

A Multicentric Clinical Survey of HIV/Aids Patients submitted to Canova Immunomodulator Treatment Associated with Antiretrovirus Medicaments

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Introduction

The acquired immunodeficiency syndrome (Aids) was described for the first time in the beginning of the 80's, characterized by deep immunosuppression, with several clinical characteristics such as fever, migraines, sore throat with pharyngitis, generalized lymphadenopathy and rash, opportunistic infections, malignant diseases and degeneration of the central nervous system (SNC). HIV/Aids is one, among the several clinical syndromes caused by a retrovirus of the family Lentivirus. HIV affects firstly the T lymphocytes, even the auxiliary T lymphocytes, and the macrophages, as well as the follicular dendritic cells of the lymphonodos ⁽¹⁾.

World statistics

It is estimated that there are more than 35 million people all over the world infected by HIV. From these, 16 million already died, and 3,5 million of them are children ⁽³⁾. The distribution of the cases shows prevalence of America, with 49.5% of the world notifications. The greatest part, 76.1%, concentrates in the United States, followed by Brazil with 10.7%. The second continent in number of notifications is Africa with 35.7% of the world cases, being Uganda and Tanzania responsible for 22% of these notifications ⁽⁴⁾. Currently 25.7 millions of the total number of infected people by the virus are in the African continent, where South Africa stands out, as the most affected country of the world. The disease has provoked, until today, more damages than the wars and the natural catastrophes that already took place in this area. According to reports of ONUSIDA, the patients with Aids in Sub-Sahara Africa, until the end of the year 2000, reached rates corresponding to 70% and 80% of the infected adults and children respectively in the whole world. The Asian continents present 6.5 millions of infected people, while Latin America and Caribbean 1.8 millions, North America 920.000, Eastern and Western Europe 1.3 millions. These given estimates are recent and denote the preoccupying evolution of the disease in the planet. Of the 16 million people who died due to Aids in the world, three-fourth is African. They were 2.4 millions in 2000, and 2.2 millions in 1999, numbers that correspond to 11 times more dead

people than in all the conflicts of the continent in this year (200 thousand deaths), according to Unicef ⁽¹⁰⁾. The data are alarming and they denote a worsening in whole the picture: with 12 million orphans from Aids and with the birth of 70 thousand HIV infected babies every year in South Africa, the continent will get at dramatic rates of mortality during the next years, suffering a great social-economic impact ⁽¹⁰⁾. The Aids virus may devastate the job market in the area of African Sub- Sahara. The workforce will decrease in more than a fifth of the population of some countries in 2020; that is what is pointed on the report of the International Work Organization (OIT). Most of the infected people have no access to the drug cocktail, what makes the disease far better controllable in the patients of the more developed countries ⁽⁵⁾.

In Brazil, according to the last study of Ministry of Health, it is estimated that 560.000 people are infected by the HIV virus (14 years old and older) ⁽⁶⁾. It is also reported by the Ministry of Health, according to diagnoses done during 1980-2000, the number of cases of Aids, in States such as São Paulo, Minas Gerais and Paraná is 92.652, 11.992 and 8.068, respectively ⁽⁸⁾.

Development mechanisms of the virus

The HIV virus penetrates into the target cell through the intracellular connection of TCD4 lymphocyte and the gp120 of the virus envelope. Then the internalization of the virus and the denudation take place, occurring the reverse transcription of the viral RNA, resulting in the production of the viral genome in the form of double helix DNA. This DNA is inserted into the genome of the host as the pro-virus HIV, by an entegrase enzyme codified by the virus. The cellular activation causes the transcription and the production of viral RNA. The structural proteins are produced and organized and the free HIV viruses are produced by viral germination in the host cell, with subsequent intern organization, by the cleavage of a protein core through a protease enzyme codified by the virus, producing ripe viral particles ⁽⁷⁾.

Treatment

The treatment with anti-retroviral must be started as soon as possible. It is recommended the use of inhibitors of the similar reverse transcriptase of nucleosides as AZT (Zidovudina), Lamivudina, Didanosina, Zalcitabina, Estavudina, Abacavir and Adefovir, inhibitors of the non-similar reverse transcriptase of nucleosides as Delavirdina, Efavirans and Nevirapina and an inhibitor of protease as Indinavir, Nelfinavir, Ritonavir, Saquinavir and Amprenavir. However, those medicines provoke several side effects as anemia, leukopenia, thrombocytopenia, nauseas, alterations of the palate, insomnia, vomits, fatigues, migraine, and lipodystrophy ⁽³⁾.

