CHAPTER V

DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

The low success rate and the increasing frequency of default from anti-tuberculosis therapy has been reported as a major barrier for controlling tuberculosis in Thailand. Of the whole country, the lower treatment success and high defaulter rate were reported about 77 % and 8.9% in Thailand and 68.9 % and 21.0% in Bangkok among all new smear positive pulmonary Tuberculosis patients in 2002 (WHO, 2003). Interrupted or incomplete treatment increases the risk of acquired drug- resistant TB, which is more dangerous than original tuberculosis (Monieetal, 1982).

In order to improve the treatment outcome, such as a success rate, and to decrease the default rates, different types of DOT observers have been introduced into the tuberculosis control programs of many countries.

Therefore, this study was designed to determine how the different types of DOT observers impact treatment outcome in terms of treatment success and default among new smear positive pulmonary tuberculosis patients in Bangkok, Thailand and to describe associated factors of treatment success and default among new smear positive pulmonary tuberculosis patients at the Bangkok Chest Clinic under Ministry of public health, and public health center 7, 16, and 23 under Bangkok Metropolitan Administration (BMA).

5. 1.1 DOT related factors

Different types of DOT observers

As for the association between different types of DOT observers and treatment success, higher treatment success was reported in heath personnel supervised DOT group (87.4%) compared with the family member supervised DOT group (68.9%) and self administration group (70.2%), with a statistical significance (p-value <0.001).

Conceming the association of default with types of DOT observer, health personnel supervised DOT group had a lower default rate (6.6%) than family member supervised DOT group (18.9%) and self administration group (21.1%), and it had a statistical significance (p-value: <.001). After controlling the confounding factors, types of DOT observer still remained significant. Therefore this study suggested that treatment success is increased if health personnel are mobilized as a DOT observer.

This was consistent with results found in other research done by Mr. Mathma B titled "Tuberculosis treatment in Nepal: a rapid assessment of government centers using different types of DOT observers (Health personnel supervised group(A), community member or family member supervised group(B) and self administration group (C)(Non- DOT group). The group A had 91% cure rate (95% CI 80.3-97.2), group B—57% (95% CI 48.8-64.0) and group C—34% (95% CI 25.1-40.4). The health personnel supervised DOT group with the best result had good access to laboratory facilities, uninterrupted drug supply, longer clinic hours, and standardized TB patient management which could explain why health personnel supervised DOT group could have the best results of treatment (Mathema et al, 2001).

Other reasons for high success rate among health personnel supervising DOT group are,

i) In Bangkok Metropolitan Administration, combination-drug form being used by health personnel rather than self-administration group and family member supervising group, and combination drug form has less side effect (8.4%) than separate drug form (30.3%). The patients with side effect had less success rate (61.9%) than that of the patient without side effect (79.3%) (p-value=0.001),

ii) DOT duration among health personnel supervised DOT group was longer than other two groups (88% of health personnel supervised DOT group and 43.3% of family member supervised DOT group were treated under DOT for 6-8 months) and this might be another reason for low success and high default rate among family member supervised DOT group. This fact can be further explained by the behavior of patients which change the DOT into non-DOT, i.e. among 180 patients under family member DOT, 101 patients (56.1) was treated under DOT for only two months of intensive phase, then changed to no observer, while only 17 patients (10.2%) of 167 patients under health personnel supervised DOT changed to non-DOT after two month DOT treatment. This findings are similar with the result of the study conducted in Southern part of Thailand by Pungrassami. The study found that 10-16% of health personnel supervised patients changed to self administration, compared to 3% of community member supervised patients and 4% of family member supervised patients and they found that change to self administration was about two-fold more likely among patients who had no living partner than those with a living partner, about

2.6-fold more likely among patients who lived in more than one place than those who lived in only one place during treatment (Pungrassami. 2002).

iii) The majority of patients under supervision of health personnel received drugs on the daily basis and it probably keeps the patient's mind on taking drugs every day without missing. This would in turn, reduce the default rate among health personnel supervised DOT group, and If the patient did not come to the health center for taking drugs, the health worker could take defaulter- tracing action immediately.

iv) Health personnel could always communicate with patient and it increased patient understanding about importance of regular drug taking and the consequence of interruption. If the patient has some kind of side effect due to taking tuberculosis drugs, they could immediately consult with doctor without delay. This could make health personnel supervised patients have more chance to success in their treatment. Please refer to the reasons for low success and high default rate among the family member supervised DOT group.

