



Characterization of TB clinical trial site in eastern Sudan

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Background/ Rationale

- Although tuberculosis is known to be endemic in Sudan, little information is available on its burden, epidemiology, health seeking behaviour of TB patients, risk factor for TB and the extent of drug resistance (El Sony et al ; 2000).
- The annual risk of infection (ARI) was estimated in Sudan at 1.8% in 1986, which translates into an estimated annual incidence rate of smear-positive TB of 90 per 100 000 person-years. It is often said that the eastern Region of Sudan might have higher rates, and recent public health records showed that >50% of the hospital admissions in one of Gadaref hospitals. Since 1986, no more recent surveys were conducted in Sudan on annual risk of infection.

Ethical clearance

- Ethical approval was obtained from the Institute Ethical Committee and from the national Ethical Committee in the Federal Ministry of Health
- All diagnosed TB patients were referred to the National TB control Program for free treatment



Objectives



- To identify a new site in Sudan for future TB clinical trials
- To determine the burden of TB in eastern Sudan

Specific aims

A- TB diseases related:

- A 1. To estimate the frequency of pulmonary TB in patients with cough
- A.2 To map and determine the burden of TB disease at community level in Kassalla and Gadarif states in eastern Sudan
- A.3 To document the health seeking behaviour of patients with long lasting cough in this region.

B- Health system related:

- B.1 To document the available system for TB care in the two states

Specific aims...

C- TB infection related:

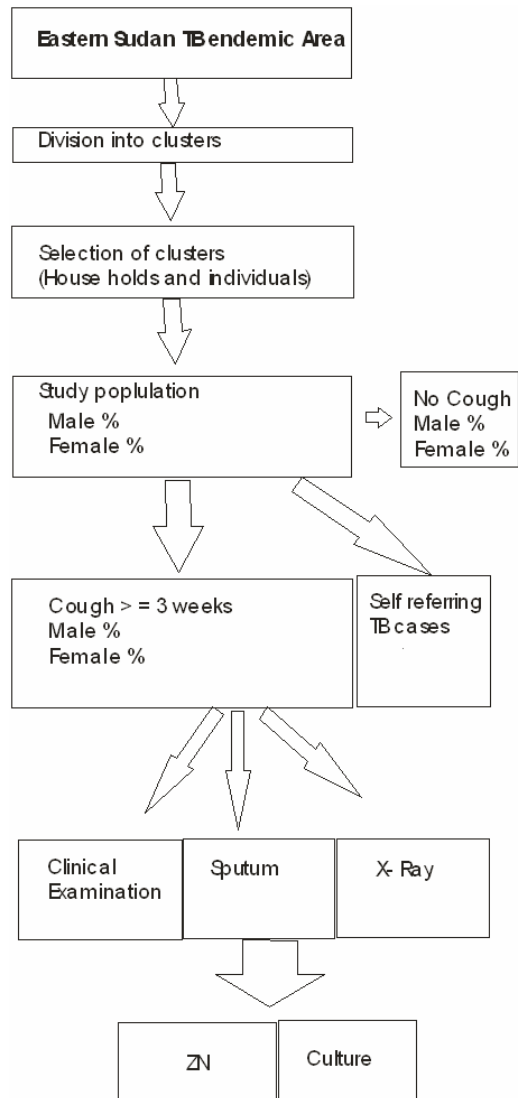
- C.1 To study the incidence rate of TB infection in selected study areas in eastern Sudan
- C. 2 To map and determine the frequency of *Mycobacterium* drug resistance to anti-tuberculous treatment in isolates from enrolled patients.
- C.3 To determine the genetic diversity of those *Mycobacterium* isolates
- C. 4 To study risk factors for the development of overt TB disease in infected persons



Methods



- Cross sectional surveys to determine the cough rate
- Clinical and bacteriological surveys for identification of TB patients
- Observational surveys for identification of possible risk factors





Study site



Map of the five study sections of KASSALA and Gedaref



Study population



- Kassala State:
- Population 1.4 Millions
- Mostly semi nomads and nomads
- Animal herders
- > 17 tribes
- Gadarif State:
- Population 1.7 millions
- Mostly settled communities
- Agriculture workers
- > 30 tribes

Study population

State	Selected villages	Interviewed households	Studied population
Kassala	30	3,000	16,763
Gadarif	50	5,000	24,417
Total	80	8,000	41,180 individuals



