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HIV CASE DETECTION AMONG TUBERCULOSIS PATIENTS IN PAKISTAN

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Key words*: Tuberculosis, HIV screening, concentrated epidemic*

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ABSTRACT

Objective: To describe feasibility and results of systematic screening of TB patients for HIV.

Design: Cross-sectional study.

Setting: Six selected sentinel sites (public DOTS clinics) in province of Sindh, Pakistan.

Participants: All TB patients aged 16-60 years registered for treatment from April 2008 to March 2012.

Measurement: Demographic information of TB patients, screening for HIV through rapid testing and confirmation by referral lab of Sindh AIDS Control Program, according to national guidelines.

Results: Of a total of 18,461 registered TB patients, 12,882 fulfilled the inclusion criteria and were given education and counseling. Of those counseled 12,552 (97.4%) were screened for HIV using a rapid test. Males made up 48% of the sample and 76.5% of patients had pulmonary TB. Of the total patients tested 42 (0.34%) were HIV-positive after confirmatory testing at the Sindh AIDS Control Program Laboratory. Prevalence of HIV among male patients was 0.66% whereas prevalence among female patients was 0.03% (p value <0.001). Prevalence of HIV among pulmonary TB patients was 0.29% and among extra pulmonary TB patients was 0.48% (p value 0.09).

Conclusion: In public DOTS clinics in Pakistan it is feasible to test TB patients for HIV. Prevalence of HIV is three times higher among TB patients as compared to the general

population in Pakistan. Routinely screening all TB patients for HIV infection, especially targeting males and ensuring antiretroviral therapy, can significantly improve TB/HIV collaborative activities in Pakistan and indentify many cases of HIV, improve health outcomes and save lives.

INTRODUCTION

In recent years Pakistan has moved from having low HIV prevalence to a concentrated HIV epidemic.[1] Prevalence of HIV among general population in Pakistan is still low (0.1%) and the estimated number of cases in the country of 180 million people is under one hundred thousand, of which only about 7000 cases are reported.[1] HIV cases detection and treatment is one of the important HIV prevention strategies. Finding HIV cases among TB patients and providing ART (antiretroviral therapy) will contribute significantly not only in HIV/AIDS prevention and improve outcomes of TB treatment in HIV positive TB patients.[2]

Pakistan ranks 5th among the countries with highest burden of TB in the world and contributes to about 63% of tuberculosis burden in the Eastern Mediterranean Region.[3] Estimated prevalence and incidence of TB (all forms) in Pakistan is 310/100,000 and 231/100,000 respectively.[4]

TB is the leading cause of death among HIV patients.[2] The unfavorable synergy between HIV and tuberculosis epidemics has added significantly to the suffering and death caused by each disease alone.[5]

In 2004 WHO released guidelines for HIV surveillance among tuberculosis patients recommending that generalized and concentrated epidemics use data from routine HIV counseling and testing of all TB patients form the basis for the surveillance.[6] Pakistan had a low-level epidemic and integration of these TB/HIV services was not prioritized. Updated guidelines recommend that all TB patients be screened for HIV and emphasized the need to establish mechanisms for delivering integrated TB and HIV services, preferably at the same time and location.[6] Furthermore surveillance provides information necessary to monitor the effectiveness of joint strategies aimed at reducing the impact of HIV among TB patients.

However, in 2010 Pakistan reported that only 2% of TB patients knew their HIV status and that nationally, only 22 TB/HIV patients were reported and only 9 put on ART.[7]

The objectives of this study were to investigate the feasibility of HIV screening among TB patients registered for treatment in selected TB treatment centres in Sindh province and to describe how HIV affects TB patients in the study area.

The specific aims of the study were to educate and counsel TB patients about HIV/AIDS, to implement TB/HIV registration at DOTS centers, to register HIV infected TB patients at ART centres for treatment and to determine the refusal rate for HIV screening among TB patients.

