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Administration of Propoelix® as an Adjuvant Therapy for Patients with HIV/AIDS in Sungailiat Hospital, Bangka

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Abstract

AIDS (Acquired Immune Deficiency Syndrome) is a syndrome exhibiting symptoms of opportunistic infections as a result of a compromised immune system due to HIV infection (Human Immunodeficiency Virus) which typically causes death. HIV/AIDS has become an epidemic both in the world and in Indonesia. It has a negative impact on many sectors hence thorough care is needed using the latest science and technology. Propolis is a natural product derived from plant resins collected by honeybees. It contains CAPE (Caffeic Acid Phenethyl Ester) and is rich in flavonoids (chrysin, catechin, galangin) which have immunomodulatory effects. The immunomodulatory effects of propolis are being considered as a form of complementary intervention to boost the immune system of HIV/AIDS patients.

Objective: To obtain clinical results by examining the effect of Propoelix® (highly potent extract of pure Propolis) on the CD4 levels of HIV/AIDS patients to evaluate the effectiveness of Propoelix® as an adjuvant therapy for HIV/AIDS patients. This case study will be conducted on HIV/AIDS patients who are currently receiving ARV treatment as well as those who are not presently receiving ARV treatment. Observations were made on all patients to examine whether there were improvements in their quality of life.

Method: HIV/AIDS patients at Sungailiat Hospital, Bangka, who were given Propoelix® were observed. Their laboratory results were also observed to detect any changes, in particular to their CD4 levels and their clinical symptoms. There were a total of 52 HIV/AIDS patients involved in this research. 45 of these patients were receiving 3 types of ARV treatments, 4 patients were receiving 2 types of ARV treatments and 3 patients were not receiving any ARV treatment. In this case study, all patients, regardless of whether they were receiving ARV treatment or not receiving any ARV treatment had shown significant improvement in their condition during the first month.

Conclusion: Propoelix® improved the clinical conditions and CD4 levels of the HIV/AIDS patients involved in this study at Sungailiat Hospital, Bangka. During the first month of Propoelix® treatment, 77% of patients who participated in the study showed an increased level of CD4. Patients who had received ARV treatment less than 6 months were more responsive towards Propoelix® treatment (mean: 99.33) compared to the patients who had received ARV treatment more than 6 months (mean: 39). 100% of participating patients reported improvement in their quality of life during this study.

Key words: HIV/AIDS, Propoelix® (Propolis Extract)

Abstrak

AIDS (Acquired Immuno Deficiency Syndrome) adalah sindrom dengan gejala infeksi oportunistik atau kanker tertentu akibat menurunnya sistem kekebalan tubuh oleh infeksi HIV (Human Immunodeficiency Virus) yang dapat menyebabkan kematian. Penanganan HIV/AIDS sesuai perkembangan ilmu pengetahuan dan teknologi menjadi mutlak diperlukan karena epidemi HIV/AIDS telah melanda dunia, termasuk Indonesia, dan menimbulkan dampak buruk dalam berbagai bidang. Propolis merupakan produk alami yang berasal dari resin tanaman yang diproduksi lebah madu, mengandung CAPE (Caffeic Acid Phenethyl Ester) dan flavonoid (chrysin, catechin, galangin) yang memiliki efek imunomodulator. Munculnya propolis sebagai imunomodulator dipertimbangkan sebagai intervensi tambahan dalam meningkatkan sistem imunitas pasien HIV/AIDS.

Tujuan penelitian: mengetahui gambaran klinis dari efek Propoelix® (ekstrak potent dari propolis murni) dalam meningkatkan kadar CD4 dan menganalisa efektifitas Propoelix® sebagai terapi tambahan pada pasien HIV/AIDS. Penelitian ini melibatkan pasien HIV/AIDS baik yang telah menggunakan ARV dan tidak menggunakan ARV. Pengamatan dilakukan pada semua pasien untuk memeriksa apakah terjadi perbaikan dalam kualitas hidup mereka.

Metode penelitian: deskriptif dengan mengamati dan menggambarkan perubahan keluhan klinis dan laboratories kadar CD4 pasien rawat jalan dan rawat inap HIV/AIDS RSUD Sungailiat, baik yang sudah maupun belum mendapat ARV, setelah pemberian terapi tambahan Propoelix®. Terdapat 52 subjek penelitian di mana 45 pasien menggunakan 3 jenis ARV, 4 pasien menggunakan 2 jenis ARV, dan 3 pasien tidak menggunakan ARV. Pada kasus menonjol, pada pasien yang menggunakan ARV maupun tanpa ARV, mengalami perbaikan klinis dan laboratoris yang nyata pada satu bulan pertama.

