Immunomodulator Canova – Aids and quality of life

I–Aids

I – A – Definition

Acquired Immune Deficiency Syndrome, it was defined originally in an empiric way by Centers for Disease Control (CDC) as a “diagnosed disease in a trustworthy way that it is, at least, moderately indicative of some underlying defect to the cellular immunity.” After the knowledge of the causal virus, HIV, before denominated (HTLV-III/LAV), and the development of sensitive and specific tests for the infection for HIV, the definition of the AIDS went through a significant revision. The current surveillance definition includes the presence of countless opportunist disturbances diagnosed in a presumptive way or defined in individuals that present laboratorial evidences of HIV infection or that doesn’t exhibit other apparent cause for the immune deficiency. On the practical point of view the doctor should consider the infection for HIV as a spectrum of disturbances including from primary infection, with or without syndrome of sharp HIV, to the advanced disease, going through the non-symptomatic bearer.

I – B – Etiology

Aids is caused by the infection with human retrovirus HIV1 or HIV2; HIV1 constitutes the most common cause of the disease all over the world; HIV2 has a sequence homology with HIV1, it is more related to virus of the immunodeficiency of the simians and it was predominantly identified in Occidental Africa. However HIV2 has also been identified in Europe, South America, Canada and United States.

I – C – Transmission

Sexual contact; blood contact – hemo-derivates and other corporal liquids (users of intravenous drugs that share polluted needles); childbirth transmission or the mother's perinatal for the infant or through the breast-feeding. There are not evidences that the virus can be transmitted by causal or family contact, or by insects.
Risk of transmission from a HIV infected health professional for his patients through evasive procedures is extremely low.

I – D – Epidemiologyc

On January 1st 1994, it was reported a cumulative number of approximately 400.000 cases in the USA, about 60% of them died. Estimates of 1 million having been infected in the USA. The principal risk groups continue being homosexual men and injectable drug users of both sexes; though, the numbers of transmitted cases through

homosexual way, above all in women, are increasing quickly. Those women also transmit infection to the children. Cases of Aids are still observed in individuals that received blood derived stuff in the past. The infection by HIV is a global pandemic, mainly in the developing countries. According to the magazine WHO, in the year 2000, we would already have 40 million of having been infected and other estimates showed 60 to 120 million.

I – E – Physiology and Immunopathogeny

1) **The primary infection:** after the initial transmission, the virus infects the cell CD4+, probably lymphocyte T, monocyte or dentritic derived cell of the bone marrow. The lymphoid system constitutes the principal establishment ranch and propagation of HIV. In its beginning architecture it is preserved though being verified a complete disorganization later, so that the efficiency of the lymph node in the capture of virion decreases, resulting in balance of the viral load among the cells of the outlying blood and the cells of the lymph nodes.

2) **Initial viremia and viral broadcasting:** For several times, they correspond in some patients to the conditions of mononucleosis in which the virus goes by the lymphoid organs and other organs of the organism being contained partially by the development of a specific HIV immune answer and reception of the virus in the lymphoid tissue.

3) **Clinic latency:** phase in which the number of cells TCD4+ decreases, however with few evident clinical discoveries. However, it is not treated of a microbiologic latency, because it happens active viral replication in viroid organs, allowing the virus to almost always be detected in the plasma through sensitive techniques as reaction of polymerase chain (RPC)

4) **Advanced HIV:** after a certain period of time (years), the count of cells TCD4+ decreases to a critical level (about 200 cells/mcl) and the patients become susceptive to opportunistic diseases.

II – Immune abnormalities in the disease for HIV

It was document a wide spectrum of immune abnormalities in patients infected by HIV that include quantitative and qualitative defects in the

function of the lymphocytes; monocytes, macrophages and cellular, cytotoxics (NK), as well as the development of self-immune phenomena.

Immune answer

The development of an immune answer is verified either humoral and cellular to HIV. The humoral answers include antibodies with connection activity and neutralization of HIV, as well as, antibodies that participate in the citotoxity cellular dependent antibody (CCDA). The immune answers to the production of specific HIV lymphocytes TCD4+ and CD8+, as well as cells NK and mononuclear mediator cells of CCAD.

III - Diagnosis

It depends on the demonstration of anti-HIV antibodies and/or of the detection of HIV or of one of its components. The standard screen test is ELISA (Enzyme-linked immunosorbent assay), sensitive higher than 99% and very specific. The most common and used confirmation test is Western-Blot, that detects antibodies against antigens of HIV of specific molecular weights.
The antigen P-24 of HIV can be certain using a reception assay, type ELISA. The plasmatic levels of the antigen P24 increase during the first weeks after the infection before the emergence of the anti-HIV antibodies. It can be accomplished a culture of HIV directly of samples of plasma or peripheral blood cell tissues; though, used more in research. The genetic material of HIV can be detected using PCR.