METHODS

We conducted a cross-sectional study of TB patients (all forms) registered in selected six sentinel sites (TB treatment centers) under the National TB Control Program in the Sindh province of Pakistan from April 2008 to March 2012. Sites were selected on basis of adequate number of TB cases registered annually, trained staff and a separate room for the education and counseling of TB patients to ensure privacy and confidentiality. All TB patients aged 16 to 60 years who gave informed consent were included in the study. These patients were provided education and counseling for HIV by trained social mobilizers ensuring confidentiality and privacy and their demographic information was recorded in TB/HIV register, maintained at each site. Demographic information included age, gender, marital status, area of residence (urban or rural), and type of tuberculosis (pulmonary or extra pulmonary). Patients were tested for HIV using Rapid HIV kit (Bioline HIV-1/2 3.0, Standard Diagnostic Inc, Kyonngi-do, Korea). Those whose rapid test results were non-reactive were given results after post-test counseling. Venous blood samples were taken from those whose rapid test results were reactive and sent to the Referral Lab

of Sindh AIDS Control Program for confirmation using the UNAIDS/Government of Pakistan HIV testing strategy based on three different test principles or test antigen. At the Referral Lab samples were initially cross checked on HIV1&11 Determine Rapid kit and all reactive samples were further tested on two different ELISA using HIV Ag/Ab Combination by Abbott Murex and HIV Ansi- labsystem kits using Multiscan MS ELISA Reader. All confirmed HIV-positive TB patients were provided results with post-test counseling and then linked to HIV treatment at Civil Hospital Karachi for further care and support services including ART according to national guidelines.

Statistical Analysis

Data were entered twice by separate operators using Epi Data version 3.1 (The EpiData Association, Odense, Denmark). Data were cleaned and analysis was performed using Statistical Package for Social Sciences (SPSS) version 16.0 (IBM Corporation). For continuous variables summary statistics were computed. Frequencies were calculated for categorical variables. Chi-Square and Fisher Exact tests (where required) were used to compare different variables between HIV-positive and HIV-negative TB patients. Bivariate analysis was performed for estimation of odds ratios and 95% confidence intervals. A p value of <0.05 was considered significant.

ETHICAL REQUIREMENT

The study was approved by the Ethical Review Committee of Bridge Consultants Foundation, which is registered with the Office of Research Protection, National Institute of Health, USA.

RESULTS

A total of 18,461 TB patients were registered for treatment at the six sentinel sites during study period. Of the total TB patients, 12,822 met the study criteria for age and received counseling. 270 did not wish to be included in the study. 97.8% (n= 12,552) accepted HIV testing. Mean age was 32 years (range 16-60 years) and 47.8% (n=6011) of these tested patients were males. Of the total screened 76.9% (n=9655) had pulmonary TB and 22.9% (n=2867) were extra-pulmonary TB patients. A total of 42 people were found to be HIV-positive for a prevalence of 0.33% (table 1). Prevalence of HIV among males was 0.66% and 0.03% among females (p value <0.001). Prevalence of HIV among extra-pulmonary TB cases was 0.48% whereas prevalence of HIV among pulmonary cases was 0.29%. Prevalence of HIV in TB patients in the 18 to 44 years age group was found to be 0.49% while prevalence of among those >44 years of age was 0.169%. Of the 42 HIV-positive patients found, 35 were successfully registered at ART site.

DISCUSSION

The study demonstrates the feasibility and acceptance of screening large number of TB patients for HIV and linking them to ARV treatment. Our study found a threefold-higher prevalence of HIV among TB patients compared to the general population, and the overwhelming majority of the HIV-infected TB patients detected were males.

The prevalence of HIV among TB patients was found to be 0.34% and while this figure is considerably less than 12%, WHO's estimate of HIV among the world TB patients it is in line with the estimates for Pakistan (0.3%).[7]

In Pakistan the male to female ratio in the reported HIV cases is 10:1.[8] This gender difference was also evident in HIV positive TB patients in our study. The prevalence of HIV was 22 times higher among male TB patients (0.68%) compared to female TB patients (0.03%). Sexual promiscuity is less common among female population as compared to male population in Pakistan.[9, 10] Moreover significant number of reported HIV/AIDS cases in Pakistan have been male overseas Pakistani workers, deported from Gulf countries.[11] Because of extra marital sexual activities of these male workers they are at greater risk of HIV infection.[12] Furthermore the current HIV epidemic in Pakistan is partially driven by IDUs, and the vast majority of IDUs in Pakistan are males.[13] Prevalence of HIV among IDUs in Karachi in Pakistan is up to 42.2%.[14]

Prevalence of HIV infection was 1.65 times higher among extrapulmonary TB cases as compared to pulmonary TB cases in our study (prevalence 0.48 Vs 0.29). P value 0.09, 95% CI 0.29-1.06. Although the difference is insignificant this could be due to small number of HIV cases detected in our study. This result compares favorably with a similar study done in India in which it was found that HIV infection is 1.3 times more likely among the extrapulmonary patients.[5] Similar results have been observed in studies done in developed countries.[15]

Refusal rate for HIV testing in our study was <3%. Since TB patients received education about HIV/AIDS by trained community mobilizers and were counseled for HIV testing, this resulted in low refusal rate in our study. In similar study done in India a refusal rate of 7.8% was

observed.[5] Screening of 12,552 TB patients in six sentinel sites with low refusal rate suggests that screening of TB patients in DOTS treatment centres is feasible and the concerns about high refusal rate are not legitimate.