Canova® consists of a homeopathic medicament, therefore highly diluted, which does not present any toxicity and is indicated in the pathologies where the immunologic system is depressed. The product is characterized by associated dilutions of *Aconitum napellus* + associations, that act as immunomodulators, stimulating the macrophages to develop morphology of activated cell (dispersed cells and big centers of a cell with non-condensed chromatin and many microvillus and pseudopods). These would

stimulate the lymphocytes, thus increasing their cytotoxic power⁽⁹⁾. They don't present any toxicity and any genotype affects to a chromosome level in human lymphocytes⁽¹¹⁾.

General objective

To study the therapeutic action of the immunomodulator Canova® associated with anti-retroviral drugs, through the HIV/Aids patients' clinical evolution, submitted to the treatment in the cities of Belo Horizonte, Campinas, Londrina/Jaguapitã, through the measuring of the following data: viral load, TCD4 lymphocytes.

Specific objective

To evaluate the medicamentous action of Canova® associated with anti-retroviral, as to the weight gaining, life quality, viral load, TCD4 lymphocytes and the occurrence of opportunistic infections during the treatment.

Methodology

Patients

60 patients between the age of 20 and 50 (20 women = 33% and 40 men = 77%) with HIV/Aids in use of anti-retroviral drugs assisted in ambulatorial services, in the cities of Belo Horizonte, Campinas and in the ambulatorial services and in the internments at the House of Support for Drugged People in Londrina/Jaguapitã. Pregnant patients were excluded.

Groups

- **Group 1–**
- Canova® + anti-retroviral analyzed with 06 months of treatment;
- **Group 2–**
- Canova® + anti-retroviral analyzed longer than 06 months.

Dosage

The medicament immunomodulator Canova® was prescribed in the following forms:

- drops V – 10 sub-lingual drops 4 times a day.
- inhalant – 2 inhalations a day.

Discussion

During the two-year-accompanying and clinical evolution, 60 HIV/Aids infected patients were studied using anti-retroviral drugs, associated to the immunomodulator Canova®, distributed according to the following variables: sex, age, risk group, weight gaining, return to the professional or leisure activities, viral load, CD₄ lymphocytes, and the occurrence of opportunistic infections during the treatment.

The patients were divided into two groups

:

- Group 1: Treatment up to 06 months.
- Group 2: Treatment after 06 months.

As to the sex, 20 women (33%) and 40 men (77%), between the age of 20 and 50 were studied, belonging to the following risk groups:

- 24 Homosexuals patient;
- 17 heterosexual;
- 02 for sanguine transfusion;
- 06 consumers of drugs;
- 10 patients not informed.

In relation to the weight gaining, the following original results were found: from the 60 studied patients, 55 (91.5%) patients gained weight, distributed in the following forms:

- Group 1 (Up to 06 months of treatment): 14 patients
- Group 2 (After 06 months): 41 patients

Evidencing that the patients of the Group 2 presented higher weight gaining than the ones of the Group 1.

In relation to the life quality, all the patients with HIV/Aids before the treatment Canova® + ARV, had bad quality of life, compared before and after the study work. During the use of the medicament in study, the return to the professional and leisure activities was observed. From the 60 patients, it was not possible to obtain information whether or not 20 patients returned to their professional activities. Of the 40 remaining patients, 7 (17.5%) came back to the habitual activities, even to work in the first 6 months of the use of the medicament.

33 patients (82.5%) came back to their professional and leisure activities after 6 months.

In relation to the viral load regarding the Group 1:

- 16 had a decrease of the viral load,
- 01 presented increase of the viral load,
- 07 patients, in agreement with the regulations of Ministry of Health, as to the reduction at the same or superior levels of 90% among four to six weeks, presented a very low reduction of the viral load according to the excellence rates of recommended results.
- 05 maintained the viral load unaffected.

Coming to a total of 29 studied patients.

While the patients of the Group 2 (after 06 months of treatment):

- 19 had a decrease of the viral load,
- 08 presented an increase of the viral load,

- 04 presented therapeutic failure,

Coming to a total of 31 studied patients.

