Chapter 3

Scope and Plan
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3.1 PREVALENCE OF GENITAL CHLAMYDIAL INFECTION IN APPARENTLY HEALTHY POPULATION OF TAMIL NADU

Even though there is abundant literature available from other countries on the epidemiological pattern of genital chlamydial infections, studies of such nature are scarce in India. Till date, no data is available in the literature on the true prevalence of genital *C. trachomatis* infection in the community population even though few studies from this country reported the prevalence of this genital pathogen in the symptomatic patients and high-risk groups seeking clinical care.

Thus, a statistically designed cross-sectional study was undertaken to find out the prevalence of genital chlamydial infection in the apparently healthy population of Tamil Nadu as the first part of this study. This pilot study was aimed to provide valuable baseline data on the epidemiology of this infection in this geographical region. It was anticipated that the data when emanated would strengthen the STD control programs in this region.
3.2 PREVALENCE OF *C. TRACHOMATIS* INFECTION IN SYMPTOMATIC STD PATIENTS

The load of chlamydial infection in different clinical manifestations has to be estimated for better management of these disease conditions. Although studies from North India reported a high prevalence of *C. trachomatis* among the STD patients, reports are scanty from the southern part of this country. Therefore the second part of the study was aimed to determine the prevalence of *C. trachomatis* infections among STD cases attending the Government general hospital, Chennai, Tamil Nadu. It was also aimed in this study to characterize the demographic and clinical features of *C. trachomatis* infection based on microbiological diagnosis.

3.3 EVALUATION OF CONVENTIONAL AND MOLECULAR DIAGNOSTIC METHODS FOR *C. TRACHOMATIS*

Since CT infections can be treated, an early diagnosis is warranted as untreated infections can lead to severe sequelae. Various diagnostic methods have been adopted for diagnosis of CT infection. However, their diagnostic efficiency varied with clinical settings of the study population and the type of samples collected. Hence in the third part of the our study, we evaluated conventional diagnostic methods like isolation in cell culture, antigen detection by direct fluorescent antibody testing (DFA) and serology with molecular markers like PCR.
3.3.1 Isolation in cell culture and antigen detection by DFA

Cell culture had been the 'gold standard' for the diagnosis of *C.trachomatis* infection because of its specific identification of the etiology. Being technically complex and labor intensive, isolation in cell culture is limited to very few laboratories for the diagnosis of CT infections. To facilitate quicker diagnosis and to help the clinician for early treatment, rapid methods such as antigen detection using immunofluorescence methods are more often used internationally. Therefore, in the third part of the study, the usefulness of *C.trachomatis* isolation in cell culture (McCoy) and antigen detection by immunofluorescence in different clinical manifestations of lower genital tract infections like urethritis, cervicitis and also in ascending upper tract infections like PID were evaluated.

3.3.2 Study on the usefulness of serological markers

In settings of high prevalence, serologic tests are generally not useful for the diagnosis of genital chlamydial infections. However, reliable serological tests could be of assistance in the diagnosis of *C.trachomatis* infection when a test for direct detection fails or difficult to perform. ELISA tests detecting the presence of specific IgM antibodies may identify recent primary infections. It is believed that IgM ELISA may prove as a useful adjunct for early diagnosis of chlamydial infection using a single clinical sample. Many studies suggest that elevated titers of specific IgA and IgG antibodies in serum indicate active or chronic chlamydial infections and may therefore serve as markers for early detection. Compared to culture and antigen
detection methods, these serologic tests (ELISA/immunoperoxidase) are simple and may identify subclinical upper genital tract infections. Therefore, we aimed at evaluating the usefulness of these serological markers/tests as a tool for diagnosis of genital chlamydial infection.

3.3.3 Standardization of in-house PCR systems for C. trachomatis

Since nucleic acid amplification is extremely sensitive and highly specific and has evolved as a powerful diagnostic tool, it offers the opportunity to screen noninvasive samples like urine. As significant proportions of infections of men and women are asymptomatic, early diagnosis using other diagnostic methods are difficult. Being highly sensitive and specific, PCR can identify even low-level infections. Recent studies have shown that estimating the true prevalence of C. trachomatis infections in many public as well as clinical settings needs highly sensitive techniques like PCR, which can be applied to noninvasive samples. We have evaluated both commercial and in-house PCR systems for CT infections in the third part of the study.

Even though nucleic acid amplification systems for C. trachomatis are commercially available and are approved (Amplicor PCR, LCx LCR), they are not cost effective for developing countries like India. Therefore, in-house PCR assays have been standardized using primers encoding different gene targets (plasmid and MOMP) and their diagnostic utility was evaluated both in invasive swab specimens and in noninvasive urine samples.
3.4 STUDY ON ASSOCIATION OF HIV WITH CT INFECTION.

3.4.1 HIV status in proven cases of *C. trachomatis* infection

It is proved that genital *C. trachomatis* infections facilitate the transmission of HIV, as the intracellular pathogenesis of chlamydiae and the damage caused to the genitalia provides more exposure to the entry of the virus. The co-infection with HIV may alter the frequency, clinical course and response to therapy of STDs like chlamydial infections. Hence, it was aimed to study the load of co-existing HIV infection prevailing in our study population.

3.4.2 *Chlamydia* positivity in proven HIV cases.

A study was also conducted in HIV seropositive cases to know the rate of genital chlamydial infection in HIV patients.