (29%)	
No	81 (66%)	85 (70%)	0.61 ²
Mean plasma HIVRNA (log copies/ml) [SD]	2.70 [1.23]	2.63 [1.13]	0.60 ³
Median CD4 cell count/mm ³ [IQR]	340 [170-576]	361 [214-502]	0.59 ³
CDC Clinical Stage			
A	65 (53%)	54 (44%)	
B	19 (15%)	33 (26%)	
C	39 (32%)	36 (29%)	0.14 ²
HAART regime			
Protease inhibitors + 2NRTI	102 (83%)	97 (80%)	
NNRTI + 2NRTI	17 (14%)	20 (17%)	
3 NRTI	4 (3%)	4 (3%)	0.84 ²
Antiretroviral naive before HAART initiation			
Yes	34 (28%)	35 (29%)	
No	89 (72%)	86 (71%)	0.94 ²
Median duration of HAART [IQR] (months)	28.6 [18.7-35.7]	26.1 [15.6-33.7]	0.20 ³

¹ Mann-Whitney test; ² Student t-test; ³ chi-square test

- ✓ Table 2 also presents the results of an "intent-to-treat analysis" (all patients whether or not assessment of adherence was available and whether or not they followed the whole three sessions in the intervention group) comparing virological outcomes.

Table 2: Evolution of adherence and virological outcomes at 6 months follow-up in HAART-treated patients included in a prospective, controlled study for evaluation of a counseling intervention to increase adherence (n=244, South – Eastern France)

	Intervention group (n=123)	Control group (n=121)	p
Total sample (n=244)			
EVOLUTION OF ADHERENCE	N (%)	N (%)	
Adherent M0	58 (58%)	64 (63%)	0.59
Adherent M6	75 (75%)	62 (61%)	0.03
VIROLOGICAL OUTCOMES			
Mean difference of VL between M6 and M0 (log copies/ml) [SD]	-0.12 [0.86] ^a	+ 0.12 [0.90] ^a	0.002 ^b
Sub-sample of patients with HIV-RNA > 40 copies/ml at M0 (n=146)	Intervention group (n=73)	Control group (n=73)	p
Mean difference of VL between M6 and M0 (log copies/ml) [SD]	-0.48 [0.96] ^a	+ 0.15 [1.13] ^a	0.001 ^b

^a p=0.03; ^b p=0.14; ^c p=0.001; ^d p=0.25 (Wilcoxon Rank Sum test)

^a test; ^b chi-square test

effects of adverse events such as lipodystrophies. This may be partly due to the specific design of our intervention. Psycho-social research had already pointed out the dynamic character of HAART-treated patients' adherence behaviors which are influenced by multiple factors varying overtime. Because the follow-up period of our study was limited to six-months, the impact of educational interventions on adherence needs further longer term investigation.

- ✓ In spite of its limitations, our study brings clear evidence in favour of the feasibility and efficacy of counseling interventions to increase adherence to HAART that could be easily implemented, with limited additional resources, in most clinical settings.