Of the 60 patients studied as to the phenotyping CD₄, 25 patients belonged to the Group 1 distributed like this:

- 07 > 300 cells,
- 17 < 300 cells,
- 01 not informed.

While in the Group 2, 35 patients were appraised in the following way:

- 24 > 300 cells,
- 11 < 300 cells.

As for the opportunistic infections analyzed during the treatment, in the Group 1 no patients presented opportunistic infections, while in the Group 2, 02 patients presented opportunistic infections, such as: oral Candidiasis, Simple Herpes and mollusks.

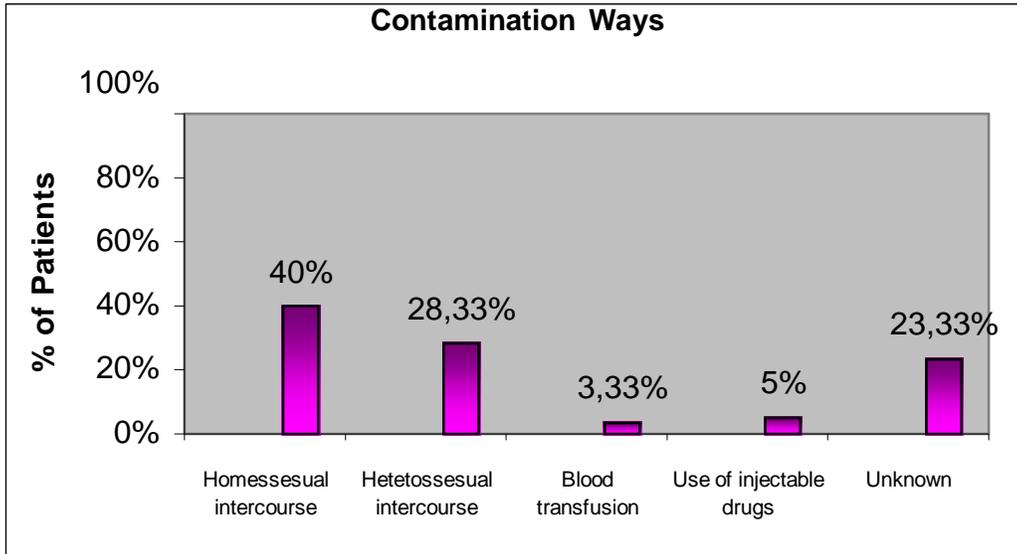
Conclusion

Individuals infected by HIV may have a greater life, associated with an increase in the life quality through his/her reintegration to the society, harmoniously working and spending some time in leisure, with the decrease of the morbidity/mortality, defined by the infection of HIV.

The study work suggests a need of more research in new appraised study works for statistical analyses.

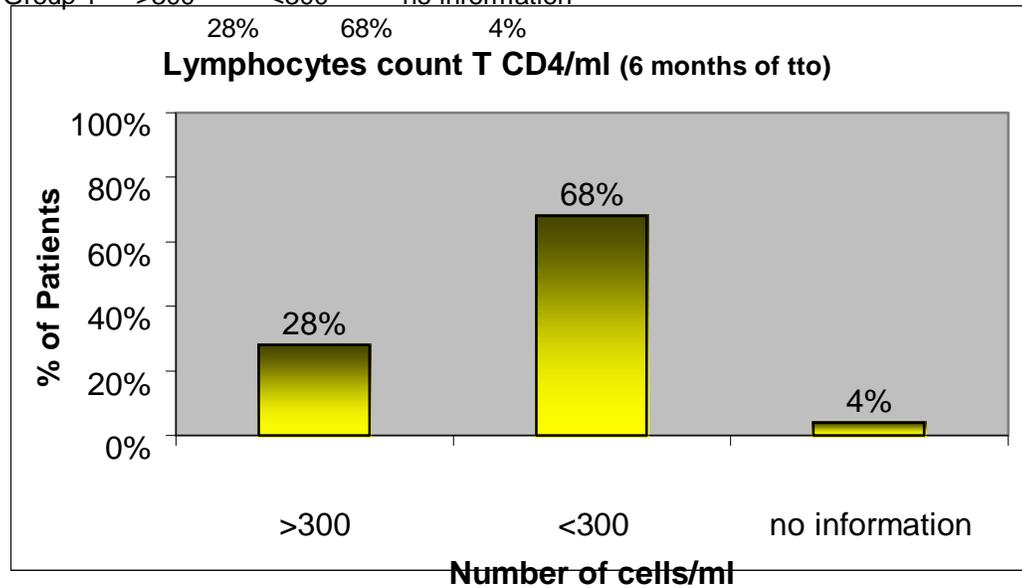
Contamination ways

Homosexual intercourse	40%
Heterosexual intercourse	28,33%
Blood transfusion	3,33%
Use of injectable drugs	5%
Unknown	23,33%

