

Establishing a cohort in a developing country: Experiences of the diabetes-tuberculosis treatment outcome cohort study



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ABSTRACT

Background: Prospective cohort studies are instrumental in generating valid scientific evidence based on identifying temporal associations between cause and effect. Researchers in a developing country like Pakistan seldom undertake cohort studies hence little is known about the challenges encountered while conducting them. We describe the retention rates among tuberculosis patients with and without diabetes, look at factors associated with loss to follow up among the cohort and assess operational factors that contributed to retention of cohort.

Methods: A prospective cohort study was initiated in October 2013 at the Gulab Devi Chest Hospital, Lahore, Pakistan. We recruited 614 new adult cases of pulmonary tuberculosis, whose diabetic status was ascertained by conducting random and fasting blood glucose tests. The cohort was followed up at the 2nd, 5th and 6th month while on anti-tuberculosis therapy (ATT) and 6 months after ATT completion to determine treatment outcomes among the two groups i.e. patients with diabetes and patients without diabetes.

Results: The overall retention rate was 81.9% ($n = 503$), with 82.3% (93/113) among patients with diabetes and 81.8% (410/501) among patients without diabetes ($p = 0.91$). Age ($p = 0.001$), area of residence ($p = 0.029$), marital status ($p = 0.001$), educational qualification ($p = <0.001$) and smoking ($p = 0.026$) were significantly associated with loss to follow up. Respondents were lost to follow up due to inability of research team to contact them as either contact numbers provided were incorrect or switched off (44/111, 39.6%).

Conclusion: We were able to retain 81.9% of PTB patients in the diabetes tuberculosis treatment outcome (DITTO) study for 12 months. Retention rates among people with and without diabetes were similar. Older age, rural residence, illiteracy and smoking were associated with loss to follow up. The study employed gender matched data collectors, had a 24-h helpline for patients and sent follow up reminders through telephone calls rather than short messaging service, which might have contributed to retention of cohort.

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1. Introduction

Cohort studies can be considered the “gold standard” among the observational epidemiological study designs, as they fulfill Hill’s *sine qua non* criterion of causality by establishing a temporal relationship between cause and effect. But the cohort study design is criticized for long periods of follow up, expense associated with them, large number of study subjects required and issues of

attrition [1]. All these issues can be extremely challenging to manage in a developing country like Pakistan, which is already struggling with a myriad of problems. To name a few; allocation of budget for health sector is minimal, health indicators are low in comparison to other Asian countries, the country belongs to the low human development category where 45.6% of the population is multi-dimensionally poor. Approximately half the population is illiterate especially females who enjoy a low status in society with restricted movement affecting their access to health care services [2,3].

The cornerstone of a prospective cohort study is effective follow up of cohort participants, and retaining them for the entire

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duration of the study, on which relies the success of such studies [4]. However, most epidemiological studies experience issues of loss to follow up which leads to reduced power of the study and a source of bias if it is differential i.e. attrition is related to either the predictor or outcome under study. It is imperative to be aware of factors, which lead to attrition so that appropriate strategies may be adopted to increase retention of cohort participants [5,6]. Being less advantaged and having poor health are factors responsible for respondents' non-participation or loss to follow up [7]. The Danish youth cohort study found drinking and tobacco use to be associated with loss to follow up [8]. A cohort study conducted in Karachi, Pakistan to estimate the incidence rate of HIV among people who inject drugs identified younger age, being homeless, lack of formal education and being incarcerated by law enforcement agencies as predictors of loss to follow up [9].

Pakistan has a high burden of TB, with an estimated incidence of 270 cases per 100,000 population in addition to its expanding population of diabetics, with a national prevalence of 6.9% [10,11]. Diabetes mellitus has detrimental effect on TB treatment outcomes such as: increased chances of relapse, failure, default and death among co-infected patients [12,13]. Hence the diabetes-tuberculosis treatment outcome (DITTO) study; a prospective cohort study was undertaken in Pakistan to assess tuberculosis treatment outcome among diabetic patients. We are aware that the results of a cohort study are a big threat to its validity if the loss to follow up is more than 20%. The participants who are lost to follow up are often seen to have a different prognosis than those who remain a part of the cohort [14]. Researchers in a developing country like Pakistan seldom undertake cohort studies, which explains the dearth of information on retention and tracking strategies employed, and challenges encountered in such studies. It has been established that diabetes is a determinant of loss to follow up among patients undergoing treatment for tuberculosis [15]. This may be attributed to financial constraints and high pill burden, which hinders the co-infected patients arrival at health facility for follow up visits [16]. Our primary objective was to describe the retention rates among tuberculosis patients with and without diabetes and secondary objectives were to look at factors associated with loss to follow up among the cohort and assess operational factors that contributed to retention of cohort.

