Pediatric Infectious Diseases Society of the Philippines Journal
Vol 15 No. 1 pp. 2-8 January –June 2014

ORIGINAL ARTICLE

COMPARISON OF TREATMENT OUTCOMES AMONG CHILDREN DIAGNOSED WITH PULMONARY TUBERCULOSIS TREATED AT THE TB DOTS AND THE PEDIATRIC OUTPATIENT DEPARTMENT*

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The authors declare that the data presented are original material and has not been previously published, accepted or considered for publication elsewhere; that the manuscript has been approved by all authors, have met the requirements for authorship.

ABSTRACT

Background: Although there are many studies on the effects of TB DOTS on the treatment outcomes of adults, there are limited studies in the pediatric population.

Objective: To compare the treatment outcomes of pediatric PTB patients who were treated in the outpatient department (OPD) and the TB DOTS Center from January 2007 – December 2011.

Methodology: A retrospective cohort study was conducted at the De La Salle University Hospital in Dasmarinas, Cavite. Charts of pediatric pulmonary tuberculosis (PTB) patients at the OPD and TB DOTS Center from January 2007 – December 2011 were reviewed. Demographic data as well as outcomes were compared.

Results: There were more patients treated for PTB at the OPD than in the DOTS, with age range between 1-3 years old. Sixty-three percent of patients at the DOTS were initially seen by private practitioners. After two months of treatment, 98.2% of patients in DOTS and 84.1% in the OPD were still compliant. The difference in percentage of patients with weight gain, relief of fever, and improved general well-being after two months between DOTS and OPD were statistically insignificant. However, the percentage of patients with relief from cough after two months of treatment was significantly higher in DOTS versus the OPD. The treatment success at the DOTS is significantly higher than in the OPD (95.4% versus 54.2%), with an approximately 1.8x times likelihood of successful treatment.

Conclusion: Patients at the DOTS who had cough were more likely to improve than in the OPD. The percentage of patients who defaulted after two months of treatment increased in the OPD. At the end of six months, the TB DOTS had better percentage of successful treatment.

KEYWORDS:

TB DOTS, pediatric pulmonary TB, TB treatment

***3rd Place PIDSP Research Contest 2013**

INTRODUCTION

Based on the 2004 statistics for health, tuberculosis (TB) is the 6th leading cause of morbidity and mortality in the Philippines. Approximately 1.5 million children are infected each year, and 40,000 develop the disease. The increasing number of cases in children is due to the spread of the disease from sputum positive adults.[1]

The control of TB in the Philippines started in 1910, when the mortality rate due to TB was at 487 per 100,000. One of the greatest impacts on the disease among the pediatric population occurred in 1970s when the BCG vaccination became part of the Expanded Program for Immunization (EPI). In 1996, the DOH launched the Directly Observed Treatment Short course (DOTS) strategy in selected cities.[1]

Involvement of private practitioners in TB control is useful to improve the diagnosis and management of the disease in patients and the patient's access to good care. Although there are many studies on the effects of TB DOTS on the treatment outcomes of adults, there are limited studies in the pediatric population. Determining the benefits of DOTS program in the treatment outcomes among children could encourage more private practitioners to make use of the referral system to the DOTS program.

Studies done on referral practices of private practitioners did not include pediatricians as the NTP in the Philippines focused on adult patients. A study done by Portero and Rubin in 2003 showed that most private practitioners had diagnosed five to ten new cases of TB per month, many of whom (87.9%) diagnosed TB based mainly on x-ray findings, and on a lesser extent based on the patient's symptoms. Only 12.3% referred their patients to the TB DOTS program. The study revealed that less than ¼ (24.2%) of private practitioners were well acquainted with the National Tuberculosis Guidelines. However, patients prefer being treated by private practitioners because of confidentiality issues, kind of and flexibility in treatment and shorter waiting time.[2] Management of private practitioners of their TB patients are often inadequate and have known to prescribe inappropriate treatment. They also rarely monitor the effects of treatment and are unable to maintain records of their patients' improvement. Only 62% of physicians provided information regarding the disease to their patients and placed emphasis on compliance. Only 58% requires a monthly check-up during the course of treatment and they estimated that only 10% to 35% of their patients come in for their monthly follow-up. [6]

The objective of this study was to compare the treatment outcomes of pediatric patients diagnosed with pulmonary tuberculosis who were enrolled in the TB DOTS program from January 2007 – December 2011. Specifically, it aimed to describe the sample population based on the following criteria: age, gender, facility that made the diagnosis (Private clinics, OPD, TB DOTS), facility that monitored the treatment (OPD, TB DOTS), and pulmonary TB Category. It also sought to determine the proportion of patients in the private versus the DOTS groups based on different clinical signs and symptoms and compare their responses to anti-TB treatment as well as the treatment outcomes.