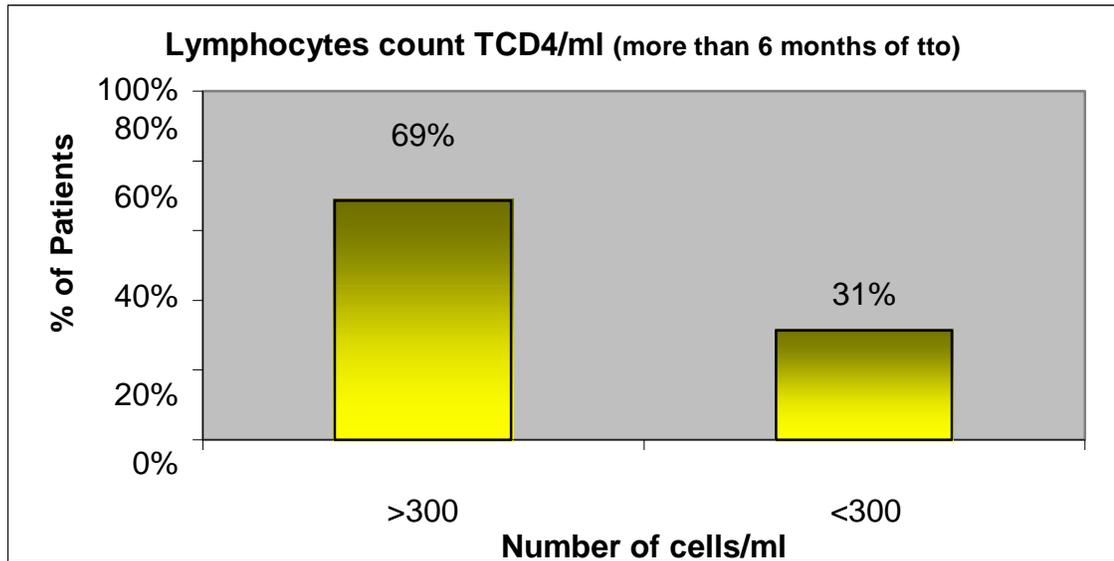


CD4

Group 1 >300 <300 no information

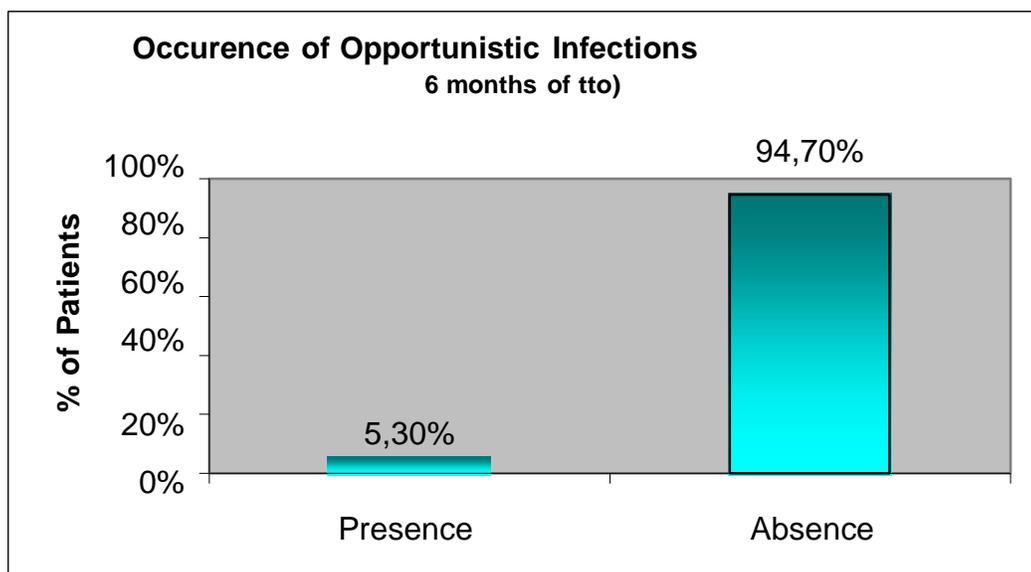


CD4
Group 2 >300 <300
69% 31%