In Pakistan the number of patients diagnosed each year with TB is about 400,000. If all of these cases were screened for HIV, about 1,200 more cases of HIV could be detected each year. As a result of this study 35 patients were put on ART. Our results demonstrates the feasibility of implementing WHO TB/HIV guidelines in Pakistan. By scaling up the screening and linking detected HIV cases to ART centers, the spread of HIV may be better controlled in Pakistan and outcome of TB treatment can be improved and many lives can be saved.[16]

AUTHOR CONTRIBUTIONS

SAS and GNM designed the study, JH and AAC conducted the data collection, AM did the laboratory analysis, all authors participated in statistical analysis. JC, JH and SAS wrote the manuscript. All authors approved the final manuscript.

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Table 1: Summary of HIV screening results among TB Patients Sindh, Pakistan 2008-2012

Variable	N	HIV Positive		OR (95% CI)	p-value
		n	%		
All who accepted testing	12,552	42	0.033		
Sex					
- Male	6,011	40	0.665	21.35(5.15-88.52)	<0.0001
- Female	6,541	2	0.030	1	
Age (years)					
- <18	2359	1	0.042	1	
- 18-44	7241	36	0.497	0.21(0.02-1.73)	0.15
- >44	2952	5	0.169	2.32(0.97-5.56)	0.06
TB Classification					
- Pulmonary	9,655	28	0.29	1	
- Extra Pulmonary	2,867	14	0.48	0.55(0.29-1.06)	0.09

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	6
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	7
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7
Discussion			
Key results	18	Summarise key results with reference to study objectives	7-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Screening for HIV among tuberculosis patients: a cross sectional study in Sindh, Pakistan

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Keywords:	Tuberculosis < INFECTIOUS DISEASES, HIV screening, Concentrated epidemic

Screening for HIV among tuberculosis patients: a cross sectional study in Sindh, Pakistan

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Key words*: Tuberculosis, HIV screening, concentrated epidemic*

Word count: 1714

ABSTRACT

Objective: To describe feasibility and results of systematic screening of TB patients for HIV.

Design: Cross-sectional study.

Setting: Six selected sentinel sites (public DOTS clinics) in province of Sindh, Pakistan.

Participants: All TB patients aged 16-60 years registered for treatment from April 2008 to March 2012.

Measurement: Demographic information of registered TB patients, screening for HIV through rapid testing and confirmation by referral lab of Sindh AIDS Control Program, according to national guidelines.

Results: Of a total of 18,461 registered TB patients, 12,882 fulfilled the inclusion criteria and were given education and counseling. Of those counseled 12,552 (97.4%) were screened for HIV using a rapid test. Males made up 48% of the sample and 76.5% of patients had pulmonary TB. Of the total patients tested, 42 (0.34%) were HIV-positive after confirmatory testing at the Sindh AIDS Control Program Laboratory. Prevalence of HIV among male patients was 0.66% whereas prevalence among female patients was 0.03% (p value <0.001). Prevalence of HIV among pulmonary TB patients was 0.29% and among extra pulmonary TB patients was 0.48% (p value 0.09).

Conclusion: In public DOTS clinics in Pakistan it is feasible to test TB patients for HIV. Prevalence of HIV is three times higher among TB patients as compared to the general population in Pakistan. Although the results are not representative of Pakistan or Sindh province they cover a large catchment area and closely match WHO estimate for the country. Routinely

screening all TB patients for HIV infection, especially targeting males and ensuring antiretroviral therapy, can significantly improve TB/HIV collaborative activities in Pakistan and identify many cases of HIV, improve health outcomes and save lives.

Article Summary

Article Focus

- To investigate the feasibility of HIV screening among TB patients registered for treatment at selected TB centers in Sindh province of Pakistan

- To describe the prevalence of HIV among TB patients in the study area.

Key Messages

- The study demonstrates the feasibility of acceptance of screening large number of TB patients for HIV.

- Prevalence of HIV among TB population is three-fold higher as compared to general population.

- Overwhelming majority of HIV infected TB patients detected were males.