METHODS

Study Design, Setting and Population

This is a retrospective cohort study in the OPD Pediatrics and TB DOTS of De La Salle University Medical Center, a tertiary hospital in Dasmarinas, Cavite. The study population included pediatric patients less than 19 years old who had been

diagnosed and treated for Pulmonary Tuberculosis at the OPD and TB DOTS center from January 2007 – December 2011. Patients not previously treated for TB, not known to have multiple drug resistance, and had data recorded during the TB treatment were included in the study. Patients with extrapulmonary TB, had no record, or had incomplete data were excluded.

Conduct of the Study

The research protocol was approved by the De La Salle Bioethics Committee, and the administration of the OPD and TB DOTS granted access to records. The patients were categorized under two groups: DOTS patients and patients managed by the Outpatient Department. The characteristics of the study population was described and baseline symptoms were recorded, including the baseline weight, presence of cough >2 weeks, fever and loss of appetite/decreased general well-being. Data from the patients' records were collected, including their symptoms and weight at the beginning of the treatment, after two months of treatment, and at the end of treatment or after 6 months. The NTP Diagnosis Form for Children and the TB Register for Children was used as data source for those patients enrolled at the TB DOTS Center. The NTP Treatment Cards were not available.

RESULTS

Demographic Characteristics of the Sample Population

A total of 253 patients were treated for PTB at the Outpatient Department and the TB DOTS from 2007 to 2011. One-hundred-nine (43.1%) patients were from the DOTS facility and 144 (56.9%) were from the OPD. The mean age of the patients was 6.5 years old; most of the patients belong to the 1-to-3 years old and 4-to-6 years old age range (26.8% and 24.1%, respectively).

Table 1. Distribution of patients based on gender

	GENDER		
	Male N (%)	Female N (%)	Total
DOTS	65 (59.6)	44 (40.4)	109
OPD	86 (59.7)	58 (40.3)	144
Total	151 (59.7)	102 (40.3)	253

Table 2. Distribution of Patients based on Age

		FACILITY		Total
		DOTS	OPD	
age	<1 yr	2	8	10
	1-3yrs	22	46	68
	4-6 yrs	37	24	61
	7-9 yrs	29	24	53
	10-12 yrs	13	12	25
	13-15 yrs	6	24	30
	>15 yrs	0	6	6
Total		109	144	253

Disease Characteristics and Diagnostic Examinations

The patients from the DOTS facility mostly received referrals from the private clinics (63.3%) and the OPD (33%). On the other hand, patients from the OPD were all diagnosed and managed in the same facility. There was only one case of PTB Category 1 who was treated at the DOTS center, while 99.6% of the patients were categorized as PTB III.

The four parameters being monitored among patients receiving anti-TB medication during their treatment were weight gain, relief of cough, relief of fever, and improved appetite/general well-being. The most common presenting symptom of patients was cough for more than two weeks (97.6%), followed by decreased appetite (74.7%) and prolonged fever (47.8%).

Comparison of Patients' Response to Treatment Between DOTS and OPD

After two months of treatment, a total of 219 (86.5%) patients were still compliant with their treatment based on their follow-ups in the DOTS facility and OPD. There were 107 (48.8%) patients from the DOTS facility and 112 (51.2%) from the OPD. Table 7 shows the number of patients who showed weight gain after two months of treatment. There were more patients from the DOTS facility who had weight gain than in the OPD (89.7% versus 80.4%). However, this difference is not statistically significant with a p-value at 0.053. After six months of treatment, only two patients at DOTS and six patients at OPD did not gain weight.