Kesimpulan: pemberian Propoelix® memperbaiki kondisi klinis dan kadar CD4 pada pasien dengan HIV/AIDS di RSUD Sungailiat, Bangka. Selama bulan pertama pengobatan Propoelix®, 77% pasien yang berpartisipasi dalam studi ini telah menunjukkan peningkatan jumlah CD4. Pasien yang menerima pengobatan ARV kurang dari 6 bulan lebih responsif terhadap pengobatan Propoelix® (mean: 99,33) dibandingkan dengan pasien yang menerima pengobatan ARV lebih dari 6 bulan (mean: 39). 100% pasien yang berpartisipasi melaporkan peningkatan kualitas hidup mereka selama penelitian ini.

Kata Kunci: HIV/AIDS, Propoelix® (Propolis Ekstrak)

(M. Fauzan dan Sulistyo Bagus, Medika 2016, Tahun ke XLII, No. 3, p. 128-138)

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- Studi kasus dilakukan terhadap 52 pasien HIV/AIDS oleh Ketua Pokja HIV/AIDS dr. M Fauzan dari RSUD Sungailiat, Bangka dan disimpulkan oleh dr. Bagus Sulistyo Budhi dari RSPAD Gatot Soebroto. Propoelix® secara signifikan efektif memperbaiki sistem imunitas pasien, terbukti dengan peningkatan jumlah CD4 (berperan dalam kekebalan tubuh) pada 77% pasien di bulan pertama penelitian.

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Introduction

AIDS (Acquired Immuno Deficiency Syndrome) is a syndrome with symptoms of opportunistic infections or certain cancers as a result of the decrease performance of the immune system by infection from HIV (Human Immunodeficiency Virus), which will ultimately lead to death. 1 Definitions for declaring the stages of HIV disease and the onset of AIDS has been revised repeatedly. The last revision was done in 1993 by the CDC (Centers for Disease Control and Prevention) based on the clinical conditions associated with HIV and CD4 + T cell count of lymphocytes. 1.2 All circumstances in category C, regardless of the circumstances of their immunosuppression degrees, are diagnosed as AIDS; Whereas all patients with CD4 + T lymphocytes <200/mm3 were diagnosed as AIDS regardless of their clinical circumstances.1,2

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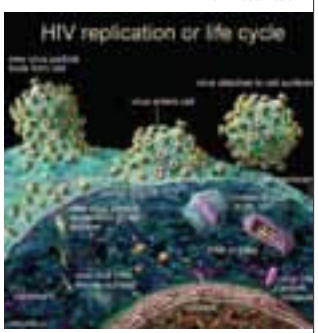

The HIV/AIDS epidemic has engulfed the world, including Indonesia. This virus is spreading fast without acknowledging state borders and layers of society. The HIV/AIDS epidemic can cause an adverse impact on national development as a whole, because in addition to affecting health, it can also affect the economy, politics, and security.

One cause of the high incidence of HIV/AIDS is high risk behavior due to lack of knowledge about HIV/AIDS, including lack of knowledge about HIV transmission, the low rate of condom usage during sex, and high rates of syringe sharing among drug users. Generally, people also regard AIDS as an infectious disease that is hazardous or lethal, but only 30-75% feel vulnerable to getting infected.

In 2005, Melati Polyclinic was established as a HIV referral center in the Pacific Islands, followed by Tulip Polyclinic Hospital at the Depati Hamzah Regional Hospital in Pangkal Pinang in 2009. Melati clinic in Sungailiat Hospital has provided six services as part of the Government's program namely VCT (Voluntary Counseling Test), CST (Care Support & Treatment), PITC (Provider Initiated Testing and Counseling), PMTCT (Prevention of Mother to Child transmition), Prophylaxis Clotrimazole and Case Manager.

Existing data shows that HIV/AIDS cases is increasing all the time.The problem is, can the provision of Propoelix® improve the patient's immune system by increasing their levels of CD4?

This study is aimed at determining the clinical overviewof the influence of Propoelix® as an adjuvant therapy in patients with HIV/AIDS; as well as to describe the levels of CD4 after receiving Propoelix® adjuvant therapy. The results are expected to be beneficial for obtaining a new approach in the effort of managing HIV/AIDS with Propoelix® adjuvant treatment and obtain a better therapeutic effectiveness for patients with HIV/AIDS.

