Mycobacterial Diseases
ISSN: 2161-1068

Jemal et al., Mycobact Dis 2015, 5:4
DOI: 10.4172/2161-1068.1000190

Research Article Open Access

Treatment Outcomes of Tuberculosis Patients in Metema Hospital, Northwest Ethiopia: A Four Years Retrospective Study

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Received date: June 29, 2015; **Accepted date:** July 15, 2015; **Published date:** July 25, 2015

Abstract

Background: Despite the availability of effective drugs, tuberculosis remains to be a major public health problem in the world. This study sought to determine treatment outcomes and to investigate associated factors for poor treatment outcomes among TB patients in Northwest Ethiopia.

Method: A retrospective cohort study was conducted using medical records of TB patients who registered and treated at Metema hospital. Bivariate and multivariate analysis was used to determine predictors of unsuccessful outcomes. Odds ratio (OR) and 95% confidence intervals (CI) were calculated. P value less than 0.05 was considered as statistically significant.

Results: Of the total 2970 patients, 2657 (89.5%) were newly diagnosed TB cases; whereas 167 (5.7%) and 146 (4.9%) were re-treatment and transfer cases, respectively. About sixty percent of the patients were male. The median age (SD) of the patients were 28 years (14.38) and 30.7% of patients were within the age group of 25-34 years. Five hundred eight (20.1%) TB patients were co-infected with HIV. With respect to the treatment outcomes, 65.3% were successfully treated, 88 (3.0%) died, 107 (3.3%) defaulted, 22 (0.7%) failed and 814 (27.4%) were transferred out. A declining trend of treatment success rate (TSR) was observed, from 73.1% in 2009 to 54.5% in 2011/12. Co-infection with HIV (P=0.00) and being male (P=0.02) were associated with unsuccessful treatment outcomes.

Conclusion: Treatment success rate (TSR) of TB patients was still low and a declining trend of TSR was observed over the study period. Co-infection with HIV and being male were found to be correlated with poor treatment outcomes. Thus, we recommend targeted medical interventions of the patients at high risk for the unfavorable treatment outcomes.

Keywords: Tuberculosis; Treatment outcome; DOTS

Introduction

Despite the availability of multiple anti-tuberculosis drugs, tuberculosis (TB) continues to be one of the major public health problems in the world. It is accounted for about 8.6 million new infections and over 1.3 million deaths each year globally [1]. About 90% of the estimated deaths and 85% of the estimated 8.6 million new cases of TB occur in developing countries, especially in Asian and African countries. Tuberculosis epidemic is being fuelled by a number of risk factors including co-infection with HIV, poverty, population expansion, malnutrition, emergence and spread of multidrug resistant (MDR) TB strains, and poor case detection and cure in resource constrained settings [2-6].

Ethiopia is one of the countries that are highly affected by TB epidemics and ranked 7th among the 22 high TB burden countries in the world [7]. The annual incidence and prevalence rates of all TB cases in Ethiopia have been estimated to be 261 and 394 per 100 000 population, respectively [8]. In the year 2008-2009, TB was the third leading cause of hospital admissions and a leading cause of in-patient deaths [9]. The reported high mortality rate among TB patients in Ethiopia has been ascribed to co-infection with HIV and the emergence of MDR M. tuberculosis strains [10].

Ethiopia has adopted the Directly Observed Treatment Short course (DOTS) recommended by the World Health Organization (WHO) since 1992 with the aim to achieve 70% case detection rate and 85% treatment success rate [7,10,11]. Implementation and expansion of DOTS strategy in the country have been shown to improve TB treatment success rates (TSR) [12-15]. According to the estimates of the federal Ministry of Health, Ethiopia has achieved 67% and 84% national cure rate and TSR respectively; while the case detection rate was 34% [7]. However, there are high discrepancies in the results of treatment outcomes being reported from different regions of the country, with frequent poor outcomes from northwest Ethiopia [12,16-18]. Thus, it is essential to monitor the treatment outcomes of TB patients routinely to identify the socio-demographic and clinical correlates for poor TB treatment outcomes.

To this end, we conducted a retrospective study of TB patients from 2009 to 2013 through medical records review. The aim of this study was to evaluate treatment outcomes and to determine predictors for unsuccessful treatment outcomes.