Strengths and Limitations

- The study covers a large catchment area and the results closely match WHO estimate for the country.
- Since the study was confined to 6 public facilities in Sindh so the results are not representative of Pakistan.

INTRODUCTION

In recent years Pakistan has moved from having low HIV prevalence to a concentrated HIV epidemic.[1] Prevalence of HIV among the general population in Pakistan is still low (0.1%) and the estimated number of cases in the country of 180 million people is under one hundred thousand, of which only about 7,000 cases are reported.[1] HIV cases detection and treatment is one of the important HIV prevention strategies. Finding HIV cases among TB patients and providing ART (antiretroviral therapy) will contribute significantly not only in HIV/AIDS prevention and improve outcomes of TB treatment in HIV positive TB patients.[2]

Pakistan ranks 5th among the countries with highest burden of TB in the world and contributes to about 63% of tuberculosis burden in the Eastern Mediterranean Region.[3]Estimated prevalence and incidence of TB (all forms) in Pakistan is310/100,000 and 231/100,000 respectively.[3]

TB is the leading cause of death among HIV patients.[2] The unfavorable synergy between HIV and tuberculosis epidemics has added significantly to the suffering and death caused by each disease alone.[4]

In 2004 WHO released guidelines for HIV surveillance among tuberculosis patients recommending that generalized and concentrated epidemics use data from routine HIV counseling and testing of all TB patients form the basis for the surveillance.[5] Pakistan had a low-level epidemic and integration of these TB/HIV services was not prioritized. Updated guidelines recommend that all TB patients be screened for HIV and emphasized the need to establish mechanisms for delivering integrated TB and HIV services, preferably at the same time and location.[5] Furthermore, surveillance provides information necessary to monitor the effectiveness of joint strategies aimed at reducing the impact of HIV among TB patients. However, in 2010 Pakistan reported that only 2% of TB patients knew their HIV status and that nationally, only 22 TB/HIV patients were reported and only 9 put on ART.[3]

The objectives of this study were to investigate the feasibility of HIV screening among TB patients registered for treatment in selected TB treatment centres in Sindh province and to describe the prevalence of HIV among TB patients in the study area.

The specific aims of the study were to educate and counsel TB patients about HIV/AIDS, to implement TB/HIV registration at DOTS centers, to register HIV infected TB patients at ART centres for treatment and to determine the refusal rate for HIV screening among TB patients.

METHODS

We conducted a cross-sectional study of TB patients (all forms) registered in selected six sentinel sites (TB treatment centers) under the National TB Control Program(NTP) in the Sindh province of Pakistan from April 2008 to March 2012.Most TB patients in Pakistan are treated at public DOTS. Three of these centers are located in Karachi and the remaining centers are situated in the central and northern districts of Sindh province. Each selected center has a catchment area

covering more than 300,000 residents. These sites were selected on basis of adequate number of TB cases registered annually, trained staff and a separate room for the education and counseling of TB patients to ensure privacy and confidentiality. All TB patients, diagnosed following NTP guidelines, aged 16 to 60 years who gave informed consent were included in the study. These patients were provided education and counseling for HIV by trained social mobilizers ensuring confidentiality and privacy and their demographic information was recorded in TB/HIV register, maintained at each site. Social mobilizers are trained persons who provided education and counseling to TB patients and performed Rapid HIV tests and maintained TB/HIV register. Demographic information collected included age, gender, area of residence (urban or rural), and type of tuberculosis (pulmonary or extra pulmonary). Data was collected interviews and recorded on the standard TB/HIV registers maintained at each site. The data was then abstracted from these registers for the study. Patients were tested for HIV using Rapid HIV kit (Bioline HIV-1/2 3.0, Standard Diagnostic Inc, Kyonngi-do,Korea). Those whose rapid test results were non-reactive were given results after post-test counseling. Venous blood samples were taken from people whose rapid test results were reactive and sent to the Referral Lab of Sindh AIDS Control Program for confirmation using the UNAIDS/Government of Pakistan HIV testing strategy based on three different test principles or test antigens. At the referral laboratory samples were initially cross checked on HIV1&11 Determine Rapid kit and all reactive samples were further tested using two different ELISA (HIV Ag/Ab Combination by Abbott Murex and HIV Ansi-labsystem kits using Multiscan MS ELISA Reader). All confirmed HIV-positive TB patients were provided results linked with reference codes and with post-test counseling and then referred to HIV treatment at Civil Hospital Karachi for further care and support services including ART according to national guidelines.