HIV-AIDS

AIDS (Acquired Immuno Deficiency Syndrome) is a syndrome with symptoms of opportunistic infections or certain cancers as a result of the decreasing performance of the immune system by HIV (Human Immunodeficiency Virus) infection, which will ultimately lead to death. 1 Definitions for declaring the stages of HIV disease and the onset of AIDS has been revised repeatedly. The last revision was done in 1993 by the CDC (Centers for Disease Control and Prevention) based on the clinical conditions associated with HIV and CD4 + T cell count of lymphocytes. 1,2

There are two dimensions of the classification of HIV infection, which are the clinical circumstances and the history of immunosuppressive degrees, symbolized in the count of CD4+T lymphocytes. Clinical circumstances associated with HIV are divided into three categories as shown in Table 2. All of the circumstances in category C regardless of the circumstances of their immunosuppressive degrees are diagnosed as AIDS, whereas all patients with CD4+T lymphocytes <200/mm3 are diagnosed as AIDS regardless of their clinical circumstances.1,2

AIDS was first recognized in the United States in 1981. At that time, the US Centers for Disease Control and Prevention (CDC) discovered pneumonia caused by Pneumocystis carinii in five homosexual men in Los Angeles and Kaposi Sarcoma in 26 homosexual men in New York and Los Angeles. In 1983, the virus

has been isolated by Montagnier, a French scientist, and in 1994 confirmed the cause as AIDS. Based on the meeting of the International Committee on Taxonomy of Viruses, WHO gave the official name of this virus as Human Immunodeficiency Virus (HIV). HIV is classified as a retrovirus that has an RNA genetic material. When the virus enters the body of the patient (host cell) then the viral RNA is converted to DNA by the reverse transcriptase enzymefrom HIV. Pro-viral DNA is then integrated into the host cell and then programmed to form the viral genes. 1

HIV tends to affect certain types of cells, which are cells that have a CD4 cell surface antigen, especially T4 lymphocytes that play an important role in regulating and maintaining the immune system. In addition to T4 lymphocytes, the virus can also infect monocytes and macrophages, Langerhans cells of the skin, dendritic cells in the lymph nodes, pulmonary alveolar macrophages, the cells of the retina, the cells of the cervix uteri, and brain microglia cells. The virus that enters the T4 lymphocytes subsequently undergoes replication so much and eventually destroys the lymphocyte cells itself. Paralysis of the immune system has resulted in a variety of opportunistic infections and malignancies which are clinical symptoms of AIDS. 2

HIV and AIDS infection is a worldwide pandemic. The number of cases of HIV infection in adults in 2000 is approximately 34 million people, and two-thirds are in sub-Saharan Africa. Additionally, an estimated 1.3 million children under 15 were living with HIV/AIDS. According to the United Nations Programme on HIV/AIDS (UNAIDS), in 1999 alone there were 5.4 million new infections worldwide, which means that 15,000 new cases every day. A total of 2.8 million people who died of AIDS makes the disease the 4th highest killer worldwide. Up to December 2001, the data showed that there were 1978 HIV positive cases and 671 AIDS cases in Indonesia. It is estimated that this number will increase to 80000-120000 in 2010. Unlike the common assumption, it turns out the way most infections in Indonesia are heterosexual sex (56%), followed by injection drug use (18.5%), then homosexual relationships (6,6%). The rest are through blood transfusion/blood products, perinatal transmission, and unknown. However, the incidence of these infections have changed over the discovery of a new case.

According to DG & MoH RI (2014), Papua, Jakarta, West Java, East Java, Bali, Riau and Western Kalimantan occupy the highest positions in the prevalence of HIV/AIDS in Indonesia. Diagnosis of HIV/AIDS id aimed at two things, which are the state of HIV and AIDS. Protocol to face every situation differs from the treatment, care, counseling, to the prognosis of the disease itself. 3

For those who will do an HIV test on their own volition, pre-test counseling is highly recommended. Early diagnosis is confirmed through laboratory tests with the instructions of clinical symptoms or of their high-risk behavior of certain individuals.

Laboratory diagnosis can be done by two methods, namely direct and indirect. Diagnosis is done directly by virus isolation from the sample, generally by electron microscope examination or detection of viral antigen, for example by Polymerase Chain Reaction (PCR). While diagnosis not directly done by looking at the response of anti-specific agents, for example, by Enzyme Linked Immuno Sorbent Assay (ELISA), Western Blot, Immunofluorescent Assay (IFA) or Radioimmunoprecipitation Assay (RIPA).