Table 3. Based on Weight gain after two months of treatment (n= completed treatment)

	Yes	No	Total
	N(%)	N (%)	N
DOTS	96(89.7)	11(10.3)	107
OPD	90(80.4)	22(19.6)	112
Total	186(84.9)	33(15.1)	219

Chi-square value=3.748, df=1, p-value=0.053

Table 4 shows the percentage of patients who had relief of cough after 2 months of treatment. It shows that all of the patients from both facilities had relief of cough after completing treatment at 6 months. Table 5 shows that the Chi-square value for the association between the persistence of cough and the facility that monitored the treatment was obtained with a p-value of 0.0015, and therefore a significant result. This data shows that the risk of persistence of cough is 60% more in the OPD than in the DOTS (RR=0.40, 0.19, 0.82). In terms of the relief from fever after treatment, all of the patients from both facilities already had relief of fever after completing treatment after 2 months. The chi-square test for this variable had a Fisher's exact p-value at 0.498, therefore was insignificant.

Table 4. Relief from cough after 2 months of treatment

	DOTS N(%)	OPD N(%)	Total N(%)
Cough present at 2 mos	6(5.6)	22(19.6)	28(12.8)
Cough absent at 2 mos	101(94.4)	90(80.4)	191(87.2)
Total	107	112	219

Table 5. Chi-Square Test for the Persistence of Cough at 2 months

Persistence of cough at 2 months	DOTS	OPD
(+) Persistence of cough	6	22
(-) Persistence of cough	99	86
	105	86

RR= 0.40 (0.19, 0.82); x^2 value 10.2, def=1, p-value = 0.0015

Table 6 shows the improved well-being of patients after two months and six months of treatment. As previously described, 63.3% of DOTS patients and 18.1% of OPD patients showed decreased well being and appetite before starting medications. After two months of treatment, almost all of the patients in the comparison groups had improved appetite. After six months of treatment, all of the patients had improved general well-being.

Table 6 shows that the Chi-square value for the association between the improved general well-being was insignificant with a p-value of 0.169.

Table 6. Improved general well being/ appetite after 2 and 6 months of treatment (n=competed treatment)

	FACILITY THAT MONITORED THE TREATMENT		
	DOTS N (%)	OPD N (%)	Total N (%)
Dec general well-being at Baseline	69(63.3)	26(18.1)	95(37.5)
Normal well-being at baseline	40(36.7)	118(81.9)	158(62.5)
Total	109	144	253
Dec general well-being at 2 mos	1(0.9)	2(1.8)	3(1.4)
Normal well-being at 2 mos	106(99.1)	108(98.2)	214(98.6)
Total	107	110	217

Table 7. Chi-Square Tests based on improved general well-being at two months

Well-being at 2 months	DOTS	OPD
Improved well-being	66	22
Unimproved well-being	1	2
	67	24

** Fisher's exact p-value = 0.169*

Comparison of Treatment outcomes

In terms of treatment success, 95.4% of the patient at DOTS had treatment success compared to the 54.2% of the OPD. Consequently, there is a higher percentage of defaulters from the OPD at 44.4% when compared with the DOTS facility (4.6%). The DOTS facility did not report any patient who had relapses, while the OPD had two cases of relapse.

Although the Chi-square for the three treatment outcomes seen in both facilities was invalid because of the low cell counts in the sub-table, Table 8 shows that the percentage of treatment success at the DOTS is significantly higher than that in the OPD with a p-value of <0.001 and Risk Ratio= 1.76 (95% CI 1.51, 2.06). Therefore, treatment success at the DOTS is 1.76 times more likely than in the OPD.

Table 8. Comparison of Treatment Success between DOTS and OPD

	Success N(%)	Failure N(%)	Total
DOTS	104 (95.4)	5 (4.6)	109
OPD	78 (54.2)	66 (45.8)	144
Total	182 (71.9)	71 (28.1)	253

Chi-square value= 5.281, df=1, p-value <0.001
Risk Ratio= 1.76 (95% CI 1.51, 2.06)

DISCUSSION

The National Tuberculosis Program guarantees free TB diagnosis and supervised treatment. Participation in the TB DOTS program is free of charge and covered under the Philippine Health Insurance program. A strong referral system of suspected TB patients from the private health sector to the public sector is very important for the proper treatment and monitoring of patients.[2]

The DOTS policy on the treatment of children with pulmonary TB states that: short course regimen with at least 3 anti-TB drugs (Isoniazid, Rifampicin and Pyrazinamide) for 2 months during the intensive phase and 2 anti-TB drugs (Isoniazid and Rifampicin) for 4 months during the maintenance phase. According to the guidelines, monitoring of the patient's response to the anti-TB drugs must be done monthly, and the patient will be examined for improvement of appetite and well-being, weight gain, and persistence or disappearance of signs and symptoms.[1]

