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Considerations of GHS classification for health hazards of chemicals

Morita, T.[1]

Department of Pathology, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Selangor[1]

ABSTRACT— Adherence to antiretroviral therapy (ART) prevents disease progression, and the emergence of resistant mutations. It also reduces morbidity, and the necessity for more frequent, complicated regimens which are also relatively more expensive. Minimum adherence levels of 95% are required for treatment success. Poor adherence to treatment remains a stumbling block to the success of treatment programs. This generates major concerns about possible resistance of the human immunodeficiency virus (HIV) to the currently available ARVs. This paper aims to describe baseline results from a cohort of 242 Malaysian patients receiving ART within the context of an intervention aimed to improve adherence and treatment outcomes among patients initiating ART. A single-blinded Randomized Controlled Clinical Trial was conducted between January and December, 2014 in Hospital Sungai Buloh. Data on socio-demographic factors, clinical symptoms and adherence behavior of respondents was collected using modified, pre-validated Adult AIDS Clinical Trials Group (AACTG) adherence questionnaires. Baseline CD4 count, viral load, weight, full blood count, blood pressure, Liver function and renal profile tests were also conducted and recorded. Data was analyzed using SPSS version 22 and R software. Patients consisted of 215 (89%) males and 27 (11%) females. 117 (48%) were Malays, 98 (40%) were Chinese, 22 (9%) were Indians while 5 (2%) were of other ethnic minorities. The mean age for the intervention group was 32.1 ± 8.7 years while the mean age for the control group was 34.7 ± 9.5 years. Mean baseline adherence was 80.1 ± 19.6 and 85.1 ± 15.8 for the intervention and control groups respectively. Overall mean baseline CD4 count of patients was 222.97 ± 143.7 cells/mm³ while overall mean viral load was 255237.85 ± 470618.9. Patients had a mean weight of 61.55 ± 11.0 kg and 61.47 ± 12.3 kg in the intervention and control groups, respectively. Males account for about 90% of those initiating ART in the HIV clinic, at a relatively low CD4 count, high viral load and sub-optimal medication adherence levels at baseline.

KEYWORDS: Adherence, Antiretroviral Therapy (ART), HIV/AIDS, CD4 count, Viral load, treatment outcomes.

1. INTRODUCTION

HIV was first diagnosed in Malaysia in 1986. By the end of 2013, there was a cumulative figure of 101,672 HIV cases reported to the Ministry of Health, 20,235 AIDS cases, and 16,340 deaths [1]. In 2002, the epidemic peaked with a rate of 28.5 per 100,000 population. Since then, there has been a steady decline achieved at a rate of 11.42 per 100,000 population in 2013 [1]. By 2013, the number of persons living with HIV/AIDS increased to 86,324 with 3,393 new infections in the same year. The introduction of harm reduction programs since 2005 has resulted in a significant decline in the number of HIV infections through needle sharing. However, in recent years, there is increasing evidence that overlapping of injecting drug use (IDU) and risky sex behavior is occurring, resulting in increased HIV infection between the different populations. In 2011, sexual transmission had superseded IDU as the key driving factor of the epidemic with a ratio of 6 sexual transmissions for every 4 IDU reported [2]. There is a significant changing trend in HIV by gender with a male: female ratio of 9.6:1 in 2000 to 3.7:1 by 2013 [1]. The incidence rate of HIV infection among adults 15-49 years old has decreased from 49% to 26% between 2001 and 2011 [3].

Malaysia with an overall HIV prevalence of 0.5% and a concentrated epidemic, has about 17,369 patients as at the end of 2013 [1] for which the Malaysian Government currently almost entirely provides all the funds for HIV treatment care and support for, at no cost to the patients on first line medications and heavily subsidized for those on second line antiretrovirals (ARVs). However, the unmet need for Antiretroviral Therapy (ART) is estimated to be 50 – 60%. Despite these efforts, the globally recognized issues of injecting drug use, stigma and discrimination as well as poor adherence to treatment (clinic visits and medication adherence) remains a stumbling block to the success of treatment programs and generates major concerns about resistance of the HIV virus to the currently available ARVs.