Statistical Analysis

Data were entered twice by separate operators using Epi Data version 3.1 (The EpiData Association, Odense, Denmark). Data were cleaned and analysis was performed using Statistical Package for Social Sciences (SPSS) version 16.0 (IBM Corporation). For continuous variables summary statistics were computed. Frequencies were calculated for categorical variables. Chi-Square and Fisher Exact tests (where required) were used to compare different variables between HIV-positive and HIV-negative TB patients. Bivariate analysis was performed for estimation of odds ratios and 95% confidence intervals. A p value of <0.05 was considered significant.

ETHICAL REQUIREMENT

The study was approved by the Ethical Review Committee of Bridge Consultants Foundation, which is registered with the Office of Research Protection, National Institute of Health, USA.

RESULTS

A total of 18,461 TB patients were registered for treatment at the six sentinel sites during study period. Of the total TB patients, 12,822 met the study criteria for age and received counseling. 270 did not wish to be included in the study. 97.8% (n= 12,552) accepted HIV testing. Mean age was 32 years (range 16-60 years) and 47.8% (n=6011) of these tested patients were males. Of the total screened 76.9% (n=9655) had pulmonary TB and 22.9% (n=2867) were extra-pulmonary TB patients. A total of 42 people were found to be HIV-positive for a prevalence of 0.34% (table 1). Prevalence of HIV among males was 0.66% and 0.03% among females (p value <0.001). Prevalence of HIV among extra-pulmonary TB cases was 0.48% whereas prevalence of HIV among pulmonary cases was 0.29%. Prevalence of HIV in TB patients between 18 and 44 years old was 0.49% while prevalence of among those older than 44 years of age was 0.169%. All 42 patients whose confirmatory tests results were returned positive returned for their results. Of the 42 HIV-positive patients found, 35 were successfully registered at ART site.

DISCUSSION

The study demonstrates the feasibility and acceptance of screening large number of TB patients for HIV and linking them to ARV treatment. Our study found a threefold-higher prevalence of HIV among TB patients compared to the general population, and the overwhelming majority of the HIV-infected TB patients detected were males.

The prevalence of HIV among TB patients was found to be 0.34% and while this figure is considerably less than 12%, WHO's estimate of HIV among the world TB patients it is in line with the estimates for Pakistan (0.3%).[3]

In Pakistan the male to female ratio in the reported HIV cases is 10:1.[6] This gender difference was also evident in HIV positive TB patients in our study. The prevalence of HIV was 22 times higher among male TB patients (0.68%) compared to female TB patients (0.03%). Sexual promiscuity has been reported as less common among female population as compared to male population in Pakistan.[7,8] Moreover significant number of reported HIV/AIDS cases in Pakistan have been male overseas Pakistani workers, deported from Gulf countries.[9] Because of extra marital sexual activities of these male workers they are at greater risk of HIV infection.[10] Furthermore the current HIV epidemic in Pakistan is partially driven by IDUs, and the vast majority of IDUs in Pakistan are males.[11] Prevalence of HIV among IDUs in Karachi in Pakistan is up to 42.2%.[12]

Prevalence of HIV infection was 1.65 times higher among extrapulmonary TB cases as compared to pulmonary TB cases in our study (prevalence 0.48%vs. 0.29%p value 0.09). Although the difference is insignificant this could be due to small number of HIV cases detected in our study. This result compares favorably with a similar study done in India in which it was found that HIV infection is 1.3 times more likely among the extrapulmonary patients.[4] Similar results have been observed in studies done in developed countries.[13]

Refusal rate for HIV testing in our study was <3%. Since TB patients received education about HIV/AIDS by trained community mobilizers and were counseled for HIV testing, this resulted in low refusal rate in our study. In similar study done in India a refusal rate of 7.8% was

observed.[4] Screening of 12,552 TB patients in six sentinel sites with low refusal rate suggests that screening of TB patients in DOTS treatment centers is feasible and the concerns about high refusal rate are not legitimate.

This study has a couple of important limitations. The study area was confined to 6 public facilities in Sindh. While all TB patients between 16 and 60 were approached for inclusion in the study the results cannot be assumed to be representative of Pakistan or even Sindh province. However, our results cover a fairly large catchment area and closely mirror the WHO estimates for the country. We were also not able to test TB patients that receive care in private sector. [14] We were unable to get confirmed data on the smear status of the TB patients. This limits the ability to better disaggregate the data analysis and should be considered in future associations.