Materials and Methods

Study design, study site and population

A retrospective cohort study was conducted to determine TB treatment outcomes among TB patients registered at Metema hospital DOTS clinic from April 2009 to August 2012. The hospital is located in the North Gondar zone, Shehidy town, Northwest Ethiopia. Metema hospital, with a capacity of 44 beds, provides services for over 1500 patient per year. The hospital has a DOTS clinic where TB patients are treated and monitored according to national tuberculosis and leprosy control program (NTLCP) guidelines [10]. The study population was all TB patients who attended and initiated treatment at Metema hospital from April 2009 to August 2012.

Characteristics	PTB+[N (%)]	PTB-[N (%)]	EPTB [N (%)]	Total [N (%)]
Age category				
0-14	78 (21.1)	213 (57.6)	79 (21.4)	370 (12.5)
15-24	237 (31.3)	404 (53.4)	115 (15.2)	756 (25.5)
25-34	285 (31.2)	506 (55.4)	122 (13.4)	913 (30.7)
35-44	138 (27.3)	297 (58.7)	71 (14.0)	506 (17.0)
45-54	80 (34.8)	129 (56.1)	21 (9.1)	230 (7.7)
55-64	41 (34.7)	58 (49.2)	19 (16.1)	118 (4.7)
>65	25 (32.5)	38 (49.4)	14 (18.2)	77 (2.6)
Sex				
Male	529 (30.0)	980 (55.6)	254 (14.4)	1763 (59.4)
Female	355 (29.4)	665 (55.1)	187 (15.5)	1207 (40.6)
Patients' category				
New	712 (26.8)	1559 (58.7)	386 (14.5)	2657 (89.5)
Relapse	113 (69.3)	42 (25.8)	8 (4.9)	163 (5.5)
Defaulter	1 (50.0)	1 (50.0)	0 (0.0)	2 (0.1)
Failure	1 (50.0)	0 (00.0)	1 (50.0)	2 (0.1)
Transfer in	57 (39.0)	43 (29.5)	46 (31.5)	146 (4.9)
HIV Status				
Negative	603 (28.4)	1216 (57.3)	305 (14.4)	2124 (71.5)
Postive	189 (31.6)	319 (53.3)	90 (15.1)	598 (20.1)
Unknown	92 (37.1)	110 (44.4)	46 (18.5)	248 (8.4)
Overall	884 (29.8)	1645 (55.4)	441 (14.8)	2970 (100)

Table 1: Demographic characteristics and HIV-status in patients with all types of Tuberculosis cases, Metema Hospital, 2009-2012. PTB+: Smear positive pulmonary tuberculosis; PTB-: Smear negative pulmonary tuberculosis; EPTB: Extra-pulmonary TB; N: Frequency.

TB diagnosis and treatment

Patients who presented to the hospital with clinical symptoms including a cough lasting for two or more weeks, fever and night sweat, shortness of breath and sputum production were examined according to the NTLCP guidelines of Ethiopia. Briefly, morning sputum samples were examined by Zeihel-Nielsen staining, for the presence of Acid fast bacilli (AFB) and/or chest radiography was performed. Further, pathological or clinical investigations were employed for diagnosis of extra-pulmonary tuberculosis (EPTB).

Treatment outcomes	Types of TB			
	PTB+ [N (%)]	PTB- [N (%)]	EPTB [N (%)]	Total [N (%)]
Cured	412 (92.6)	25 (5.6)	8 (1.8)	445 (15.0)
Completed	215 (14.4)	973 (65.1)	306 (20.5)	1494 (50.3)
Failure	8 (36.4)	9 (40.9)	5 (22.7)	22 (0.7)
Defaulter	25 (23.4)	70 (65.4)	12 (11.2)	107 (3.3)
Died	29 (33.0)	46 (52.3)	13 (14.8)	88 (3.0)
Transferred out	195 (24.0)	522 (64.1)	97 (11.9)	814 (27.4)
Overall	884 (29.8)	1645 (55.4)	441 (14.8)	2970

Table 2: Treatment outcomes of TB patients at DOTs clinic of Metema Hospital, 2009-2012. PTB+: Smear positive pulmonary tuberculosis; PTB-: Smear negative pulmonary tuberculosis; EPTB: Extra-pulmonary TB; N: Frequency.