However some other studies showed different results from this study. A study conducted in Thailand by Pungrassami P. found that there were no significant differences in treatment success between different DOT observers. The result showed that the treatment success rates were 87.1%, 89.7% and 85.3% of health personnel, community member and family member supervised DOT group, respectively (Pungrassami, 2002). A similar result was seen in a study conducted by Dr, Kamolartankul P, and treatment success rate was 80% in health personnel supervised group, 84% in family member supervised group

and 79% in community volunteer supervised groups. Based on these findings, the researchers concluded that DOT appears especially suited for treatment at decentralized facilities. While a general focus on program performance can improve outcomes, DOT provides significant additional benefits, and if basic conditions are met, a DOT strategy can be tailored to country specific condition by exploring multiple observation options, without decreasing its effectiveness (Kamolratanakul.1999). As seen in all the above previous studies, family members and community members could play the role of DOT supervisor, in a similar fashion as health personnel.

DOT and Non-DOT

Treatment success rate was higher in DOT group (77.8%), compared to the non-DOT groups (70.2%), and there was a marginal association between DOT and treatment success (p-value = 0.058).

As for the default rate, non-DOT group had a higher default rate (21.1%) compared to the DOT group (13.0%) with statistical significance (p-value:0.017).

This result is consistent with other studies. A study done in India was found that approximately, 30% of non-DOT patients commonly made mistakes in taking drugs. The common mistakes include missing doses of medicines, selective avoidance of some medicines and dividing doses in appropriately (Narain, 2002). The researcher also found that without DOT, the cure rate in TB patients was less than 60% and often much lower. Whereas in DOT group, it was possible to achieve cure rate in excess of 90% (Narain, 2002).

A similar result was found in the study of Thailand (AKK, 1999).

A study carried out in Nepal also found that the compliance rate was higher among those who were observed by someone else compared to those who were not supervised (Tara, 2003). A similar result was also found in WHO report-2002 (WHO, 2003) and in the study of Thailand, (Kamolratanakul, 1999).

All these findings can be explained by the fact that directly observed treatment ensures the patients to take tuberculosis drugs correctly without interruption during the long term treatment period (6-8months) and without direct observation, it is difficult to anticipate that who could interrupt their treatment or could make mistakes in taking drugs. Therefore Directly observed treatment can increase the treatment success rate and decrease the default rate.

However inconsistent results were found in some other studies. Dr. Merrick found in their study that the self- supervision group (non-DOT) achieved better outcomes than DOT group among re-treatment patients (74% versus 42%) and it had been explained that re-treatment patients had less chance to be cured than those new TB patients, if they failed to comply. Therefore, they were well motivated by this reason after receiving health education (Merrick, 1998). This finding emphasizes the importance of health education to the TB patients.

In this study, the reason for marginal significance in success rate among DOT and non- DOT groups is that family member supervised DOT group had a low success rates (68.9%), even though health personnel supervised DOT group had a significantly high treatment success rate (87.4%). This is because family member supervised patients lived far from Bangkok chest clinic under Ministry of public health. Bangkok chest clinic has a responsibility to take care of all the tuberculosis patients living in Bangkok and Public health centers under

Bangkok Metropolitan Administration (BMA) has only the responsibility to take care of the patients living in their own catchment's areas. This makes supervisory activities in Bangkok chest clinic of MoPH difficult when their patients were defaulted.

Another reason for low success rate among family member supervised DOT group is that large numbers of patients under supervision of family member had only two month supervision. For instance, 101 case (56.1%) of 180 cases under family member observers were treated under DOT only for two months. This means that 56.1% of family member supervised TB patients became self administration group after two months of intensive phase treatment.

However DOT group had a significantly low default rate (13.0%) compared with non-DOT group (21.1%) and this result is consistent with other studies (Pethchawn,2002; Narain, 2002; Akkslip, 1999; Kamolratanakul 1999).