2. METHODS AND MATERIALS

A single-blinded Randomized Controlled Clinical Trial was conducted between January and December, 2014 in Hospital Sungai Buloh. It is the largest infectious disease hospital and one the foremost reference hospitals in Malaysia. It has over 6,000 HIV/AIDS patients on treatment and care, accounting for 35 – 40% of about 17,000+ patients currently on Highly Active Antiretroviral Therapy (HAART) in various centres across Malaysia. The centre provides a wide range of HIV/AIDS prevention, care and treatment services including diagnostics, pharmaceutical, clinical and support services to an average of 1000 HIV-positive patients per year, out of which an average of 400 - 500 patients are initiated on HAART yearly based on eligibility criteria. It maintains a high standard and quality of care based on international best practices and guidelines. It also provides training and research services including continuous medical education, specialist training and knowledge management. Sample size calculation was done using the formula for calculating sample size in hypothesis testing by comparing two means [14] which returned a sample size (n) maximized at 121 per group. Therefore, a total sample size of 242 was applied for this study. Patients who were assessed and found to be eligible for ART commencement based on 2013 WHO guidelines, and with valid telephone numbers and able to read text messages were included in the study and randomized to either of two treatment arms based on simple, complete randomization technique in a ratio 1:1 for intervention and control groups, respectively. Written allocation of assignment was sealed in individual opaque envelopes marked with study identification numbers which was made available in the study clinic to allocate the target number of participants. After consenting to participate (by filling and signing a consent form) and meeting the inclusion criteria, screened subjects were enrolled and immediately afterwards were assigned to a randomized study arm by the study coordinator opening the sealed envelopes to determine allocation.

Random allocation considered and eliminated all forms of possible bias based on the socio-demographic characteristics of the clients. Baseline data on socio-demographic factors, clinical symptoms including TB status and Opportunistic Infection (OI) index, and adherence behaviour (over 2-4 weeks of adherence preparation and vitamin training) of respondents was collected using modified and pre-validated Adults AIDS Clinical Trial Group (AACTG) adherence questionnaires. Baseline CD4 count, viral load, weight, full blood count, blood pressure, Liver function and renal profile tests were also conducted and recorded. A “Reminder module” which included standardized weekly SMS medication reminders (sent at 9am every Monday); SMS reminder 3 days prior to scheduled clinic appointments (individualized and sent at lunch time), and an average of 90 second lunch hour telephone call reminders a day prior to scheduled clinic appointment (in addition to standard care - routine adherence counselling) was delivered consistently for 24 weeks to respondents in the intervention group by 2 trained PLHIV (research assistants) while respondents in the control group received standard care only. Each patient in the intervention group had a minimum of three (during clinic visits at month 1, month 3 and month 6) individual counselling sessions with the research assistants lasting an average of 15 minutes per encounter. To ensure confidentiality, typical medication reminder text messages included a short slogan in Malay language “Apa khabar” “Ini untuk menberithau anda ubat” meaning “How are you?” “This is to remind you of your medications”.

Appointment reminder text message was “Apa khabar” “Tolong ingat tarikh temu janji lusa” meaning “How are you?” “Remember your appointment day after tomorrow” and telephone conversation was standardized and short, with the message “Apa khabar” “Tolong ingat tarikh temu janji besok” meaning “How are you?” “Remember your appointment tomorrow”. Patients were not required to provide any responses to the text messages. However, a log of text message communications and telephone calls was recorded and kept.

