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Evaluation Of Side Effects Of First-Line Antiretroviral (ARV) Therapy In HIV Patients At Kassi-Kassi Public Health Center Of Makassar

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ABSTRACT

The treatment for HIV/AIDS therapy is by administering antiretrovirals (ARVs) for life, therefore it is necessary to monitor patients for side effects or symptoms of ARV toxicity. The aim of this study is to evaluate the side effects of drugs in HIV sufferers who were taking first-line antiretroviral (ARV) drugs at the Kassi-Kassi Public Health Centre of Makassar. This research was quantitative research with descriptive research type. The results showed that of the 36 patients who met the inclusion and exclusion criteria based on their characteristics, the majority of respondents were male (91.67%), in the 25-54 year age group (72.22%), and had a tertiary level education (58.33%). Based on the length of time they received antiretroviral drug therapy (ARV), the majority of patients were in the 6 months-5 years category (80.56%), with the most widely used ARV combination being tenofovir + lamivudine + efavirenz (47.22%). The number of patients who did not experience ARV side effects was greater (50.7%) than those who experienced side effects. The most common side effects include:dizziness, nausea, rash, fatigue and sleep disturbances. Even though several patients experienced ARV side effects, judging from the medical records, after treatment of ARV side effects, the patients continued therapy well.

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INTRODUCTION

Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome (HIV/AIDS) continues to be a major global public health challenge. According to global burden of disease statistics in 2019, approximately 36.8 million people were living with HIV, and 0.86 million deaths due to HIV worldwide [1]. Human Immunodeficiency Virus (HIV) is a virus that attacks the immune system and causes a decrease in the human body's resistance. Acquired Immunodeficiency Syndrome (AIDS) is a collection of various disease symptoms as a result of a decline in the body's immune system and function [2].

South Sulawesi Province as a region of Eastern Indonesia was once the second largest province after Papua in terms of HIV-AIDS prevalence. Distribution of cases by region in

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South Sulawesi, most in the cities of Makassar, Pare-pare, Gowa and Bulukumba [3]. The main strategy for HIV prevention and control is to achieve Triple 95s or 95-95-95 by 2030, namely: 95% of PLHIV know their status, 95% of PLHIV are on ARV, and 95% of PLHIV on ARV are virally suppressed. Unfortunately, Indonesia is still lagging behind in achieving this target. As of December 2022, the first 95 percent achievement is still at 81% and only half (41%) have received ARV treatment; whereas only 19% of PLHIV on ARV treatment had their virus suppressed [4].

The medical management of HIV infection is ARV treatment, which aims to reduce the risk of HIV transmission, prevent the worsening of opportunistic infections, suppress the multiplication of the virus maximally and continuously, and improve the sufferer's quality of life. The first-line ARV used in Indonesia currently is a fixed dose combination (KDT) containing tenofovir, lamivudine/emtricitabine, and efavirenz [5]. Antiretroviral therapy (ARV) is a prolonged therapy and requires a comprehensive approach. Long-term therapy also needs to be monitored for side effects or symptoms of ARV toxicity in patients. Long-term use of an ARV regimen consisting of several ARV drugs requires special attention [6]. An adverse drug reaction (ADR) can be defined as a seriously adverse or unpleasant reaction resulting from an intervention related to the use of a medicinal product; Side effects usually predict harm from future administration and require prevention, or special treatment, or changes in dosing regimen [7]

Medicines, no matter how safe and effective, always come with the risk of unavoidable side effects. Although modern medicine has changed the way disease is managed and controlled, despite all its benefits, evidence continues to show that adverse reactions to medicines are common, often preventable, leading to disease, disability, and even death. Moreover, in several countries, ADR is ranked in the top 10 causes of death [8].