5.1. 2 Socio-demographic characteristics

Age

Association of age and treatment success and default: The younger age group had higher success rate than the older age groups, and there was a significant association between different age groups and treatment success (p-value: 0.046) in this study. This result was consistent with association between different age group and default in this study. It can be explained by the fact that younger age group had higher compliance with treatment and younger generation take the disease more seriously and they had adequate knowledge about the disease and its treatment (Tara 2001). Other reason for higher success

rate among younger age group was the significantly lower Proportion of regular alcohol consumption among younger age group in comparison with older age group (p-value:0.003). Another reason for higher success rate among younger age people which could explain in the study was that younger age respondents had a high level of social support from their family and a high level of peer support (Tara, 2001). In addition to this, the younger age group people are more likely to adopt scientific knowledge and are more willing to share their feelings without hesitation to their friends. This increases support from friends and family. A similar study result was also found in the study conducted by Doveren (Doveren, 2001). All the above described reasons could explain the reason for higher default rate among older age group as well.

Gender

Gender: Nearly two thirds (69.7%) of study subjects were male which was almost similar to studies conducted in Nepal (Ministry of Health 2001 & Tara, 2003) and in Vietman (Nguyen, 2000). In almost all areas where TB is a public health problem, the incidence of TB among women is less than men. This might be due to the fact that males have a greater chance of exposure to tuberculosis during their working period and seek work in different places, especially in developing countries.

Association between gender and treatment success and default: In this study, it was found that there was a nearly equal proportion of study subject in terms of gender with treatment success and default without significant association between gender and treatment success and default (p-value: 0.288

and 0.231). Consistent study results were reported in some studies (Boyles, 2002; Nguyen, 2000). However, studies done in Nepal and Vietnam found that females had higher cure rate compared to males. It was explained that while men dropped out from treatment due to pressures to return to work or due to alcohol and drug addiction, women default from treatment because of the pressures of housework and the strain of keeping their disease secret due to the social stigma (Ministry of Health, 2001; Suhadev, 1995; Morankar, Suryawanshi, 2000; WHO, 2000).

Marital status and its association of treatment success and default

More than half (55%) of the study subjects were married. The result is similar to a study done in Nepal (Tara 2003). The treatment success and default rates were not different between various marital status in this study (p-value = 0.949 and 0.708). This is in agreement with a study conducted in Southern Vietnam by Nguyen which showed that there was no significant difference in compliance among different marital status (Nguyen 2000).

On the other hand, some studies showed that the compliance rate was higher in the single group than the married, widow and separated group, and it was explained that most of the single patients had high and moderate level of knowledge compared to married and others group and if single young male or female gets TB, they try to treat disease because of the difficulty in getting married with tuberculosis. Whereas, if the married female gets the disease, she tries to hide her disease because she is afraid to get a divorce from her husband. (Morankar, Suryanwanshi, 2000; Tara 2003; Chiu 1997)

Occupation

Concerning the occupation of study subjects, over one fourth of study subjects (28.8%) were involved in laboring and farming, 23.7% were in private services, a similar proportion (23.9%) of study subjects were unemployed, and, a few (1.5%) were government officials and the remaining (13.7 %) were in others group, which included students and children. A similar proportion was found in another study (Tara. 2003). All these findings could further explain that TB mainly occurs in poor people and it is strongly related with poverty.

Treatment success rate was higher among patients whose occupation were government officials (87.5%), private enterprise employee (83.7%) and others such as student and children (81.7%) than those whose occupations were housewife (76.7%), farmer or laborer (70.5%) and unemployed (67.7%) with significant association (p-value=0.027).

The farmer/ Laborer group and unemployed group reported a high default rate (22.1% and 18.5%, respectively), while private employee, students/children group, and housewife group reported lower default rate (11.4%, 9.9% and 9.3% respectively), and among government officials, nobody had been defaulted(0.0%), (p-value=0.037).

After controlling the confounding factors, occupation of study subjects still remained significant with treatment success and default. Therefore this study suggested that treatment success is increased if more attention is given to those laborer or unemployed patients.