A patient who tested AFB positive (AFB+) with one or more initial sputum smear examination by direct microscopy, or AFB+ with one sputum examination and radiographic abnormalities consistent with pulmonary TB was classified as smear positive pulmonary TB (PTB+) case. A patient who does not meet the above criteria for PTB+ case but with at least two sputum smear examinations negative for AFB, clinical symptoms and radiographic abnormality consistent with active PTB, not responding to a course of broad-spectrum antibiotics; and a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy; or culture positive but sputum smear negative results was grouped as smear negative pulmonary TB (PTB-) case. On the other hand, EPTB was defined as a patient with tuberculosis of organs other than lungs with diagnosis based on one culture-positive specimen, or histological or strong clinical evidence consistent with the active extra-pulmonary disease. All patients who diagnosed positive for TB were registered, treated and monitored at DOTS clinic of Metema Hospital as per the NTLCP guidelines.

Newly diagnosed TB patients were treated with rifampicin (R), isoniazid (H), pyrazinamide (Z), ethambutol (E) (RHZE) combinations for the first two months under direct supervisions of a health worker. This followed by self-administered RH or EH during the continuation phase. Re-treatment cases were treated with RHZES for 2 months, ERHZ for another 1 month, and ERH for 5 months [10].

Definitions

TB treatment outcomes were defined in line with the WHO definitions of TB cases [11]. *Cured:* a patient who was initially sputum smear-positive and completed with negative sputum smears at the end of treatment. *Failed:* a patient with a smear positive TB initially and remained smear-positive at month 5 or later during treatment despite the correct intake of medication. *Treatment completed:* A patient who

has completed treatment but without bacteriology result. *Defaulted:* A patient who has not taken antiTB drugs for 2 months or more consecutively. *Died:* a patient who died during the course of TB treatment regardless of the causes of death. *Transferred out:* a patient with unknown treatment outcomes because of transfer to another TB Unit. *Successfully treated:* when a patient has cured or completed treatment.

Data collection

Data were collected from the DOTS registration book developed by the NTLCP of Ethiopia in conjunction with the Federal Ministry of Health. Socio-demographic variables such as, age and sex, and clinical characteristics including category of TB at the start (new, relapse, defaulter), types of TB (whether pulmonary or extra-pulmonary), co-morbidity with HIV/AIDS, and treatment outcomes were collected from the DOTS registration book.

	Apr, 2009-Aug, 2009	Sept, 2009-Aug, 2010	Sep, 2010-Aug, 2011	Sept, 2011-Aug, 2012
Cured	282 (32.3)	79 (9.0)	52 (6.4)	32 (7.9)
Died	25 (2.9)	24 (2.7)	32 (3.9)	7 (1.7)
Failure	6 (0.7)	7 (0.8)	9 (1.1)	0 (0.0)
Defaulter	23 (2.6)	41 (4.7)	30 (3.7)	13 (3.2)
TO	181 (20.7)	251 (28.8)	217 (26.6)	165 (40.6)
Completed	358 (40.8)	471 (54.0)	477 (58.4)	189 (46.6)
PTB+	413 (47.3)	217 (24.9)	163 (20.0)	91 (22.4)
PTB-	319 (36.5)	544 (62.3)	556 (68.1)	226 (55.7)
EPTB	142 (16.2)	112 (12.8)	98 (12.0)	89 (21.9)
Overall	874	873	817	406

Table 3: Trends of treatment outcomes and Tuberculosis types across the study period at DOTs clinic of Metema Hospital, 2009-2012. PTB +: Smear positive pulmonary tuberculosis; PTB-: Smear negative pulmonary tuberculosis; EPTB: Extra-pulmonary TB; N: Frequency; TO: Transferred Out.

Statistical analysis

Data were entered, cleaned and analysed using SPSS version 20 statistical package (SPSS, Chicago, IL, USA). Cleaning of data was done to check consistency and completeness of the data set. Frequencies and proportions were used to describe the study population in relation to relevant variables. Bivariate and multivariate logistic regressions were used to identify significant predictors. The degree of association between independent and dependent variables was assessed using odds ratio (OR) with 95% confidence interval (CI). P value of less than 0.05 was considered as statistically significant.