The use of ARVs has side effects that can arise in various manifestations such as hematology, clinical chemistry, urinalysis, gastrointestinal, musculoskeletal, neurology and endocrine. These side effects range from mild to severe in HIV sufferers. Mild side effects that often appear include bloating, nausea and diarrhea which appear only once or continue to persist during therapy. Based on research conducted by Puspasari, Wisaksana and Ruslami (2018) at Dr. Hasan Sadikin Bandung The most common side effects in the adult population are nausea, dizziness, itching, rash and vomiting [9]. In previous research it was known that as many as 88% of HIV patients who took ARVs experienced liver function abnormalities, however the abnormalities were still mild abnormalities (Pathania et al., 2017), in the research of Meriyani et al., (2018) as many as 15.80% of patients HIV taking ARVs experiences mild toxicity and moderate toxicity [10].

The use of antiretoviral therapy, like the use of drugs for other diseases, must be evaluated primarily regarding its suitability to established standards. One of the pharmacist's responsibilities is to evaluate drug use, which is a standard pharmaceutical service in hospitals. One other important goal is to serve as a source of information to improve the tolerability and effectiveness of treatment in HIV patients by encouraging early recognition of side effects in order to improve drug use in the future.

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METHOD

The type of research used was descriptive observational evaluating the side effects of drugs in HIV sufferers who are taking first-line antiretroviral (ARV). Sampling was carried out in August-October 2023 at the Kassi-Kassi Makassar Community Health Center and sample examination was carried out at RSUP dr. Wahidin Sudirohusodo Makassar. The sample population in this study was all HIV sufferers who took first-line antiretroviral (ARV) drugs at the Kassi-Kassi Community Health Center of Makassar with totaling 427 people. Determining the sample size in this study used the convenience sampling method, a technique for selecting research subjects based on inclusion and exclusion criteria with a total of 36 respondents. The examination tool used was Thermo Sciantific Indiko Plus.

RESULTS AND DISCUSSION

Table 1 Characteristics of Research Subjects by Gender

Category	N	Percentage (%)
Gender		
Man	33	91.67%
Woman	3	8.33%
Total	36	100%

(Source: Primary Data, 2023)

Table 1 shows that there were 33 (91.67%) male subjects and 3 (8.33%) female subjects.

Table 2 Characteristics of Research Subjects Based on Age

Age	Range	N	Percentage
Teenager	12-17	1	2.78%
Mature Young	18-24	9	25%
Mature	25-54	26	72.22%
Total		36	100%

(Source: Primary Data, 2023)

Based on the age category of teenagers (12-17 years) there were 1 (2.78%) subjects, the young adult age group (18-24 years) as many as 9 (25%) subjects and the age group (25-54 years) as many as 26 (72 .22%) subjects.

Table 3 Characteristics of Research Subjects by Education Level

Category	N	Percentage (%)
Level of education:		
elementary school	0	0%
Junior High School	3	8.33%
Senior High School	12	33.3%
University	21	58.33%
Total	36	100%

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Source: (Primary Data, 2023)

Table 4 Characteristics of Research Subjects by Employment Status

Category	N	Percentage (%)
Job status		
Work	23	63.88%
No work	13	36.11%
Total	36	100%

Source: (Primary Data, 2023)

Based on the education level category, there were 3 (8.33%) subjects, junior high school, 12 (33.3%) high school subjects, 21 (58.33%) PT subjects.

Table 5 Characteristics of Research Subjects Based on Education Level

Category	N	Percentage (%)
Duration of ARV therapy		
6 months-5 years	29	80.56%
6 years-10 years	3	8.33%
11 years-15 years	1	2.78%
16 years-20 years	3	8.33%

Source: (Primary Data, 2023)

Based on the length of antiretroviral drug therapy (ARV) with the highest percentage being 6 months – 5 years as many as 29 (80.56%) subjects, the duration of antiretroviral drug therapy (ARV) was 6 – 10 years and 16 – 20 years each with 3 (8, 33%) subjects and the duration of therapy was 11 – 15 years, there was 1 (2.78%) subject.