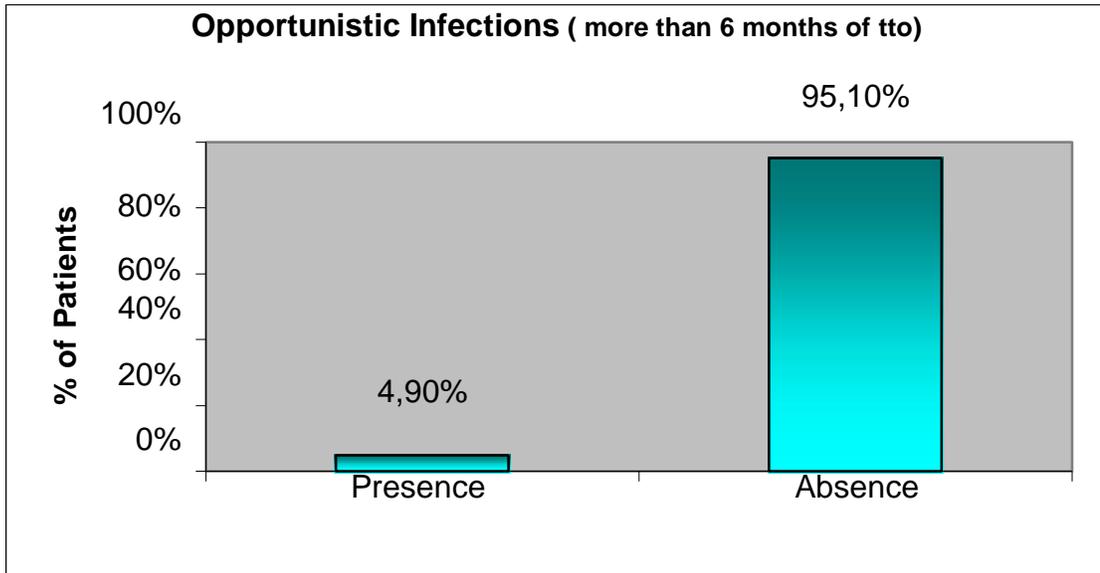


Opportunistic infections

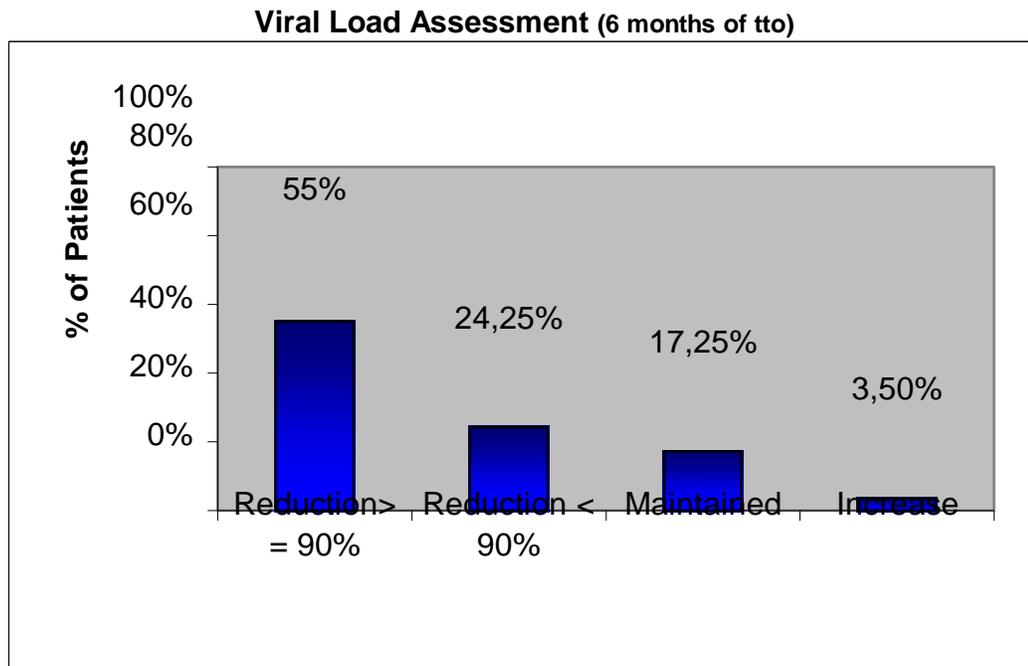
Group 1 Presence Absence
5,30% 94,70%



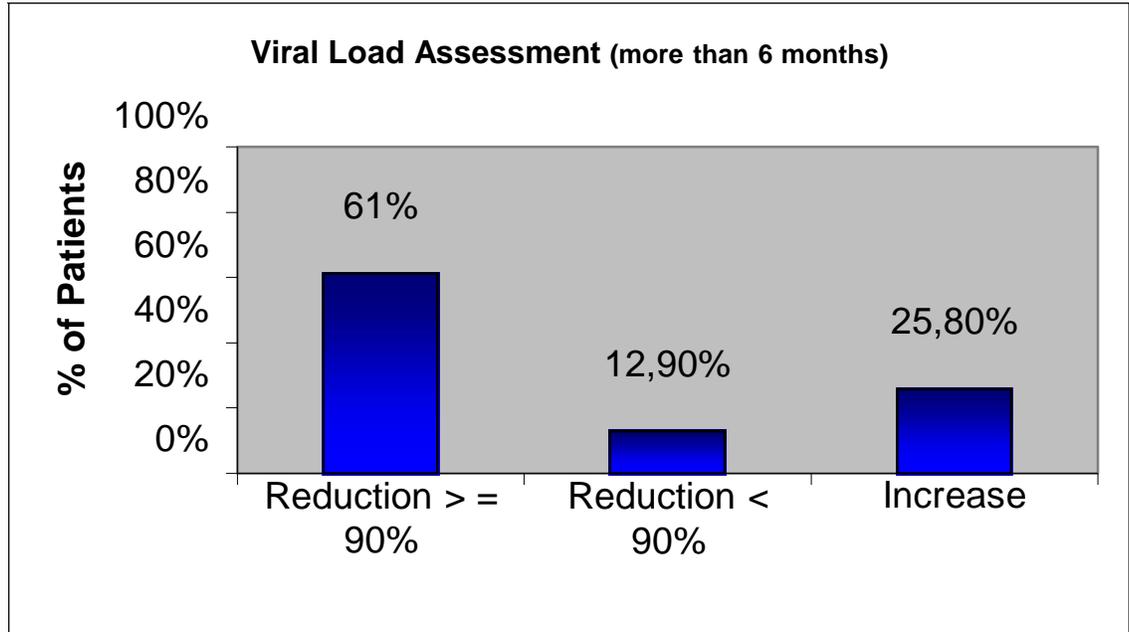