IV – Clinical manifestations divided in groups by CDC

Group I – Syndrome of sharp HIV
Group II – Non-symptomatic Infection
Group III – Generalized persistent adenopathy
Group IV - Other diseases
Subgroup A – Systemic disease (fever, weight loss, diarrhea).
Subgroup B – Neurological disease
Subgroup C – Secondary infectious diseases
Subgroup D – Secondary neoplasm
Subgroup E – Other conditions.

V–Treatments

We used the antiretroviral and protease inhibitors.
Nucleoside analogue inhibitors of the reverse transcriptase.

Obviously the several collateral effects are largely justified due to the treatment abandonment by the patient and also to the increase of the cost for patient's accompaniment with the necessary complemented exams.

1 – Justification for the use of Immunomodulator Canova

Traditionally the therapeutic effectiveness is evaluated in infectology, through biomedical parameters (free interval from disease and toxicity), but the results of the treatments need to be measured in terms of the physical and psychological limitations to the patient. That explains the need of settling down the impact of the disease and of its treatment, about the quality of life of the patient. Since it was recognized, the longer life and its quality became the two main objectives of the treatment in Aids. In the analysis of the data of a study, the life quality can be seen under two angles: one in that it has less importance than the longer life; and the other, in which two paradigms (where the patient's autonomy is settled) should be expressed objectively, so that they can be measured; the popular idea of what is good and the measures of the welfare.

The concern with those measurements has provoked the validation of indexes of life quality with base in the evaluation of the general physical conditions, functional capacity (for work and domestic activities), social interaction in the work and family atmosphere, cognitive function (concentration and memory) and emotional state (anxiety and depression).

However, professionals of health, researchers, administrators and patients have been confusing the concept of life quality. It is not a sensation of well being, but of the quality of health that can differently be defined and noticed by patients in a similar biomedical situation.

On the other hand, when several therapeutic situations come out, the bioethical principle of the autonomy requests that the patient be informed of the possible collateral effects, allowing that he can establish the parameters of life quality associated to those effects. This brings consequences for the evaluation of the life quality in the therapeutic studies, reason why the disposal of indexes is needed to allow comparing the life quality associated to each one of those several options.

Longer life and its quality can diverge between two treatments. A treatment can be better than the other in longer life terms, but not in the life quality and vice-versa, needing to be those two variables analyzed as an only result. That is why the proposition of the expectation of adjusted life to the life quality as an objective, measurable parameter.

The indicators of life quality also matter for the decisions in public health as the lease of resources and registrations of new medicine and equipment. Also, because the use of the literature as justification for the incorporation of new treatments suffers restrictions, in function of:

1) Publishing of partial results;
2) except the goal-analysis, most of the authors do not use systematic methods of obtaining, establishing and synthesizing revision data;
3) speed in which therapeutics proposals appear;
4) the lack of disseminated publishing of non-conclusive or negative therapeutics results.

The concept of life quality has also been used to justify palliative therapeutic indications of questionable results, when it should be incorporated the infect logic practice to support medical decisions and to establish the validity of the applied treatments. Establishment of indexes of life quality would also support public politics, because, life quality would become the number factor of a benefit-cost relationship that the administrator would use it more as indicator of health and base of fair and even decision.
Life quality and cost have been usually considered together in the context of clinical studies and some types of economical evaluation can use certain measures of life quality to settle down benefit-cost of a treatment.
On its side, to include the evaluation of costs in a study it must be questioned:

1) If the study treats the theme with economical repercussion;
2) If the results of the study will base the decisions of doctors, patient, buyers, providers and administrators.

In experimental studies, the inclusion of the evaluation of results increases the information on the disease and toxicity of the treatments. The life quality can be constituted in a prognostic factor, and, if it is needed to settle down the cost-benefit relationship of the researched treatment, with objective of being determined its social value towards the other sanitary doctor's attendance priorities, it can also constitute an indicator of health. It is urgent that we look to determine, among the Brazilian patients, which criteria of life quality they judge important, and to find indexes that allow us to apply treatments far more responsible and aligned with their expectation and the bioethical principle of the autonomy.

2 – Objective

Introduction of a treatment for people who have aids with larger adhesion index; without collateral effects; smaller frequency of opportunist infections, this is: improvement in the life quality, improvement in the health quality of those patients, already stigmatized by that overpowering disease.

3 – Clinical parameters for the patients' choice

a) In antiretroviral use;
b) In worse clinical conditions (weigh loss, anorexia, opportunist infection, etc.);
c) Low self-esteem.

4 – Laboratory parameters for the patients' choice

a) CD4 lower than 350 mc/l;
b) Higher viral load;
c) Alterations in routine exams for accompaniment of HIV (glycemia, cholesterol, triglycerides, TGO/TGP, aminase, anemia and leukopenia).

Immunomodulator Canova
Drops V (viral)

Aconitum napellus + associations

DROPS

- 10 sublingual drops 4 times a day (shake energetically before using);
- in the morning before breakfast;
- half hour before the meals;
- at night when lying down.