These findings are consistent with other studies done by Boyles in Nepal. The study found that different occupation groups had a significant association

with treatment success and default. High success rate among government servants was explained by the fact that they can manage their time to receive DOT treatment within working hours without losing their earnings, whereas laborer and farmers might have difficulty in this regard. Laborers and farmers have to earn money for their daily life and this might lead them to be defaulters. This could also explain why laborers and farmers reported higher default rate than others (Boyles, 2002; Tara, 2003).

However some studies done in other area/countries showed that occupation was not associated with treatment success or default. (Kandel, 2000).

5.1.3 Patients' behavior

Alcohol consumption

Among 518 study subjects in total, the information about alcohol consumption was available only in125 patients (24.1%). Out of 125 patients, 83 cases (66.4 %) had a habit of drinking alcohol and 42 had no habit to drink alcohol, and 95.2 % of 42 those patients who had no a habit of drinking alcohol succeeded in their treatment compared to 79% among 83 patients who had a habit of drinking alcohol, and there was a significant association between alcohol consumption and treatment success (p-value: 0.021). As for the relation between alcohol consumption and default, default rate was higher (8.4%) among those who had a habit to drink alcohol than those who had no habit to drink (2.4%), but there was no statistical association with treatment default in this study (p-value=0.192).

A study conducted by WHO, had a similar result and the high default rate was explained by alcohol and drug abuse among male patients (WHO, 2000). This explanation strongly supports the result of this study.

5.1.4 Health service related factors

Drug supply intervals

This study found that the daily and every two weeks drug supplied groups had a significantly higher treatment success rate compared to the other groups with a significant association (p-value = 0.026).

As for the default rate, drug supply interval had a statistic significance with default rate (p-value=0.006).

The higher success rate among the daily and every two week supply group could be explained by the fact that the majority of health personnel supervised DOT group were supplied drugs on the daily basis or once every two week (16.2%) basis, while majority of family member supervised group were supplied drugs on a weekly basis (80.0%) and self administration group—on monthly basis(71.3%). High default rate among weekly supply group could also be explained by the fact that a majority of the family member supervised group received drugs on the weekly basis.

Drug formulation

In comparison of success rate between separate drug group (A) and combination group (B), group B had a higher success rate (82.6%) and lower default rate (11.8%) than group A (71.5% and 17.6%) with statistical significance

in treatment success (p-value=0.005) but no significance in default rate (p-value=0.082).

The reason for high success rate among combination drug group is that the combination drugs formulation is convenient to take and they have less side effect than separate form drugs. This reduced side effect resulted in higher success rate.

DOT duration

Treatment success rate was higher (89.8%) among 6 month DOT group than 2 month DOT group and self administration group (55.9% and 69.7%) with significant association (p-value<0.001). Default rate was much lower in 6 month DOT group (6.7%) than two month DOT group and self administration group (25.4% and 20.6% respectively) with statistical significance (p-value<0.001). It could be explained that directly observed treatment for the whole course of treatment could take immediate action on complicated cases such as default or side effect and so on. Therefore treatment success could get much more benefit from the direct observation for the whole course of treatment rather than the shorter period of direct observation. The fact that more than half of default (55% of 80 defaulters) occurred in continuous phase, can support more on the importance of 6 to 8 month DOT as well.

In this study, only 43.3% of family member supervised DOT group and 88.0% of health personnel supervised DOT group were treated under DOT for whole course of treatment. This might be another reason for low success and high default rate among family member supervised DOT group.

However another study conducted in Thailand by Dr. Pethawan et al showed that the practice of strict DOT during the first two months of treatment was not

associated with sputum conversion and treatment success in the study area. In that study, adjusted odds ratio for no sputum conversion and unsuccessful treatment were 1.1 (95%CI 0.6-2.1) and 1.3 (95%CI 0.6-2.8), respectively, for those who practiced strict DOT vs. the rest (Petchawn, 2002).