In Pakistan the number of patients diagnosed each year with TB is about 400,000. If all of these cases were screened for HIV, about 1,200 more cases of HIV could be detected each year. In Sindh, there are around 70,000 TB cases reported each year and the potential for HIV case detection scalable screening are still quite large. As a result of this study 35 patients were put on ART. Our results demonstrate the feasibility of implementing WHO TB/HIV guidelines in Pakistan. By scaling up the screening and linking detected HIV cases to ART centers, the spread of HIV may be better controlled in Pakistan and outcome of TB treatment can be improved and many lives can be saved.[15]

AUTHOR CONTRIBUTIONS

SAS and GNM designed the study, JH and AAC conducted the data collection, AM did the laboratory analysis, all authors participated in statistical analysis. JH, JC and SAS wrote the manuscript. All authors approved the final manuscript.

FUNDING STATEMENT

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COMPETING INTERESTS STATEMENT

There are no competing interests

DATA SHARING STATEMENT

As per request of other researchers data may be shared to benefit the society.

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Characteristic	N	n	Percent
Sex	12,552		
- **Male**		6,011	47.88%
- **Female**		6,541	52.11%
Age	12,552		
- **<18**		2,359	18.8%
- **18-44**		7,241	57.7%
- **>44**		2,952	23.5%
TB Diagnosis	12,552		
- **Pulmonary**		9,655	76.9%
- **Extra Pulmonary**		2,867	22.8%
HIV Positive	12,552	42	0.33%

Table 2: Associations of HIV screening results among TB Patients Sindh, Pakistan 2008-2012

Variable	HIV Positive		OR (95% CI)	p-value
	n	%		
Sex				
- Male	40	0.665	21.35(5.15-88.52)	<0.0001
- Female	2	0.030	1	
Age (years)				
- <18	1	0.042	1	
- 18-44	36	0.497	0.21(0.02-1.73)	0.15
- >44	5	0.169	2.32(0.97-5.56)	0.06
TB Classification				
- Pulmonary	28	0.29	1	
- Extra Pulmonary	14	0.48	0.55(0.29-1.06)	0.09

Screening for HIV among tuberculosis patients: a cross sectional study in Sindh, Pakistan

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Key words*: Tuberculosis, HIV screening, concentrated epidemic*

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ABSTRACT

Objective: To describe feasibility and results of systematic screening of TB patients for HIV.

Design: Cross-sectional study.

Setting: Six selected sentinel sites (public DOTS clinics) in province of Sindh, Pakistan.

Participants: All TB patients aged 16-60 years registered for treatment from April 2008 to March 2012.

Measurement: Demographic information of registered TB patients, screening for HIV through rapid testing and confirmation by referral lab of Sindh AIDS Control Program, according to national guidelines.

Results: Of a total of 18,461 registered TB patients, 12,882 fulfilled the inclusion criteria and were given education and counseling. Of those counseled 12,552 (97.4%) were screened for HIV using a rapid test. Males made up 48% of the sample and 76.5% of patients had pulmonary TB. Of the total patients tested, 42 (0.34%) were HIV-positive after confirmatory testing at the Sindh AIDS Control Program Laboratory. Prevalence of HIV among male patients was 0.66% whereas prevalence among female patients was 0.03% (p value <0.001). Prevalence of HIV among pulmonary TB patients was 0.29% and among extra pulmonary TB patients was 0.48% (p value 0.09).

Conclusion: In public DOTS clinics in Pakistan it is feasible to test TB patients for HIV. Prevalence of HIV is three times higher among TB patients as compared to the general population in Pakistan. Although the results are not representative of Pakistan or Sindh province they cover a large catchment area and closely match WHO estimate for the country. Routinely

screening all TB patients for HIV infection, especially targeting males and ensuring antiretroviral therapy, can significantly improve TB/HIV collaborative activities in Pakistan and identify many cases of HIV, improve health outcomes and save lives.

INTRODUCTION

In recent years Pakistan has moved from having low HIV prevalence to a concentrated HIV epidemic.[1] Prevalence of HIV among the general population in Pakistan is still low (0.1%) and the estimated number of cases in the country of 180 million people is under one hundred thousand, of which only about 7,000 cases are reported.[1] HIV cases detection and treatment is one of the important HIV prevention strategies. Finding HIV cases among TB patients and providing ART (antiretroviral therapy) will contribute significantly not only in HIV/AIDS prevention and improve outcomes of TB treatment in HIV positive TB patients.[2]