Diagnosis of HIV that are commonly used in the first place is the ELISA test because it has a high sensitivity (98-100%). However, it lacks in specificity, so positive ELISA test results must be confirmed by the

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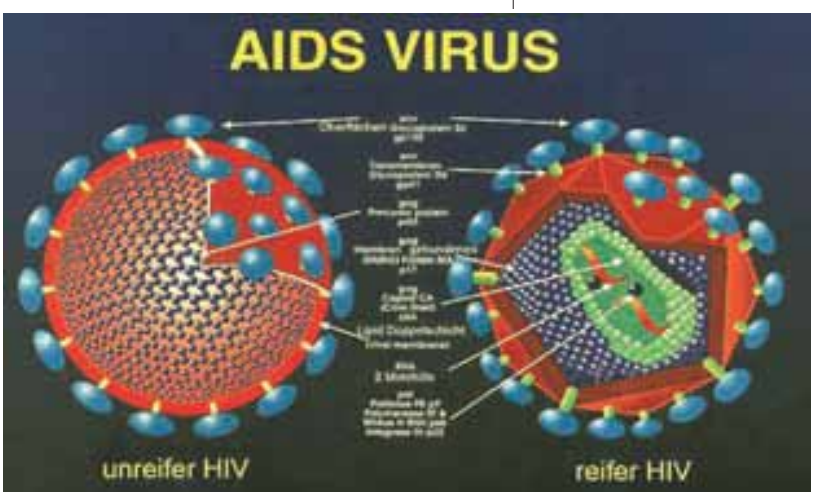

Western Blot test wich has a high specificity (99,6-100%). Whereas PCR is usually performed on an infant who still has antimaternal substancesso that it hampers serological examinations and in high risk groups before seroconversion happens.1,2,3

AIDS is the final stage of HIV infection. Patients are declared as having AIDS whenfurther progression of HIV infection shows the opportunistic infections and cancers threatening. In addition to that, CDC in 1993 has set a condition called AIDS as described above. 1

Treatment of opportunistic diseases with antibiotics often work well. So are treatments of chemotherapy for malignancy due to HIV/AIDS. However, it turns out the disease often relapse and ultimately lead to death, because these drugs basically cannot improve immunity. Therefore, many efforts were made to inhibit the replication of the HIV virus. Until now, antiretroviral drugs have been developed.

Antiretroviral Medication

For antiretroviral medications, Nukleosiea Reverse Transcriptase Inhibitor (NRTI) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) is used. One of the NRTI antiretroviral medication is AZT (Azidothimidine)/Zidovudine. AZT is an antiretroviral drug that is most commonly used and recommended for patients with a CD4 cell count less than 500 cells. The side effects of AZ commonly are headache, malaise, asthenia, insomnia, and vivid dreams.4 One or more of these side effects will appear in about half of the people taking this medication. Additionally, there may be nausea, anorexia and myalgia, but these symptoms usually diminish after 6 months of usage. 1 Patients with headaches can be given analgesics, while those with insomnia are given antihistamines or short acting benzodiazepine, and patients with nausea are given antimimetics. These side effects lead to many who are previously asymptomatic stop treatment because they feel more "healthy" compared to when using this medication. Patients should be encouraged to continue treatment with AZT for six weeks before doctors exchange it with other antiretrovirals. There are also linked mood disorders such as depression and mania with AZT's use. 3

In addition to AZT, there are didanosines (ddI) given to patients with HIV/AIDS with a CD4 count less than 500 who were intolerant of the side effects of AZT or have been AZT users for at least 16 weeks, but it still shows the progression of the disease. During the beginning of usage, the patient may feel an increase in energy. However, forsome people it is perceived as nervousness or anxiety. Insomnia can be overcome by not taking this medication around the clock to sleep or change to a single dose in the morning.4 Other side effects that are common include insomnia (25% patients), confusion (2% of patients), seizures (3%), and mania .3

Dideoxycitidine (ddC) is also anHIV/AIDS antiretroviral medication. Although it is still closely associated with ddI, ddC rarely cause insomnia (1% of patients). Other side effects such as headaches, dizziness, confusion, impaired concentration, asthenia, depression, and seizures rarely occur.4

Another NRTI antiretroviral is Stavudine (d4T). These drugs have no effect on cognitive functioning, emotion, and behavior that are not significant as well as rare, including mania, depression, insomnia, etc.3,4

In addition to the above medications, drugs known as protease inhibitors are also metabolized by the cytochrome P-450 liver so that it can increase the plasma levels

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of other drugs, including psychotropic such as benzodiazepines, SSRIs, buproprion, etc. Those included as antiretroviral protease inhibitors are Saquinavir, Ritonavir, Indinavir, etc.1