5.1.5 Patients' physical and disease condition related factors

Initial AFB status

The result of this study showed that the patients with more positive sputum status had significantly higher treatment success rate (79.6%) compared to those patients with less positive sputum status (+:76.7% and ++: 67.1%), with significant association (p-value = 0.027), But it did not have a constant direction. However it can be assumed that the more the smear is positive, the more the patient is infectious, and the more the patients' smear result is severe, the more the patients be motivated to follow the instruction given by the doctor, because they knew that if they were not cured, they would infect other people including their loved family members. Therefore in this study more severe smear positive patients had higher treatment success rate.

Sputum conversion status at the end of the intensive phase treatment

Health personnel and family member supervised DOT groups had a higher sputum conversion rates (72.5% and 71.1%) than self administration group (62.8%). This could be explained by the fact that 11.1% of self administration group had no test at the end of the intensive phase treatment, and

26.8% still had a smear positive result, compared to the health personnel supervised group (5.4% and 22.2%) and family member supervised DOT group (10.6% and 17.8%), respectively, and sputum conversion status was significantly associated with the treatment success. The result showed that the patient with AFB negative result at the end of the 2nd month of treatment had a higher treatment success rate (85.7%) than those with the AFB positive result at the end of the 2nd month of treatment (71.1%), with the significant association (p-value: 0.001). This helps explain further why health personnel supervised DOT group had higher success and low default rates

After controlling the confounding factors, sputum negative conversion status still remained significant with treatment success and default. Therefore this study suggested that treatment success will be increased, if the sputum negative conversion rate at the end of intensive phase treatment increases.

Side effect

Among 518 study subjects, 118 cases (22.8%) had side effects, and the side effect had a significant association (p-value=0.001) with the treatment success. For instance, treatment success rate was higher among the patients without side effect (79.3%) than those with a side effect (61.9%). After controlling the confounding factors, existence of side effect of TB drugs still remained significant with treatment success. Therefore this study suggested that treatment success will be increased if more attention is given to management on side effect.

According to the side effect proportion by the different types of DOT observer, 30.0% of the family member supervised patients, 7.8% of health personnel

supervised DOT group, and 29.8% of self administration group had side effect, respectively.

This can be explained by the assumption that health personnel supervised patients were always under observation of doctors and health personnel could properly manage the patients when they had some problems. However family member supervised group and self administration group were not always under the observation of health workers except when they came to health center for collecting drugs. This made it difficult to consult with a doctor all the time, particularly when they had some problems.

Less side effect among health personnel supervised DOT group could be explained by the fact that majority of health personnel supervised DOT group took the combination drug form which had a less side effect than the separate drug form.

5. 2 Conclusion

This study was a retrospective analytical study to assess the effectiveness of different types of DOT observers on treatment outcome along with other confounding factors with the following objectives 1) to investigate the difference in treatment outcomes between different types of DOT observers among new smear positive pulmonary TB patients registered in Bangkok chest clinic under MoPH and, Public health center 7, 16 and 23 under Bangkok Metropolitan Administration (BMA) during the period of Oct. 2002 to September 2004. and 2) To determine the socioeconomic, demographic and behavioral factors, and disease conditions of TB patients influencing on treatment outcomes among new smear positive pulmonary TB patients registered in Bangkok chest clinic under

MoPH and, Public health center 7, 16 and 23 under BMA during the period of Oct. 2002 to September 2004.

However this study was conducted in Bangkok Chest clinic under Ministry of Public Health, Public health center 7, 16 and 23 under Bangkok Metropolitan Administration, which may not be a true representation of the situation for effectiveness of different types of DOT observers on treatment outcome throughout the urban area of Thailand. There are many private hospitals and clinics, where patients can visit. The tuberculosis patient can also buy anti-TB drugs without prescription from the drug store.

In addition, the prepared checklists for data collection was limited to what was listed on the medical record. Therefore further necessary information could not be obtained. The medical record was the main source of the information in this study.

In conclusion, the main findings of this study are as follows.

1) Different types of DOT observers: Health personnel supervised DOT group reported the highest success (87.4%) and lowest default (6.6%) rates compared to other two groups i.e. family member supervised group (68.9% and 18.9%) and self administration group (70.2% and 21.1%) (p-value <0.001 in both success and default).