Noncompliance decreases the chances of cure, increases the risk of relapse and drug-resistance.[3] The DOTS strategy increased the cure rate of TB of patients to more than 85%.[1]

In a study on the TB control in China in 2005, 70% of adult patients diagnosed with PTB who were not enrolled in the DOTS program were expected to have failures in completing their treatment. Only 21% of these patients who were not enrolled in the government programs and were getting treated in the general hospitals were given the recommended and standardized anti-TB treatment. Patients defer consult with a physician for their symptoms due to financial difficulty, the social stigma of having TB, lack of knowledge about the symptoms of TB, and lack of knowledge on the available free care for TB.[9]

The data in this study shows that there were more patients treated for PTB at the OPD than in the DOTS center, hence there were more patients who were buying their own medications out of their own pockets. The age range of patients in both facilities was between 1-3 years old, which is also where the highest mortality rate occurs. Sixty-three percent of patients at the DOTS facility were initially seen by private practitioners and was referred to DOTS for treatment and monitoring. This is higher than the referral percentage of 20% seen in the National Prevalence Survey in 1997. It is also notable that only 33% of the patients in DOTS were referrals from the OPD, since most of the patients at the OPD were from the low-income families and needed financial assistance for their medical expenses.

A total of 219 patients (86.5%) were still compliant to treatment after two months of treatment in both DOTS and OPD. This result was consistent with other studies done abroad. However, there were more compliant patients in the DOTS in comparison to the study done in Thailand by Anuwatnonthaate et al in 2008 (98.2% versus 95%), but less in the OPD or self-administered treatment (84.1% versus 86%).

This could be attributed to the financial burden of anti-TB treatment put upon the patients at the OPD. In contrast to the patients at the DOTS who received free medications, the medications at the OPD were self-provided. The study of Mishra on the significance of the professional-patient interaction on the adherence to treatment may be seen in this study. The TB DOTS is a specialized facility that caters only to patients undergoing diagnostics and treatment for TB. They are able to conduct lectures to their patients and may have the materials for proper information dissemination. Unlike in the OPD, the pediatric residents treat patients of different diseases and therefore may lack the time and resources to conduct lectures wherein they can answer the patients' questions on treatment. Also, there is no specific schedule for the patients to follow-up at the OPD and therefore patients arrive at the OPD in different times of the week.

Based on the response to treatment of the patients, the difference in percentage of patients with weight gain, relief of fever, and improved general well-being after two months between DOTS and OPD were statistically insignificant. However, the percentage of patients with relief of cough after two months of treatment was significantly higher in the DOTS group versus the OPD group. The percentage of treatment success at the DOTS was also significantly higher than in the OPD (95.4% versus 54.2%), with a likelihood of approximately 1.8 to be successful.

Despite the statistically insignificant difference in the response to treatment between the DOTS and OPD, there was a significant difference in the

treatment outcomes of patients. The cost of buying their own drugs can be a significant factor for the higher incidence of treatment defaulters at the OPD. Consequently, the free medications at the DOTS facility may have contributed to the higher percentage of treatment success at the DOTS center. The treatment regimen prescribed to the patients may also be a factor in the difference in the treatment response of the patients. However, this factor was not investigated in this study and will be a part of the recommendations of the author.

CONCLUSION

Patients undergoing treatment at the TB DOTS facility are more likely to have improvement in their cough than those in the OPD. In terms of relief of fever, improvement in appetite, or weight gain, there was no difference. There was an increased percentage of patients who have defaulted as early as after two months of treatment in the OPD. At the end of six months of treatment, the TB DOTS had the better percentage of treatment success.

RECOMMENDATIONS

The knowledge of the residents at the OPD on the National Tuberculosis Guidelines should be evaluated to determine the cause of the low referral rates of the OPD to the DOTS facility. The DOTS facility is composed mainly of nurses, and it lacks the services of pediatricians or pediatric pulmonologists who can detect any complications or problems that patients may encounter during their treatment. The reasons for the high percentage of treatment defaulters at the OPD should be investigated in order to create programs for better compliance and better referral system. Coordination between the OPD and the DOTS clinic should also be explored.

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