Ethics statements

This study was conducted in accordance with the research ethics of the University of Gondar. Ethical clearance was obtained from the institutional ethical review board of the University of Gondar. As this was a retrospective cohort study, the consent of patients was not obtained. However, patient information was handled anonymously with an assuring confidentiality.

Results

Demographic and clinical characteristics of the study participants

A total of 2970 TB patients were registered at Metema hospital DOTS center for treatment between April 2009 and August 2012. Of these, 2657 (89.5%) were newly diagnosed TB cases and the remaining were re-treatments cases (Table 1). The median age (+SD) of the patients were 28 years (14.38) and 30.7% of patients were within the age range of 25-34 years. About sixty percent of study participants were male, with male to female ratio 1.5:1. With respect to the type of TB, PTB- case was the most prevalent 1645 (55.4%) as compared to PTB+ 884(29.8%) and EPTB 441 (14.8%) cases. five hundred ninety-eight (20.1%) TB patients were confirmed to be co-infected with HIV and 248 (8.4%) patients were involuntary to be diagnosed for HIV.

Treatment outcomes

Of the total 2970 patients who initiated anti-TB treatment, 1939 (65.3%) had successfully treated (15.0% with cure and 50.3% with completed the treatment). Smear-positive PTB patients constitute a larger proportion of patients who had completed the treatment with cure compared to the remaining TB types (Table 2). The overall death, defaulter and failure rates among the study participants were 88(3.0%), 107 (3.3%) and 22 (0.7%) respectively.

The treatment outcome of all TB patients across the years is depicted in Table 3. The cure rate of tuberculosis patients showed a steadily declining trend over the study period from 282 (32.3%) in 2009 to 52 (6.4%) in 2010/11, albeit the slight increase (7.9%) in 2011/12. In contrast, the transferred out rate was increased over the study period from 181 (20.7%) in 2009 to 165 (40.6%) in 2011/12 (Table 3). Overall, treatment success rate (TSR) was declined across the study period.

Treatment outcomes of TB patients in relation to age, sex, baseline patients' category and HIV status are summarized in Table 4. Of the total 88 patients who died, 40 patients had co-infected with HIV. None of previously defaulted and failed patients who admitted for re-treatment showed poor outcomes in this study. However, relatively high death rates were observed among transfer patients 8 (5.5%) and those who were re-treated for relapse TB cases 6 (3.7 %).

Univariate and multivariable logistic regression analysis was performed to identify socio-demographic and clinical predictors for unsuccessful treatment outcomes among the study participants (Table 5). The analysis revealed that being male sex (p=0.02) and co-infection with HIV (AOR:0.45, 95% CI 0.34-0.64, P=0.00) were the independent predictors for poor treatment outcomes.

Discussion

The effectiveness of tuberculosis treatment has been improved substantially since the implementation and expansion of DOTS strategy [12-16]. However, this strategy is being challenged by poor treatment outcomes including low adherence, treatment failure and death in many countries, especially in low and middle-income countries [17,19-22]. The WHO has recommended routine monitoring of treatment outcomes in order to determine the

effectiveness of TB control program and to circumvent the adverse outcomes. In this study, we evaluated the treatment outcomes of 2970 tuberculosis patients who registered at Metema hospital DOTS clinic over a period of five years.