A combination of treatments provides better effects. Combinations in the form of antiretroviral drugs with several different mechanisms of action and different work places can lower the dose of each medication and minimalize side effects. Since the discovery of antiretroviral protease inhibitors, AZT was never used again as a monotherapy. Nevertheless, AZT remains an important component in combinations as protease inhibitors cannot penetrate the blood-brain barrier, making it ineffective in treating neurocognitive disorders. However, the combination of these drugs can hamper the progression of these disorders with a process that until now is not yet clearly known, but still possible as it can reduce the viral load. Examples may include the triple combination (AZT + dd-C + Saquinavir) or double (+ Saquinavir AZT) or (AZT + ddC) .2,5

In addition to the above medications, medication for opportunistic infections and malignancies is also required. Opportunistic infectionscommonly found in patients with HIV/AIDS are herpes simplex, candidiasis, pneumocystis carinii pneumonia, tuberculosis, and Sarkoma kaposi.1,3,4

Meanwhile, CD4 become markers on the surface of white blood cells of humans, particularly lymphocytes. CD4 cells in people with lowered immune system are very important, since the reduced value of CD4 cells in the human body indicates reduced white blood cells or lymphocytes that were supposed to play a role in fighting infections that enter the human body. In people with a good immune system, the number of CD4 range from 1400 to 1500. Whereas in people with impaired immune systems (eg in people infected with HIV) the number of CD4will decrease over time (in some cases can even reach zero).

Propolis Extract

Propolis is a natural product derived from plant resins collected by honeybees. Propolis functions as a shield for beehives; preventing diseases and parasites from infiltrating the nest, inhibit spoilage, and prevents the growth of fungi and bacteria. The color depends on the source of its growth, but it is usually dark brown. Propolis is sticky at room temperature or above (20°C). Whereas if it's lower, it will become hard and brittle.

This product has been used since 300 BC by the Greeks, Romans, and Egyptians for healing because it has anti-inflammatory properties. Initially, ancient Egyptian pastors used propolis as one of the ingredients to preserve mummies. In the world of Arabic medicine, propolis is identified by Ibnu Sina as dark wax, as the excess dirt from the hive. Meanwhile, translucent was is known as ingredients to make the nest. Dark wax is known to have cleaning properties. However, it is also written in the notes of Ibnu Sina that it will cause sneezing if inhaled. Ancient Assyrians believe propolis to be drugs that can fight cancer and tumor. Meanwhile, the Greeks used it to treat ulcers. InGeorgian traditional medicine, an ointment containing propolis was discovered to treat several diseases. Propolis is used for newborns or swabbed on toys. Propolis is also used to treat warts, respiratory disorders, and also burns and angina.

In any climates worldwide, poplar bud exudates (mainly of Populus nigra L) is the main source of resin collected. Propolis poplar has about 50 kinds of substances, particularly resin and balsam plants (50%), wax (30%), essential oils (10%) and pollen (5%). Biologically active compounds can also be found in propolis balsam, including polyphenolic compounds (Caffeic acid phenethyl ester [CAPE]), flavonoids (chrysin, catechin, galangin), derivative stilbene (resveratrol), and fatty acids. These compounds, in particular CAPE and flavonoids, are shown to have anti-inflammatory activity and immunomodulating potential in laboratory experiments. CAPE significantly hampers cytokine production and Lymphokine, including TNF-α, IL-2, IL-10, IL-12, IFN, and inhibits the proliferation of T cells.

The Propoelix super extraction, obtained using unique extraction process, acts to eliminate materials not needed by the body (such as resin), as well to maintain active ingredients in unique, water-soluble forms. Propoelix can be given as an adjuvant therapy to patients with HIV/AIDS.

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Patients with HIV/AIDS experience a decrease in their bodies' immune system. The properties of the propolis extract, which is a substance with immunomodulatory, anti-fungal and anti-inflammatory abilities, is expected to be able to improve the clinical condition and laboratory parameters in patients with HIV/AIDS as additional therapy.

Materials and Methods

The nature of this research is descriptive, by observing and describing the HIV/AIDS patients at the Sungailiat Regional Hospital, both those who had received ARV and those who hadn't, and were given the Propoelix additional therapy.

The study took place at the Sungailiat Regional Hospital, Bangka. Sungailiat Regional Hospital is a public hospital owned by the Bangka Regency Regional Government located in Sungailiat and is well known by the local people, both in Sungailiat and in the island of Bangka. In the beginning, this hospital was originally a Lung Hospital owned by the Catholic Mission that was nationalized and officially opened on 12 November 1970 as a D-class hospital. The study went for 6 months, from February to August 2014.