Table 6 Risk factors for HIV transmission in research subjects

Risk Factors for Transmission	N	Percentage
Sex	17	47.2%
IDU (Injecting Drug User)	10	27.7%
Sex and IDU (Injecting Drug User)	5	13.8%
Tattoos	2	5.55%
Without explanation	2	5.55%
Total	36	100%

Based on risk factors for HIV transmission with the highest percentage in risky sexual relations (47%), IDU (Injecting Drug User) (27.7%), Sex and IDU (Injecting Drug User) (13.8%), Tattoos and without information (5.55%).

Table 7 First-line Antiretroviral (ARV) Combinations in Study Subjects

Combination	N	Percentage (%)
TDF + 3TC + EFV	17	47.22%
TDF+3TC+DTG	16	44.44%

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3TC + ZDV +NVP	1	2.78%
TDF + FTC	2	5.56%
Total	36	100%

Source: (Primary Data, 2023)

Information :
TDF = Tenofovir;
3TC = Lamivudine;
EVF = Efavirenz ;
DTG = Dolutegravir ;
ZDV = Zidovudine;
NVP = Nevirapine ;
FTC = Emtricitabine

Based on the combination of ARVs most commonly used by HIV patients, tenofovir + lamivudine + efavirenz was 17 (47.22) subjects. The combination of tenofovir + lamivudine + dolutegravir was 16 (44.44%) subjects. The combination of lamivudine + zidovudine + nevirapine was 1 (2.78%) subject. And the combination of tenofovir + emtricitabine was 2 (5.56%) subjects.

Table 8 Side Effects of ARV Therapy on Research Subjects

Side effects	N	Percentage
Didn't feel any side effects	20	55.5%
Light	8	22.2%
Currently	6	16.66%
Heavy	2	5.55%
Total	36	100%

Based on complaints of side effects from ARV therapy, HIV/AIDS patients with the highest percentages were not experiencing side effects (55.5%), experiencing mild (22.2%), moderate (16.66%) and severe (5.55%) side effects.).

Table 9 Types of side effects from ARV use in patients

Side effects	N	Percentage (%)
Dizzy	9	23.07%
Nauseous vomit	6	15.38%
Hearing disorders	0	0%
Blurred Vision	2	5.12%
Skin Rash	5	13.88%
Changes in Skin Color	2	5.55%
Fatigue	6	15.38%
Anemia	0	0%
Sleep Disorders	6	15.38
Depression	1	2.56%
Neuropathy	0	0

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Side effects	N	Percentage (%)
Diarrhea	2	5.55%
Total	39	100%

Based on the characteristics of the study, there were more HIV patients who took first-line antiretroviral (ARV) drugs who were male, namely 33 subjects. Based on the information obtained, the majority of HIV sufferers at the research location were men rather than women because most of them experienced sexual deviation (homosexuality). This is in line with the HIV/AIDS development data report for the first quarter of 2021, which states that the frequency of men suffering from HIV is greater than that of women (69%). based on risk factors, as many as 27.2% of homosexuals are MSM (26.3%) and transgender (0.9%) population groups.

Based on age characteristics, there were 14 HIV subjects who took first-line antiretroviral (ARV) in the adult age range, namely 25-54 years. This can happen because as adults have entered the productive age where a person is active in carrying out risky sexual activities such as having multiple partners, having unprotected sex, practicing sex between men (MSM), using illegal drugs and sharing needles. or the use of non-sterile injection equipment, which can cause HIV transmission and those in productive age have limited access to health and HIV prevention services, such as HIV testing, counseling and antiretroviral therapy due to being busy doing their jobs.

The results of this study are in line with research (Yuliandra et al., 2017) which states that the majority of HIV patients are in the productive age range, namely the age range of 26-45 years. This research is also supported by the HIV/AIDS development data report for the first quarter of 2021, which states that the 25-49 year age group is the group with the largest number of HIV/AIDS sufferers (71.3%). This happens because the productive age group is the age range where a person is active in sexual relations and is involved in drug and drug abuse, which significantly increases the risk of HIV transmission.