3. RESULTS

Table 1 indicated that out of the 242 patients in the sample, 215 (88.8%) of them were males and 27 (11.2%) were females. Malays constituted the overall majority (n = 117, 48.3%) of respondents in the sample, 40.5% were Chinese (n = 98), 9.1% were Indians (n = 22) and 2.1% (n = 5) were of other minority ethnic origin such as Ibans. The overall mean age of respondents in the sample was 33.4 ± 9.2 SD (95% CI: 32.23 – 34.56) years and ranged from 18 to 64 years. The mean age for males was 33.1 ± 8.7 SD (95% CI: 31.93 – 34.27) years, while the mean age for females was 35.7 ± 12.3 SD (95% CI: 30.82 – 40.59). The income distribution of respondents showed that an overall majority of respondents (n = 188, 73.6%) earned RM 3499 and below, while 26.4% earned above RM 3500. Majority (n = 170, 70.2%) of the respondents attained educational level of less than bachelor degree while only 74 (29.7%) attained bachelor degree and above. Overall, majority (59.9%) of respondents were private organization employees, 14.9% were self-employed, and 12.8% were unemployed. Government employees were of relative minority (n = 21, 8.7%) while only 9 respondents (3.7%) reported other forms of employment such as students. Slightly over half (52.9%) of the respondents lived in urban location, 36% in semi-urban and 11.2% in rural location. Females had lower (75.19 ± 24.8) mean baseline adherence compared to males (83.77 ± 17.2). However, this difference did not reach statistical significance (t = 1.354, df =240, P=.19). Overall, mean baseline adherence did not differ significantly by age group (F (4, 237) = 0.425, P=.79), ethnicity (F (3, 238) = 0.150, P=.93), income distribution (F (4, 237) = 0.156, P=.96), education level (t = -1.173, df =240, P=.24) and employment status (F (4, 237) = 1.144, P=.33). Patients who resided in semi-urban areas had significantly higher mean baseline adherence (90.90 ± 8.9) compared to those who resided in urban (80.25 ± 19.7) and rural (68.93 ± 32.0) locations.

4. DISCUSSION

The mean age (in years) of 242 respondents was 33.4 ± 9.2 SD (58% were of the age group 30-39 years) which is similar to the findings of previous studies in Malaysia, [1], [2] Kenya [11] and Brazil. [15] According to WHO, poverty is a significant determinant of disease occurrence. Very few studies have identified poor financial incentives that include out-of-pocket expenses and high transportation costs from frequent hospital visits as some of the factors that contribute to non-adherence. These may explain why patients from rural areas had poorer adherence as shown in this study. Thrice as many respondents in the current study as in a similar study in Kelantan, Malaysia earned RM 1,500 and above. The reverse was true for those who earned below RM 1,500. This is perhaps due to geographical variation in earning capacity and cost of living between residents of Kelantan and Selangor, Malaysia which may potentially affect adherence. Despite this distribution, we found that among patients initiating ART in Selangor, mean adherence at baseline was not dependent on patient’s income status. We found about five times as many persons in Selangor as Kelantan16 attended tertiary education and also had higher mean baseline adherence. This population of PLHIV graduates is also 43% higher than what was reported elsewhere in Botswana [17]. State-specific socio-economic and cultural dynamics which influence access and affordability of tertiary education between and among populations, may explain these variations. However, our study as above also showed that educational level does not have significant effect on baseline adherence.

5. CONCLUSION

Overall, the cohort of 242 patients involved in this trial were largely males (88.8%), with a mean age of 33.1 (95% CI: 31.93 – 34.27) years but higher mean baseline adherence than females. Semi-urban dwellers had higher baseline adherence than urban and rural dwellers. Mean baseline adherence of participants in the sample did not differ by other socio-demographic, patient or condition-related factors. However, significant group differences in the mean age, ethnic distribution and education level of participants was observed between treatment arms. On the average, this cohort initiated ART at suboptimal baseline adherence, low CD4 count and high viral load, with about 20% of patients needing adherence interventions from the outset, in addition to routine strategic and collaborative treatment adherence planning between the patient and the care-giver before commencement of and during the course of ART, in order to achieve successful treatment outcomes.

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