Characteristics	Treatment Outcomes					TO	Total
	Successfully treated		Unsuccessful treated				
Age Category	Cured	Completed	Defaulter	Failure	Died		
0-14	39 (10.5)	217 (58.6)	12 (3.2)	3 (0.8)	15 (4.1)	84 (22.7)	370
15-24	122 (16.1)	365 (48.3)	22 (2.9)	7 (0.9)	22 (2.9)	218 (28.8)	756
25-34	144 (15.8)	449 (49.2)	39 (4.3)	6 (0.7)	28 (3.1)	247 (27.1)	913
35-44	64 (12.6)	259 (51.2)	23 (4.5)	3 (0.6)	10 (2.0)	147 (29.1)	506
45-54	40 (17.4)	105 (45.7)	6 (2.6)	2 (0.9)	9 (3.9)	68 (29.6)	230
55-64	20 (19.9)	65 (55.1)	5 (4.2)	1 (0.8)	1 (0.8)	26 (22.0)	118
>65	16 (20.8)	34 (44.2)	0 (0.0)	0 (0.0)	3 (3.9)	24 (31.2)	77
Sex							
Male	257 (14.6)	869 (49.3)	70 (4.0)	13 (0.7)	61 (3.5)	493 (28.0)	1763
Female	188 (15.6)	625 (51.8)	37 (3.1)	9 (0.7)	27 (2.2)	321 (26.6)	1207
Patients' category							
New	367 (13.8)	1368 (51.5)	102 (3.8)	19 (0.7)	74 (2.8)	727 (27.4)	2657
Relapse	47 (28.8)	61 (37.4)	3 (1.8)	2 (1.2)	6 (3.7)	44 (27.0)	163
Defaulter	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2
Failure	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	2
Transfer in	29 (19.9)	64 (43.8)	2 (1.4)	1 (0.7)	8 (5.5)	42 (28.8)	146
HIV Status							
Negative	296 (13.9)	1094 (51.5)	73 (3.4)	14 (0.7)	43 (2.0)	604 (28.4)	2124
Postive	90 (15.1)	276 (46.2)	25 (4.2)	7 (1.2)	40 (6.7)	160 (26.8)	598
Unknown	59 (23.8)	124 (50.0)	9 (3.6)	1 (0.4)	5 (2.0)	50 (20.2)	248

Table 4: Treatment outcomes of TB patients in relation to demographic and clinical characteristics, Metema Hospital, 2009-2012. .

Characters	Treatment success		COR (95% CI)			
	Yes [N (%)]	No [N(%)]		P value	AOR (95% CI)	P value
Age Category						
0-14	256 (89.5)	30 (10.5)	1.05 (0.67-1.65)	0.83	0.96 (0.61-1.52)	0.88
15-24	487 (90.5)	51 (9.5)	1.18 (0.81-1.71)	0.4	1.11 (0.76-1.63)	0.58
25-34	593 (89.0)	73 (11.0)	1	-	1	-
35-44	323 (90.0)	36 (10)	1.11 (0.73-1.68)	0.64	1.03 (0.67-1.57)	0.91
45-54	145 (89.5)	17 (10.5)	1.05 (0.60-1.83)	0.86	0.97 (0.55-1.70)	0.9
55-64	85 (92.4)	7 (7.6)	1.49 (0.66-3.35)	0.33	1.39 (0.62-3.15)	0.42
>65	50 (94.3)	3 (5.7)	2.05 (0.62-6.75)	0.24	1.89 (0.57-6.25)	0.29

Sex						
Male	1126 (88.7)	144 (11.3)	1	-	1	-
Female	813 (91.8)	73 (8.2)	1.4 (1.06-1.91)	0.02	1.44 (1.07-1.94)	0.02
Types of TB						
PTB+	627 (91.0)	62 (9.0)	0.97 (0.61-1.53)	0.88	0.99 (0.62-1.57)	0.95
PTB-	998 (88.9)	125 (11.1)	0.76 (0.50-1.16)	0.2	0.77 (0.51-1.18)	0.23
EPTB	314 (91.3)	30 (8.7)	1	-	1	-
HIV Status						
Negative	1390 (91.4)	130 (8.6)	1	-	1	-
Postive	366 (83.6)	72 (16.4)	0.48 (0.35-0.65)	0	0.47 (0.35-0.64)	0
Unknown	183 (92.4)	15 (7.6)	1,14 (0.65-1.99)	0.64	1.10 (0.63-1.93)	0.73

Table 5: Treatment success rate in TB patients at DOTs clinic of Metema Hospital in relation to demographic and clinical characteristics, 2009-2012. PTB+: Smear positive pulmonary tuberculosis; PTB-: Smear negative pulmonary tuberculosis; EPTB: Extra-pulmonary TB; N: Frequency; COR: Crude Odds Ration; AOR: Adjusted Odds Ratio.

In this study, we found 65.3% overall treatment success for all TB cases. This finding was below the national TSR (84%) [7], and the 94.8% and 83.6% TSRs reported from Enfranz, northwest Ethiopia and Arsi, central Ethiopia, respectively [15,16]. But, it was higher than the rates reported from Gondar hospital (29.5%), Bahir dar (26%) and Debre Markos hospital (59.3%), Ethiopia [17,18,23]. The observed low TSR in this study could be in part ascribed to high transfer out cases (27.4%), which was excluded from analysis in some studies [15,16]. However, we noted that the overall defaulter, death, and failure rates were similar to reports by a number of other studies from the country [15,16,18,23].