Subjects of the study are patients receiving inpatient and outpatient treatments at the Sungailiat Regional Hospital, as well as all patients who came for treatment who have been diagnosed HIV positive, and received prior or recent ARV treatments. ARV and Propoelix were given as adjuvant therapy with a dosage of 2 x 200 mg/hari.

Table 1: Characteristics of HIV patients in Sungailiat Hospital,

No	Subject (n=52)	Mean ± SD	Median (Min-Max)
1	Age (year)	36,33 ± 9,44	35 (15-60)
2	ARV Duration (month)	21,94 ± 20,71	15 (1-96)

Table 1: Characteristics of HIV patients in Sungailiat Hospital, Bangka

CD4	Mean ± SD	Median (Min-Max)
CD4 Baseline	298,71 ± 23,17	281 (2-828)
CD4 1st Month	346,11 ± 23,31	313 (48-996)
CD4 6th Month	379,88 ± 19,63	347 (64-922)

Results

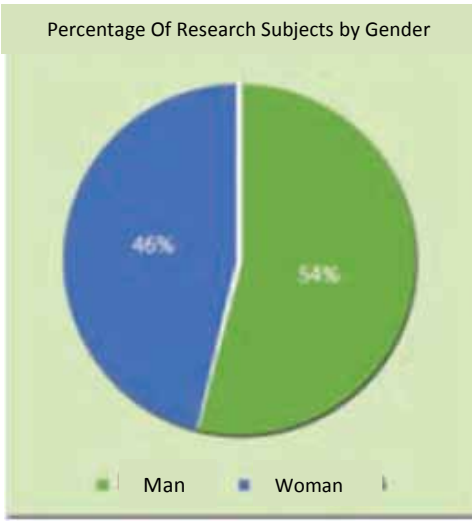
Cases that were specific and stood out during the study were: Case 1, a man, Mr. H, 42, and had only used antiretroviral for 1 month with three different types of ARV who was receiving inpatient treatment at the hospital. He first came in with a CD4 count of 4 cells/mm2. After one month of taking the ARV drugs with Propoelix added to the mix, the CD4 count went up to 127 cells/mm2 with an improved clinical condition and able to ride a motorcycle. After 6 months, the CD4 count went up to 148 cells/mm2. The clinical condition of the patient also showed real improvement, and laboratory tests showed improvements in his CD4 count.

Case 2, a man named Mr. B, 36 years old, who didn't consume any antiretroviral drugs, and who was receiving inpatient treatment at the hospital. When he first came in, he had a CD4 count of 17 cells/mm2. After 1 month taking the drugs and Propoelix, his CD4 count increased to 97 cells/mm2 with an improved clinical condition. After 6 months, his CD4 count went up to 168 cells/mm2. Gradually, changes in the patient who didn't take ARV also showed real clinical and laboratory changes.

Table 1 describes the characteristics of the research subjects from a total of 52 people with an average age of 36.33 years. The youngest age being 15 years old and the oldest is 60 years old. Usage of antiretroviral drugs for subjects averages 21.94 months long and the research subjects have been treated to a medical institution for more than 1 year.

Percentage of research subjects based on gender is that 54% (n = 28) are male, and 46% (n = 24) are women. While the percentage of research subjects using antiretroviral (ARV) is that 86% (n = 45) usedthree types of antiretrovirals, 8% (n = 4) used two types of antiretrovirals, and 6% (n = 3) did not use drugs.

The proportion of CD4 cell change after 1 month of Propoelix® usage compared to continuous usage of ARVs isthat 77% (n = 40) experienced an increase and 23% (n = 12) experienced a decline in CD4 levels. While the proportion of CD4 cell changes after 6 months of Propoelix® addition compared to experienced a decrease in CD4 levels.