Group 2 Presence Absence
 4,90% 95,10%



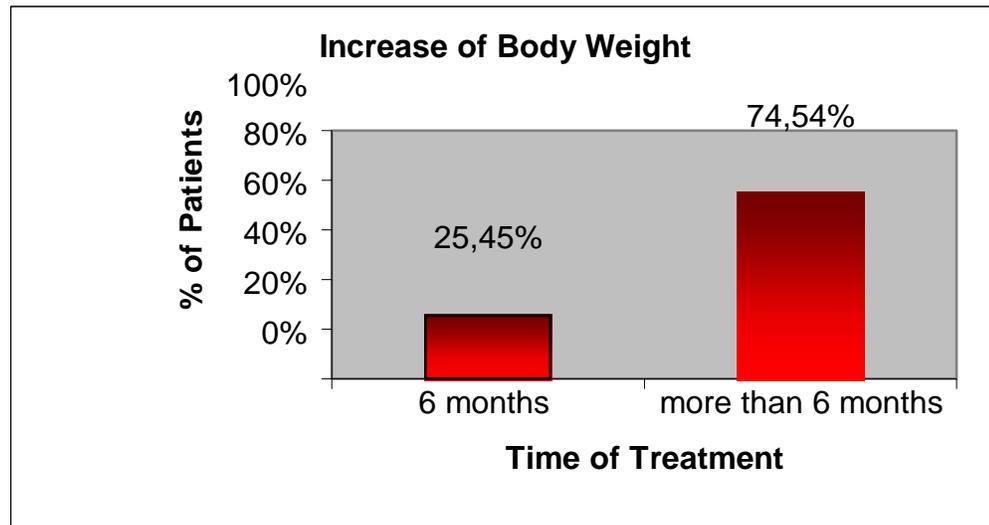
Viral load
 Group 1 Reduction Reduction Maintained Increase
 55% 24,25% 17,25% 3,50%