2) Change to no observer (non- DOT): Among 180 family member supervised patients, 56.1% changed to no observer after two month intensive phase treatment , while 10.2% health personnel supervised patients (17 of 167 patients) became non-DOT after intensive phase treatment. Behavior of change

to no observer greatly affected on treatment success and default.

3) Direct Observation Treatment (DOT): Directly observed treatment (DOT) can improve the treatment success, particularly in case of DOT for the whole course of treatment, rather than for only two months.

4) Age: Majority (86.0 %) of the study subject are in the economically most productive age; 15 to 54 years old. The younger age group had higher success rate than the older age groups. On the other hand, older age group had higher default rate than younger age group

5) Gender: In this study, male apparently have more chance to get TB than female. However gender had no statistical association with treatment success and default.

6) Marital status: The treatment success and default rates were not statistically associated with different marital status in this study.

7) Occupation: Different occupation groups had a strong association with treatment success and default. High success rate was in government servant and low success and high default rates were in farming and laboring group people.

8) Drug formulation: The formulation of TB drugs had a significant association with treatment success (p-value:0.005). Combination form of tuberculosis drugs have less side effect and higher success rate in comparison with separate form of tuberculosis drugs.

9) Duration of DOT: The duration of DOT had a significant association with a treatment success and default. Longer duration of DOT, higher success and lower default rates.

10) Sputum conversion status at the end of intensive phase treatment: The sputum conversion status at the end of the intensive phase treatment can predict the treatment outcome because the sputum status at the end of the second month of treatment has a significant association with the treatment success.

11) Side effect of drugs: Side effect is significantly associated with the treatment success. The less side effect, the higher success rate.

In general, it could be concluded that different types of DOT observers and its practice in terms of duration of DOT, drug formulation, and some socio-demographic characteristics such as age and occupation and so on had a significant association with treatment success and default. In addition, logistic regression method was used to compute OR (95%CI) and p-value. After controlling the confounding factors, types of DOT observers, side effect, sputum conversion status, and occupation still remained significantly related with treatment success. And as for default, types of DOT observer, sputum conversion status at the end of intensive phase treatment, occupation of patients and side effect still remained as significant factors related with default.

5. 3 Limitation of Study

- The data was collected only from the medical record as a secondary data, and face to face interview with study population was impossible in this time due to time constraints and language barrier.
- This study did not represent the whole picture of TB control program activity in Thailand and possibly limited generalizability.

- There may have been sampling bias due to incomplete capture of medical records for those self administration group. However there was almost 100% capture for DOT groups.

5.4 Benefits of Study

- First step towards looking at effect of different DOT observers on treatment outcome in Bangkok, Thailand.
- Inform the concerned authorities about the situation of TB treatment in Bangkok, Thailand so that they can take into their consideration for the future planning.

5.5 Recommendation

5.5.1 Recommendation for the tuberculosis control program.

1) Health personnel appears to be the first option as a DOT observer for the successful treatment
2) Family member might also be appropriate as a DOT observer. More attention should be given to behavior of family member supervised patients to change to no observer, particularly after the intensive phase treatment, which is greatly affecting the DOT advantage.
3) DOTS should be carried out for the whole course of treatment, instead of only for two or three months, particularly for family member supervised DOT group.

4) In TB control program, more concern should be given to increasing treatment success among those vulnerable group people such as unemployed, farmer and laborer including some special measures such as incentive.
5) Health education should be strengthened about the harm of drinking alcohol on tuberculosis treatment compliance.
6) In order to improve the treatment success rate and to make drug taking more convenient for patients, the combination form of tuberculosis drugs are recommended for the tuberculosis control program.

5.5.2 Recommendation for the future research study

1) When feasible, the data should be collected directly from the patients, health staff, and observers in order to get more information, which are not available in medical record so as to determine more decisive factors linked with treatment outcome.
2) In the future research, the study location should be selected more broadly among the public health centers under BMA in order to represent the overall picture of TB control program in Bangkok, Thailand
3) In the future study, effectiveness should be more thoroughly assessed by more detailed consideration of treatment outcome, such as failure, default, transfer out and death.

4) In the future study, the definition of DOT and types of DOT observer should be more precisely defined with the consideration of actual practice of DOT.