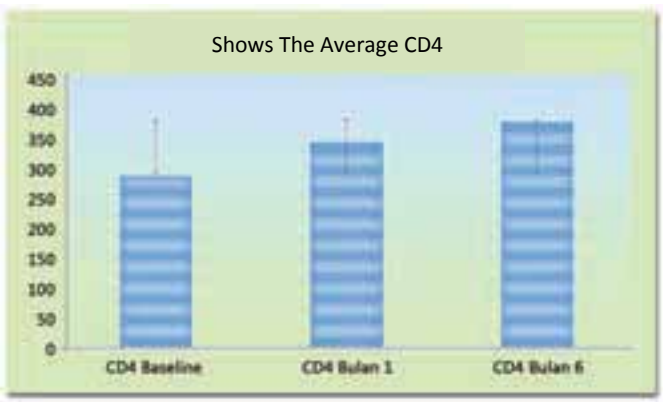


Graph 1: Percentage of research subjects by gender

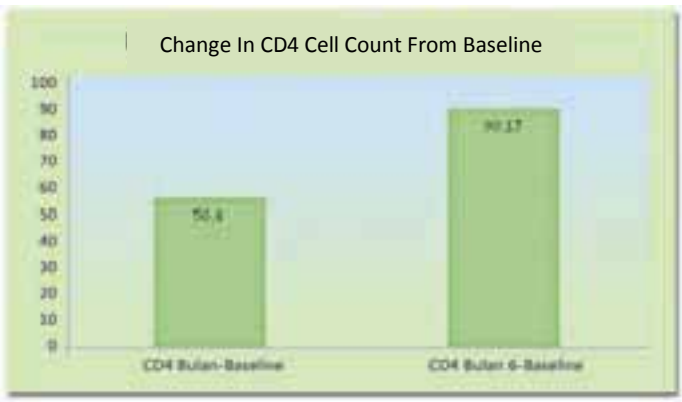
tion after 1 month of receiving adjuvant therapy.

Table 3 illustrates that an increase in average CD4 levels in patients given adjuvant therapy of Propoelix® with the use of antiretroviral drugs, both less than 6 months and more than 6 months. The number of patients on antiretrovirals for less than 6 months add up to 15 people and patients on antiretrovirals for more than 6 months is 37 people. The average CD4 levels in the first month and sixth months increased compared with the CD4 baseline.

Table 4 illustrates the change in CD4 cell counts among patients who had ARV therapy before 6 months and after 6 or more months. There are greater changes of CD4 in patients receiving antiretroviral



Graph 2 shows the average of CD4 at baseline, 1 month after administration of Propoelix®, and after 6 months of adjuvant therapy.



Graph 3: The measurement of the average change in CD4 cell count after 1 month and6 months of additional therapy Propoelix®

Patients with HIV/AIDS experience a decrease in their bodies' immune system. The properties of the propolis extract, which is a substance with immunomodulatory, anti-fungal and anti-inflammatory abilities, is expected to be able to improve the clinical condition and laboratory parameters in patients with HIV/AIDS as additional therapy.

Graph 3 illustrates the measurement results of the average change in CD4 cell count after administration of Propoelix® for 1 month which continues until 6 months. The graph showed changes after the first 1 month which increased by 56.40/mm2 from baseline averagesan increase of 90.17/mm2after 6 months. Changes in CD4 counts increased markedly on the observa-

therapy for less than 6 months in the observation of 1 month and 6 months from baseline.

From the data a above, we can conclude that changes in CD4 levels that improved or increased can be obtained through the addition of propolis as a therapy to patients with less than 6 months of ARV use. Changes in the CD4 count were more clearly noticeable in the first month of use compared to the changes in the CD4 in the 6th month.

Nearly all subjects stated that their physical condition was better. The patients' subjective conditions were complaints and statements during follow up. Patients who dropped out due to failure to follow up during the therapy process were mostly

caused by inconsistency in attending the therapy sessions.

Several cases stood out with clinical improvements from treatments in the ICU. A month later, patients were able to conduct activities as before, and were even able to ride their motorcycles.

This was also showsn in the CD4 count which was originally only 4/mm2, and after 1 month of receiving adjuvant Propoelix therapy increased to 127/mm2, and after 6 months the CD4 count was 148/mm2.

The CD4 count in patients who were not given ARV prior to the provision of Propoelix also showed an increase. The average increase in CD4 was later calculated from all subjects after receiving adjuvant Propoelix therapy.

Table 3:
The relationship between CD4 level with the length of ARV use

	ARV Duration Category	N	Mean ± SD	Median (Min-Max)
CD4 Baseline	< 6 months	15	218,80±210,99	103 (4-670)
	> 6 months	37	320,08±235,499	301(2-828)
CD4 1st Month	< 6 months	15	314,13±283,647	155(63-996)
	> 6 months	37	399,08±212,343	317(48-804)
CD4 6th Month	< 6 months	15	332,73±1196,811	333(108-751)
	> 6 months	37	399,00±195,03	631(64-922)

Table 4:
The changes in CD4 count in the beginning and during treatment period compared to the length of ARV use

	ARV Duration Category	N	Mean ± SD	Median (Min-Max)
CD4 Baseline	< 6 months	15	99,33±120,09	67 (-35-332)
	> 6 months	37	39±77,41	301(-135-273)
CD4 1st Month	< 6 months	15	117,93±89,10	92(-47-320)
	> 6 months	37	117,93±89,10	79(-108-328)
CD4 6th Month	< 6 months	15	18,6±115,71	32(-245-268)
	> 6 months	37	39,92±70,75	37(-92-290)

Propoelix boosted the CD4 count in patients with HIV/AIDS. Increase in the first month from the baseline was quite visible compared to after 6 months of adjuvant therapy.