Group 2	Reduction	Reduction	Increase
	61%	12,90%	25,80%

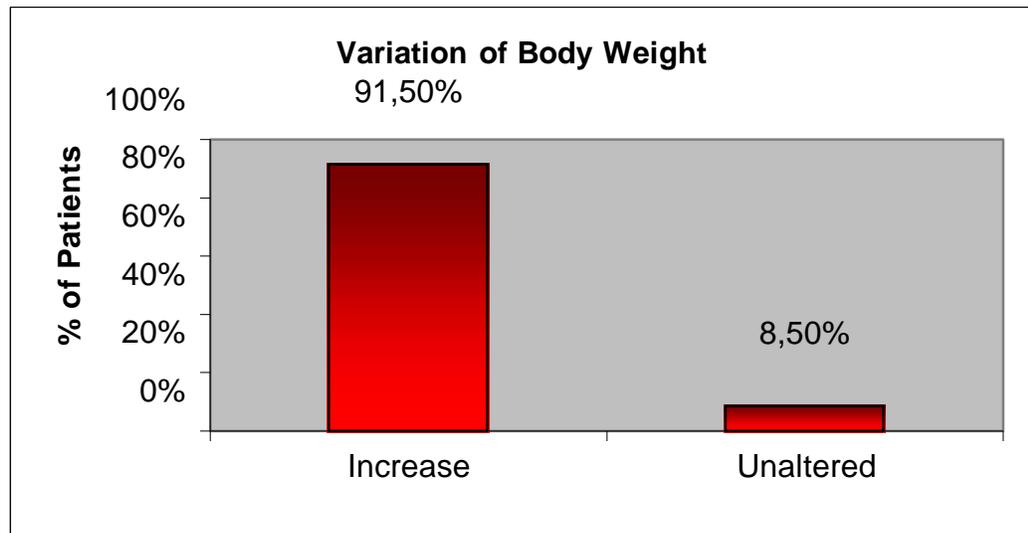


6 months	more than 6 months
25,45%	74,54%



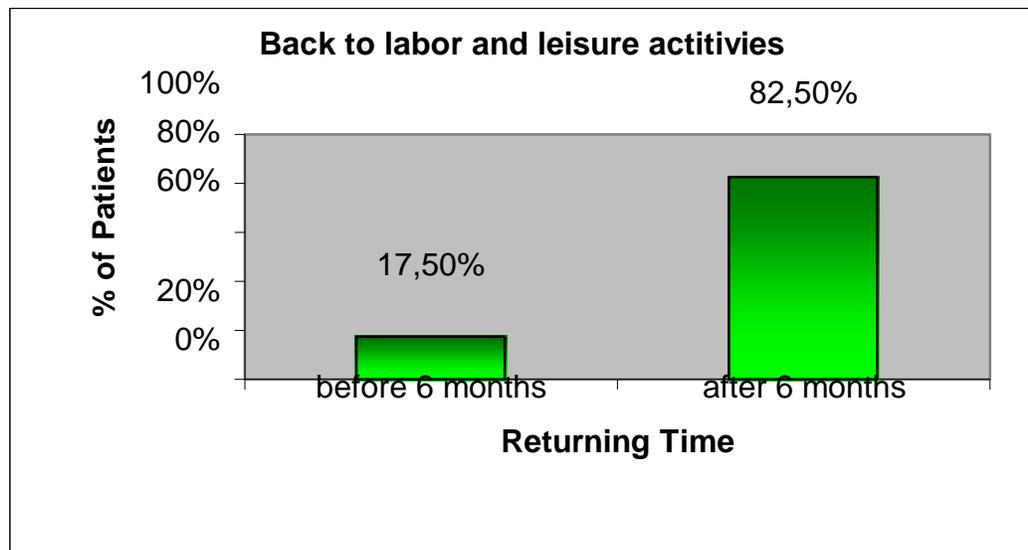
Weight

Increase 91,50%
Unaltered 8,50%



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before 6 months 17,50%
after 6 months 82,50%



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