Pakistan ranks 5th among the countries with highest burden of TB in the world and contributes to about 63% of tuberculosis burden in the Eastern Mediterranean Region.[3]Estimated prevalence and incidence of TB (all forms) in Pakistan is310/100,000 and 231/100,000 respectively.[3]

TB is the leading cause of death among HIV patients.[2] The unfavorable synergy between HIV and tuberculosis epidemics has added significantly to the suffering and death caused by each disease alone.[4]

In 2004 WHO released guidelines for HIV surveillance among tuberculosis patients recommending that generalized and concentrated epidemics use data from routine HIV counseling and testing of all TB patients form the basis for the surveillance.[5] Pakistan had a low-level epidemic and integration of these TB/HIV services was not prioritized. Updated guidelines recommend that all TB patients be screened for HIV and emphasized the need to establish mechanisms for delivering integrated TB and HIV services, preferably at the same time and location.[5] Furthermore, surveillance provides information necessary to monitor the effectiveness of joint strategies aimed at reducing the impact of HIV among TB patients.

However, in 2010 Pakistan reported that only 2% of TB patients knew their HIV status and that nationally, only 22 TB/HIV patients were reported and only 9 put on ART.[3]

The objectives of this study were to investigate the feasibility of HIV screening among TB patients registered for treatment in selected TB treatment centres in Sindh province and to describe the prevalence of HIV among TB patients in the study area.

The specific aims of the study were to educate and counsel TB patients about HIV/AIDS, to implement TB/HIV registration at DOTS centers, to register HIV infected TB patients at ART centres for treatment and to determine the refusal rate for HIV screening among TB patients.

METHODS

We conducted a cross-sectional study of TB patients (all forms) registered in selected six sentinel sites (TB treatment centers) under the National TB Control Program(NTP) in the Sindh province of Pakistan from April 2008 to March 2012.Most TB patients in Pakistan are treated at public DOTS. Three of these centers are located in Karachi and the remaining centers are situated in the central and northern districts of Sindh province. Each selected center has a catchment area covering more than 300,000 residents. These sites were selected on basis of adequate number of TB cases registered annually, trained staff and a separate room for the education and counseling of TB patients to ensure privacy and confidentiality. All TB patients, diagnosed following NTP guidelines, aged 16 to 60 years who gave informed consent were included in the study. These patients were provided education and counseling for HIV by trained social mobilizers ensuring confidentiality and privacy and their demographic information was recorded in TB/HIV register, maintained at each site. Social mobilizers are trained persons who provided education and counseling to TB patients and performed Rapid HIV tests and maintained TB/HIV register.

Demographic information collected included age, gender, area of residence (urban or rural), and type of tuberculosis (pulmonary or extra pulmonary). Data was collected interviews and recorded on the standard TB/HIV registers maintained at each site. The data was then abstracted from these registers for the study. Patients were tested for HIV using Rapid HIV kit (Bioline HIV-1/2 3.0, Standard Diagnostic Inc, Kyonngi-do,Korea). Those whose rapid test results were non-reactive were given results after post-test counseling. Venous blood samples were taken from people whose rapid test results were reactive and sent to the Referral Lab of Sindh AIDS Control Program for confirmation using the UNAIDS/Government of Pakistan HIV testing strategy based on three different test principles or test antigens. At the referral laboratory samples were initially cross checked on HIV1&11 Determine Rapid kit and all reactive samples were further tested using two different ELISA (HIV Ag/Ab Combination by Abbott Murex and HIV Ansi-labsystem kits using Multiscan MS ELISA Reader). All confirmed HIV-positive TB patients were provided results linked with reference codes and with post-test counseling and then referred to HIV treatment at Civil Hospital Karachi for further care and support services including ART according to national guidelines.

Statistical Analysis

Data were entered twice by separate operators using Epi Data version 3.1 (The EpiData Association, Odense, Denmark). Data were cleaned and analysis was performed using Statistical Package for Social Sciences (SPSS) version 16.0 (IBM Corporation). For continuous variables summary statistics were computed. Frequencies were calculated for categorical variables. Chi-Square and Fisher Exact tests (where required) were used to compare different variables between HIV-positive and HIV-negative TB patients. Bivariate analysis was performed for estimation of odds ratios and 95% confidence intervals. A p value of <0.05 was considered significant.

ETHICAL REQUIREMENT

The study was approved by the Ethical Review Committee of Bridge Consultants Foundation, which is registered with the Office of Research Protection, National Institute of Health, USA.