Immunomodulator Canova
INHALANT

Aconitum napellus + associations

INHALANT

- Apply three times a day, 3 ml of the medicine. Preferably use ultrasonic one (shake energetically before applying).

Comment
The medication should be prescribed for 60 days, when new exams should be made for evolution evaluation. The medication in sequence should be prescribed in agreement with the evaluation by the patient's doctor, reminding that in most of the patients the previously recommended prescription is necessary for at least of four months.

Observation
The decrease of the dose is made in the amount of the medicine and never in the amount of times, the multiple sequential incentive is priority.

Partial results obtained in São Lourenço's Policlínica after 30 days of the use of the Immunomodulator Canova.

Using clinical criteria and evaluation done by the patient through the questionnaire of punctuation 1 to 9 that follows enclosure to the work. In the evaluation team a psychologist and a welfare worker were part of it. The patient accepted the treatment by signature of term of responsibility.

Partial conclusion with 30 days of Canova.

In the patients' evaluation we obtained a surprising average; from 1 to 9, average was around 7,5. The parameters of clinical evaluation and life quality also surprised us:

- Improvement of the general health conditions;
- easy: patient with smile;
- 5% of weight gaining;
- sleep improvement and appetite;
- a patient returning to work (eventual jobs);
- a patient with improvements of the cramps, previously unbearable;
- a patient that finished his/her alopecia and he/she started walking and helping in the domestic activity;
- a patient that in the 1st week was confused and lethargic, led by his wife, already in the 3rd week attending alone and illustrious.
- a patient that increased his/her physical capacity, practicing exercises.

Logically we obtained increase in the patients' self-esteem favoring with that the acceptance of his/her current condition.

Observation

It was selected in agreement with the mentioned criteria, 25% of the treated patients in this Unit of Health. We are awaiting new complemental exams for confirmation of the brilliant clinical results obtained.

Evaluation of life quality

Use the following scale to evaluate his/her current satisfaction towards the different aspects of his/her daily life. Choose any number of this list (1 to 9) and indicate your scale in the following questions:

1 = extremely unsatisfied
2 = very unsatisfied
3 = moderately unsatisfied
4 = little unsatisfied
5 = neutral
6 = little satisfied
7 = moderately satisfied
8 = very satisfied
9 = extremely satisfied

1. Humor–feeling of sadness, concern, happiness, etc.
2. Self–esteem.
3. Trust, self-assertion and comfort in social situations.
4. Energy and sensation of health.
5. Problems of health (diabetes, high pressure, etc.)
6. General appearance.
7. Social life.
8. Recreational and leisure activities.
9. Physical mobility and physical activity.
10. Amentary habits.
11. Corporal image.
12. Life quality in general.

Summarize of the results obtained with Immunomodulator Canova® in our service after six months of treatment

Criteria of Evaluation:

- Worse social conditions;
- higher viral load;
- lower CD4 indexes;
- longer time of antiretroviral use;
- Patient of difficult adhesion, alcoholics, smokers.

General observation

The explanation on what it is, and what the purpose of stimulating the defense of the organism is, brought a clear improvement in the relationship between doctor-patient in which we are total sure that was outstanding point to the reliability and also larger approach of these sick ones that they started to come to our service more assiduously, offering larger and better conviviality opportunity with their difficulties and mainly with the great evil that surrounds them: social exclusion.

The Obtained Results:

1. Improvement of the general health conditions;
2. great part of the patients with increase of the disposition for simple activities that previously didn't perform;
3. around 10% of weight gain;
4. appetite improvement;
5. insomnia decrease (great frequency observed by us);
6. decrease of cramps;
7. patient with better perspectives in relation to the future of his/her disease;
8. accentuated decrease of the opportunist infections (candidiasis, etc);
9. Increase of the total leucocytes, CD4, decrease of viral load.

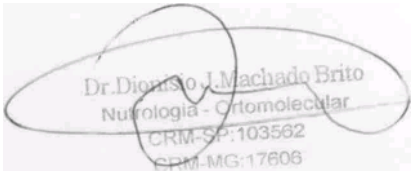
The result, independent of the social condition, was practically the same reached in the work developed by Dra. Maria das Graças Sasaki in Curitiba, showing that, patient even with feeding not so balanced in proteins etc, developed lymphocytes T with activities antiretroviral added to the treatment with the cocktail.
Obviously, for being a medicine without collateral effects, of easy applying, fast results, key point in thinking about the economy with medicines for hospital infections and better life quality for our patients, we concluded:

1. It is of extreme need that Ministry of Health incorporates to the antiretroviral therapeutic arsenal the Immunomodulator Canova®;
2. The doctor-patient interaction was sensational, improving the humor and the self-esteem of the patients.

Final conclusion

Immunomodulator Canova® showed to be efficient and of easy acceptability.
There was 100% of adhesion of the patients to the treatment with Immunomodulator Canova®, with the results showed previously.

For us from the DST/Aids it is rewarding to follow up the evolution and the patient's enthusiasm treated with Canova® after the results obtained during this study work.



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