2. Materials & methods

Details of this prospective longitudinal study have been previously published [17]. In brief, a prospective cohort study was undertaken at the Gulab Devi Chest Hospital (GDH), a tertiary care hospital in Lahore, Pakistan. GDH is one of the oldest cardiothoracic hospitals in South Asia, which was established in 1934. It is a 1500 bed hospital, which provides free diagnostic and treatment services to TB patients of all socioeconomic backgrounds, from all over the country.

The cohort of 614 PTB patients was recruited between October 2013 and March 2014 from the outpatient department of GDH. PTB patients who were diagnosed, registered and obtained treatment at GDH were enrolled in the study if they fulfilled the inclusion criteria and were willing to participate. The inclusion criteria comprised of: a new adult (≥ 15 years of age) pulmonary tuberculosis (PTB) patient, both sputum smear positive and negative who had never taken TB drugs in the past or had taken them for less than 4 weeks, was registered with GDH for his/her anti-tuberculosis treatment, consented to participate and could provide his/her contact details. Patients were requested to provide home addresses and two telephone numbers (landline or mobile) belonging either to them, a family member or neighbour to facilitate the follow up process. The diagnosis of PTB, both sputum smear positive and sputum

smear negative was made according to the definition given by the National Tuberculosis Control Program (NTP) [18]. According to NTP a new case was a PTB patient who had never taken ATT in the past or had taken it for less than 4 weeks and had not registered with NTP. In order to establish a new case, patients' self-report regarding past history of tuberculosis was initiated.

The diabetic status of patients was ascertained. People with diabetes gave a self-history of the disease, which was verified by inquiring about the hypoglycaemic drugs that they were consuming. They were included in the study as patients with known diabetes. All others were tested for diabetes through random blood glucose (RBG) test at the time of enrollment. Patients with RBG value ≥ 110 mg/dl were tested through the fasting blood glucose (FBG) test at the first follow up visit. Patients having a FBG ≥ 126 mg/dl were labeled as patients with diabetes. Based on the result of FBG test patients were divided into two groups, those exposed i.e. patients with diabetes and those unexposed i.e. patients without diabetes. Both groups were followed up prospectively at 2nd, 5th and 6th month while on ATT and 6 months after completion of ATT in order to compare the treatment outcomes in the exposed and the unexposed groups. Follow up was completed in March 2015. The treatment outcome definitions provided by the NTP and WHO were adhered to in the study [18,19]. Treatment outcomes observed included: cured, treatment completed, treatment failure, defaulted, transferred out, patients who died during the ATT, and those who relapsed. Two full time data collectors, both male and female were hired for data collection. The sources of data included a pretested patient questionnaire which comprised of questions on patients socio-demographics, lifestyle and behavioural characteristics, history of co-morbidity, clinical presentation of tuberculosis, sputum smear microscopy for assessment of treatment outcomes, blood tests for estimation of glycosylated hemoglobin of patients with diabetes and anthropometric examination for assessment of body mass index. The known and newly diagnosed diabetes patients were referred to a specialist for free management of their diabetes.

Efforts were made to minimize loss to follow up. Reminder telephone calls were made a week before scheduled appointment. Approximately 10–20 telephone calls were made till contact with participant was established. At each visit, participants contact details were reviewed and participants were given the date of their subsequent appointment, on their Patient Identification Card. Additionally, participants were provided with Rs.100 (US \$0.95) as compensation for the time provided to the study. The PTB patients who were lost to follow up were contacted through telephone calls to ascertain the reasons for their loss from the cohort.

The data thus collected were entered and analyzed using the statistical package for social sciences (SPSS) version 16. We undertook a descriptive analysis whereby we calculated: 1) the number and proportion of persons with selected demographic and social characteristics at baseline; 2) the number and proportion of persons lost to follow up at each of the follow up visits according to their diabetic status and 3) the number and proportion of factors identified by respondents for loss to follow up. We then determined the association between age group, gender, area of residence, educational qualification, marital status, history of smoking and diabetic status with loss to follow up using Chi-square statistics significant at a p-value of ≤ 0.05 .

Patients were explained the purpose of the study and schedule of follow-up visits. Written informed consent was obtained from eligible patients volunteering to participate in the study. The illiterate patients requested the data collectors to give them a verbal overview of the consent form. Ethical approval was sought from the Institutional Ethical Review Committee (IERC) of Health Services Academy, Islamabad before initiating the study, which was duly granted. Permission was also taken from the administration

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