RESULTS

A total of 18,461 TB patients were registered for treatment at the six sentinel sites during study period. Of the total TB patients, 12,822 met the study criteria for age and received counseling. 270 did not wish to be included in the study. 97.8% (n= 12,552) accepted HIV testing. Mean age was 32 years (range 16-60 years) and 47.8% (n=6011) of these tested patients were males. Of the total screened 76.9% (n=9655) had pulmonary TB and 22.9% (n=2867) were extra-pulmonary TB patients. A total of 42 people were found to be HIV-positive for a prevalence of 0.34% (table 1). Prevalence of HIV among males was 0.66% and 0.03% among females (p value <0.001). Prevalence of HIV among extra-pulmonary TB cases was 0.48% whereas prevalence of HIV among pulmonary cases was 0.29%. Prevalence of HIV in TB patients between 18 and 44 years old was 0.49% while prevalence of among those older than 44 years of age was 0.169%. All 42 patients whose confirmatory tests results were returned positive returned for their results. Of the 42 HIV-positive patients found, 35 were successfully registered at ART site.

DISCUSSION

The study demonstrates the feasibility and acceptance of screening large number of TB patients for HIV and linking them to ARV treatment. Our study found a threefold-higher prevalence of HIV among TB patients compared to the general population, and the overwhelming majority of the HIV-infected TB patients detected were males.

The prevalence of HIV among TB patients was found to be 0.34% and while this figure is considerably less than 12%, WHO's estimate of HIV among the world TB patients it is in line with the estimates for Pakistan (0.3%).[3]

In Pakistan the male to female ratio in the reported HIV cases is 10:1.[6] This gender difference was also evident in HIV positive TB patients in our study. The prevalence of HIV was 22 times higher among male TB patients (0.68%) compared to female TB patients (0.03%). Sexual promiscuity has been reported as less common among female population as compared to male population in Pakistan.[7,8] Moreover significant number of reported HIV/AIDS cases in Pakistan have been male overseas Pakistani workers, deported from Gulf countries.[9] Because of extra marital sexual activities of these male workers they are at greater risk of HIV infection.[10] Furthermore the current HIV epidemic in Pakistan is partially driven by IDUs, and the vast majority of IDUs in Pakistan are males.[11] Prevalence of HIV among IDUs in Karachi in Pakistan is up to 42.2%.[12]

Prevalence of HIV infection was 1.65 times higher among extrapulmonary TB cases as compared to pulmonary TB cases in our study (prevalence 0.48%vs. 0.29%p value 0.09). Although the difference is insignificant this could be due to small number of HIV cases detected in our study. This result compares favorably with a similar study done in India in which it was found that HIV infection is 1.3 times more likely among the extrapulmonary patients.[4] Similar results have been observed in studies done in developed countries.[13]

Refusal rate for HIV testing in our study was <3%. Since TB patients received education about HIV/AIDS by trained community mobilizers and were counseled for HIV testing, this resulted in low refusal rate in our study. In similar study done in India a refusal rate of 7.8% was

observed.[4] Screening of 12,552 TB patients in six sentinel sites with low refusal rate suggests that screening of TB patients in DOTS treatment centers is feasible and the concerns about high refusal rate are not legitimate.

This study has a couple of important limitations. The study area was confined to 6 public facilities in Sindh. While all TB patients between 16 and 60 were approached for inclusion in the study the results cannot be assumed to be representative of Pakistan or even Sindh province. However, our results cover a fairly large catchment area and closely mirror the WHO estimates for the country. We were also not able to test TB patients that receive care in private sector. [14] We were unable to get confirmed data on the smear status of the TB patients. This limits the ability to better disaggregate the data analysis and should be considered in future associations.

In Pakistan the number of patients diagnosed each year with TB is about 400,000. If all of these cases were screened for HIV, about 1,200 more cases of HIV could be detected each year. In Sindh, there are around 70,000 TB cases reported each year and the potential for HIV case detection scalable screening are still quite large. As a result of this study 35 patients were put on ART. Our results demonstrate the feasibility of implementing WHO TB/HIV guidelines in Pakistan. By scaling up the screening and linking detected HIV cases to ART centers, the spread of HIV may be better controlled in Pakistan and outcome of TB treatment can be improved and many lives can be saved.[15]

AUTHOR CONTRIBUTIONS

SAS and GNM designed the study, JH and AAC conducted the data collection, AM did the laboratory analysis, all authors participated in statistical analysis. JH, JC and SAS wrote the manuscript. All authors approved the final manuscript.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	6
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	7
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7
Discussion			
Key results	18	Summarise key results with reference to study objectives	7-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.