Further, a declining trend of treatment success was observed over the study period which could be largely attributable to the high transfer out rate after 2011; may be due to expansions of DOTS centers in the area. Yet, a steadily declining trend of cure rate, even during the years with a similar transfer out rates, needs to be addressed.

Our cohort analysis revealed higher proportions of defaulters (65.4%) and deaths (52.3%) among smear negative pulmonary TB patients, consistent with a finding of previous study [24]; but the reasons for this discrepancy are not clear. A high death rate among PTB- patients could be due to delays in diagnosis and treatment, and high proportion of HIV co-infection (53.3% of all HIV+ cases) in this group (data not shown). This finding suggests a need for alternative intervention methods to improve the outcomes of patients suffering from this type of tuberculosis. Further, the higher failure and death rates among relapse patients might suggest a higher prevalence of MDR-TB in this group as previously reported [25-28]. A study by Esmael et al., for example, had showed 6.4 times higher likelihood of MDR-TB infection among re-treatment patients than new cases. Similarly, the WHO has estimated about 10-folds higher prevalence of MDR-TB in previously treated patients than treatment naïve patients [27,28]. Taken together, our finding suggests further investigations of re-treatment patients to determine the extent of MDR-TB in the area and to guide clinical action.

In order to determine the predictors for poor outcomes, we analysed demographic and clinical determinants of treatment outcomes. Our data showed that HIV co-infection and male sex were associated with high likelihood of experiencing unsuccessful treatment outcomes. This was in agreement with a number of previously published studies [10,16,24,29]. HIV infection in TB patients may result in negative sputum-smear and normal chest radiographs, thus challenging TB diagnosis [30-33]. This might result in delayed case detection and initiation of TB treatment which, in turn, led to poor outcomes. Furthermore, TB/HIV co-infection often associates with poor response to TB-medications due to malabsorption of anti-tuberculosis drugs, overlap toxicity in ART patients and/or due to the risk of immune reconstitution inflammatory syndrome [34]. Thus, this finding highlights the need for alternative approaches for effective diagnosis and coordinated treatments of TB and HIV to reduce morbidity and mortality resulting from these infections.

Poor treatment outcomes were observed among male patients especially in those in the age group of 25-34 years. This might be related to higher tendencies of this group to alcohol and drug abuse, and travelling a long distance (for economic reasons) that might result in interruption of their medication as well as due to high prevalence of HIV in this group. However, the underlining predictors of poor outcomes among male patients including biochemical, behavioral, cultural and socioeconomic determinants need to be identified. In contrast to several studies, types of TB and age of patients did not significantly associate with unsuccessful treatment outcomes in this study [16,24,29]. This is probably due to the differences in the study population.

Due to the inherent features of retrospective study design we employed, this study has some limitations. The study is lacking inclusion of important variables which may affect treatment outcomes including latency of treatment initiation, distance from DOTS center, economic status, and co-morbidities with intestinal parasites/other diseases. Despite the limitations, the results of this study may have an implication for policy makers and TB program managers to gain important insights into the correlates of unsuccessful treatment outcomes of TB cases in this part of Ethiopia.

Conclusion

The result of this study showed that treatment success of TB patients at Metema hospital is still low. Moreover, there was a declining trend of TSR over the study period that needs to be addressed urgently. In this study, TB/HIV co-infections and male sex were risk factors for poor treatment outcomes. Thus, we recommend targeted medical interventions for the patients who are at high risk of unfavorable treatment outcomes.

Authors' contributions

FM, BT, TD: Conception and designing of the study; MJ, AE, DT, TA, ME: data collection, entry into SPSS software and clean up. TD: conducted data analysis, interpreted the results and wrote the manuscript for publication. FM: reviewed the initial and final drafts of the manuscript. All authors read and approved the final manuscript.

Acknowledgements

We acknowledge the Metema Hospital physicians, counselling nurses and laboratory staff for their kind cooperation during data collection.

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