Based on the duration of therapy, the highest group of HIV patients who took first-line antiretroviral (ARV) was 6 months – 5 years with a total of 30 people (83.33%). This is related to the implementation of the Voluntary Counseling and Testing (VCT) program at the Kassi-Kassi Health Center Makassar in 2014. Voluntary Counseling and Testing (VCT) which in Indonesian means voluntary HIV counseling and testing with the aim of helping prevent the transmission of HIV/AIDS, This program is implemented simultaneously with the administration of antiretroviral (ARV) drugs to patients who are declared HIV positive. This program started in 2014 but from 2020 to 2021 this program did not run well due to Covid-19, which is why the largest group who took ARV treatment for a long time was in the range of 6 months – 5 years.

Based on the table of 7 types of First Line Antiretroviral (ARV) drugs, it shows that the combination of ARVs most frequently used in this study was in the form of FDC (Efavirenz 600 mg, lamivudine 300 mg, tenofovir 300 mg), namely 17 people (47.22%). According to Minister of Health Regulation no. 87 of 2014 concerning Antiretroviral Treatment Guidelines, ARV treatment must involve the use of three types of drugs that are effective and at the right

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dose in the blood, known as ART (antiretroviral therapy). The recommended first-line treatment guidelines generally use a combination of two NRTI (Nucleoside Reverse Transcriptase Inhibitor) class drugs and one NNRTI (Non-Nucleoside Reverse Transcriptase Inhibitor) drug (Ministry of Health of the Republic of Indonesia, 2015). According to Widiyanti et al., (2015) antiretroviral (ARV) therapy is generally carried out through a combination of drugs because it can reduce the incidence of resistance and lower the possibility of side effects.

The results of the study showed that of the 36 patients who were interviewed regarding side effects that occurred during antiretroviral (ARV) treatment at the Kassi-Kassi Health Center, 16 patients experienced side effects and 20 patients did not experience any side effects. This is because each person has a different reaction to antiretroviral drugs. In the results of this study, most side effects occurred in the first 2 weeks to 3 months, this is in accordance with the guidelines in the Minister of Health (2014) where side effects usually occur in the first few weeks after initiation.

The types of side effects experienced by patients vary according to the ARV regimen consumed[11]. In table 8 the most common side effects are dizziness, nausea, rash, fatigue and sleep disturbances. These results are in accordance with research conducted by (Putra, 2021) where the side effects that often occur are dizziness, nausea and vomiting [12]Side effects on the central nervous system (CNS) such as dizziness, hallucinations are thought to be due to the effects of administration of the NNRTI group, namely efavirenz (E FV).[13]Meanwhile, gastrointestinal (GI) disorders can occur in the NRTI group, namely lamivudine and tenofovir in the form of nausea and vomiting [14].

Dermatological side effects such as skin rashes often occur due to administration of NNRTIs, namely nevirapine and efavirenz [13]. The occurrence of skin rashes caused by use. nevirapine and efavirenz by 3-20% due to nevirapine and efavirenz by 8.2% [15;16]. The side effects of nevirapine and efavirenz even caused 2 patients to experience Steven Johnson Syndrome at Dr Soekardjo Regional Hospital. Side effects on the digestive tract in the form of nausea, vomiting and diarrhoea usually occur in the first few weeks after using ARVs[5]. One of the patients suffered from digestive disorders, namely diarrhoea for up to 2 months [17].

CONCLUSION

The main conclusions of the study may be presented in a short conclusions section, which may stand alone or form a subsection of a discussion or results. Based on the length of time they received antiretroviral drug therapy (ARV), the majority of patients are in the 6 months-5 years category (80.56%), with the most widely used ARV combination being tenofovir + lamivudine + efavirenz (47.22%). The number of patients who do not experience ARV side effects is greater (50.7%) than those who experience side effects. The most common side effects include:dizziness, nausea, rash, fatigue and sleep disturbances. Even though several patients experience ARV side effects, judging from the medical records, after treatment of ARV side effects, the patients continue therapy well.

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