The way propolis works as an immunomodulator, anti-inflammation and anti-bacterial has been conveyed through various studies. The immunomodulater properties in Brazillian green propolis were shown in mice, according to Sforcin & co. (2010), were displayed by activating the first stages of immune response by boosting the expression of TLR-2 and TLR-4 and the production of proinflammation cytokine (IL-1 and IL-6) produced by the macrofage and lien cells, which contributed to the identification of microorganisms and activate the lymphocytes by antigen presenting cells. This effect was obtained with a 200 mg/kg dosage.

Sforcin, et al. (2007) explained that propolis derived from poplar and baccharis has immunostimulant effects by increasing the production of antibodies and activating the B and T lymphocytes. At 2.5, 5 and 10 mg/kg dosages, the Brazillian green propolis showed an increase in the generation of hydrogen peroxide to kill micro-organisms (Orsi, 2000), and had an effect of inhibiting the proliferation of splenocytes and acted as immunosuppressors to the lymphoproliferative response (You, et. Al, 1998).

A study performed by Ansorge et al. (2003) showed that the Caffeic Acid Phenethyl Ester (CAPE) in propolis and flavonoid quercetin, as well as hesperidin, mediated the suppression of DNA synthesis in the mononuclear cells of the human peripheral blood cells and the T cells of CD4. CAPE, in dosages of 1.5 and 10 mikroMol, has an effect of inhibiting the transcription of the nF-kB and NFAT factors, thus affecting the inhibition of the transcription of the IL-2 gen, expression of IL-2R and proliferation of the T cells (Marquez et al, 2004).

Flavonoids isolated from Phillanthus niruri have the immunomodulatory activities against the lymphocytes. It had been proven that the proliferation of lymphocyte increased by twice its normal rate in the DPPH assay.

The anti-inflammatory activities of propolis have been reported in various research models. The provision of 200 mg/kg of propolis in a short amount of time (3 days) to mice hinders the production of IFN in the splenocyte culture. Mouse C57BL/6, which was subjected to 200 mg/kg of Brazillian green propolis for 14 days showed anti-inflammation activities with the inhibition of the production of IL-1β, IL-6, IFN- , IL-2, and IL-10 by lien cells which commonly occurs in chronic inflammation.

The Naringenin flavonoid inhibited the ability of C. Trachomatis to phosphorilate the p38 in the macrophage, thus showing a mechanism that could potentially weaken

the production acapacity of the inflammation mediator. Naringenin is an immunomodulator in inflammations triggeded by C. Trachomatis, which is mediated by TLR2, TLR4 and the CD86 receptors in the macrophages infected through the p38 MAPK channel.

The 10% Brazillian green propolis stimulated the production of antibodies (Sforcin & co, 2005). The provision of CAPE in dosages of 5, 10 and 20 mg/kg to BALB/c mice increased the production of their antibodies (Park & co, 2004).

In-vitro tests whowed that propolis was able to directly interact with microorganisms, and in-vivo tests showed that propolis could stimulate the immune system and activate mechanisms involved in killing microorganisms. Propolis has been proven to have effects that are in synergy anti-microbial drugs. Oksuz (2006) proved that propolis reduced antibiotic resistance against bacterial walls synergized with the antibiotic mechanism in the ribosome.

Liberio, et al (2009) explained a summary of the effects of propolis on a group of Streptococcus mutans and suggested the potential of propolis or from its composition as a chariostatic material and a step further in biotechnological products to control caries or other infections. Santos, et al (2008) evaluated the clinical efficacy of the latest Brazillian propolis gel formulation in patients diagnosed with denture stomatitis and proved a complete remission of clinical symptoms in the palate edema and erythema. He also suggested that the gel was efficient and could serve as alternative topical medicine for denture stomatitis therapy.

Conclusion

From reported cases of HIV/AIDS patients who received the Propoelix adjuvant treatment the following results were obtained: There were changes in the CD4 count of patients who received the Propoelix adjuvant treatment. The difference is more visible in the first month compared to the sixth month. This means that provision of propolis extract improved the patients' immune system.

The provision of Propoelix improved the clinical and laboratory condition of patients with HIV/AIDS at the Sungailiat Regional Hospital, Bangka. 100% of patients who participated in the study reported an improvement in their quality of life during the study. There needs to be a follow up to this research to further develop it with a higher research method.

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