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Study of vitamin C levels in relationship to stress hormone response and acute phase reaction in patients with newly diagnosed pulmonary tuberculosis

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CHAPTER 4: PATIENTS AND METHODS

4.1 Study design

This was a prospective study of consecutive patients admitted to Helen Joseph Hospital between March 2002 and October 2002 with newly diagnosed pulmonary tuberculosis and control patients without tuberculosis. . Patients with newly diagnosed active pulmonary tuberculosis were compared with control patients having a diagnosis other than tuberculosis. Stress hormones measured included cortisol, dopamine, norepinephrine and epinephrine, while acute phase responses measured were C- reactive protein and ferritin. The demographic, clinical, radiographic and laboratory parameters of the two groups (study and control) were compared. Urine cotinine levels were measured as an indicator of cigarette smoking in study patients and controls to determine any relationship between smoking and vitamin C levels, stress hormones and acute phase responses. A total of one hundred sixty patients were recruited in the study after informed written consent was obtained. Patients could withdraw from the study at any time without providing any reasons and the withdrawal did not impact on their medical treatment. Where necessary, interpreters of local languages assisted in informing and obtaining the consent. Patients were managed by their respective ward doctors. Study patients with tuberculosis were treated with standard anti-tuberculosis regimens after appropriate samples were obtained. Blood

and urine samples were obtained by the researcher for study purposes. There was no follow-up of the patients by the study team and the study team did not influence patients' management at all.

4.2 Subject selection

4.2.1 Study patients inclusion criteria

Inclusion criteria for study patients were;

- Consecutive patients admitted to Helen Joseph Hospital,
- Age over 18 years,
- History, physical examination and radiological abnormalities consistent with pulmonary tuberculosis,
- Sputum (at least one) Ziehl Nielsen, positive
- No anti- tuberculosis chemo- therapy at the onset of the study,
- Informed written consent.

4.2.2 Study patients exclusion criteria

Exclusion criteria for study patients were;

- Previous tuberculosis infection and treatment,
- Concomitant immuno- suppression e.g cytotoxic drugs,
- Comorbid illness e.g.cardiomyopathy, diabetes mellitus, chronic renal failure,

- Known HIV positive status with AIDS defining illness or on highly active antiretroviral therapy (HAART).

4.2.3 Control patients inclusion criteria

The control group consisted of patients who were age, gender, race and suburb of residence matched with the study patients.

Inclusion criteria for the control patients were;

- Consecutive patients admitted to Helen Joseph Hospital,
- Diagnosis other than tuberculosis,
- Age over 18,
- Informed written consent

4.2.4 Exclusion criteria for control patients were the same as for the study group

4.2.5 Sample size

There were a total of one hundred and sixty patients (160), of whom seventy one (71) were study patients with active pulmonary tuberculosis and eighty nine (89) control patients without tuberculosis. The sample size of 160 was derived using the normal distribution curves of the variables.