Results

Ecology of study site



Kassalla



Gadarif

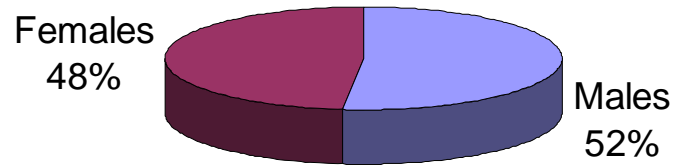




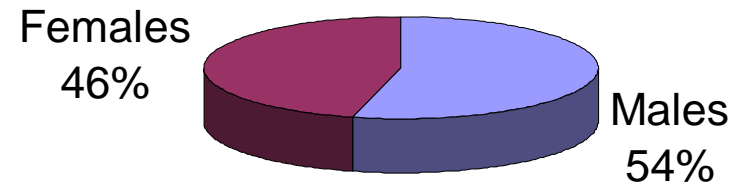
Gender ratio



Kassala

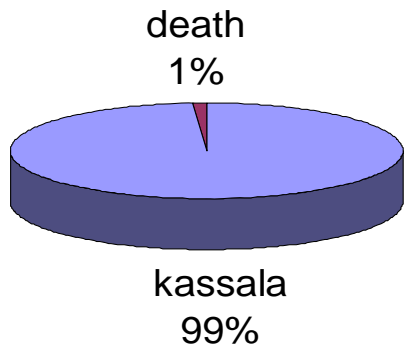


Gadarif

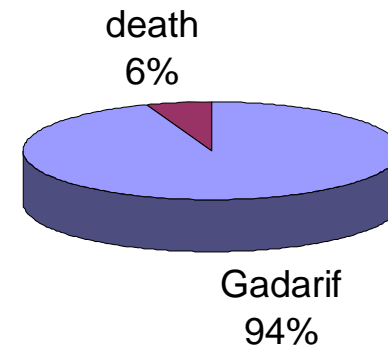


Crude Mortality in Kassala and Gadarif

Death rate in Kassala



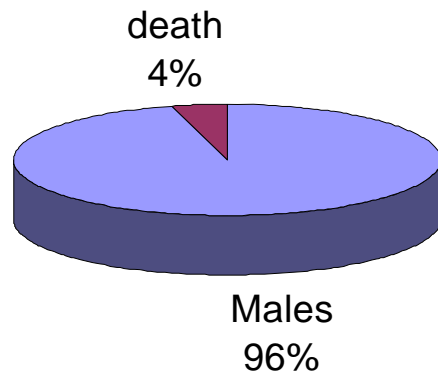
Deat rate in Gadarif



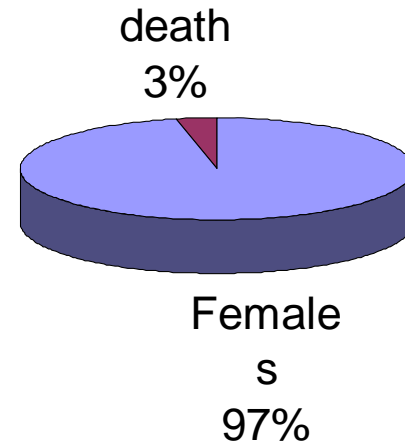


Crude mortality rate in the study area 2000 to 2005

Death among males



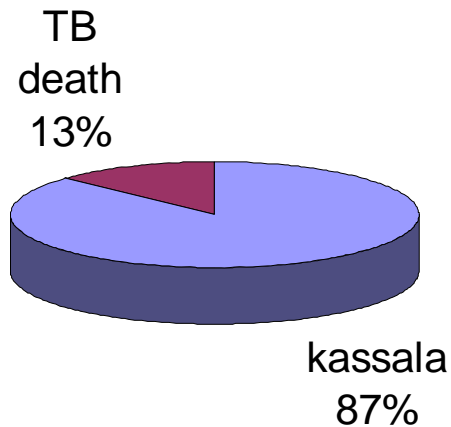
Death among females



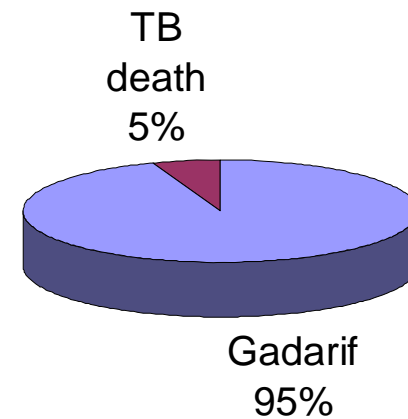


TB specific death rate 2000 - 2005

TB death

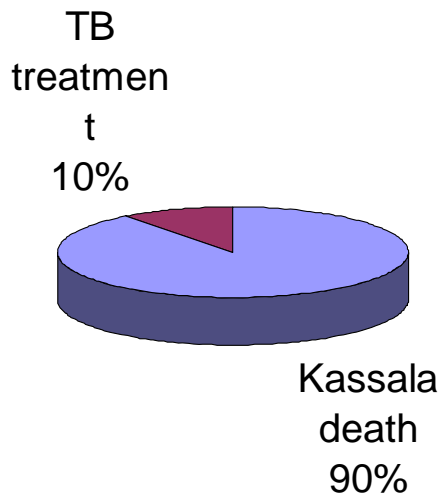


Gadarif TB death

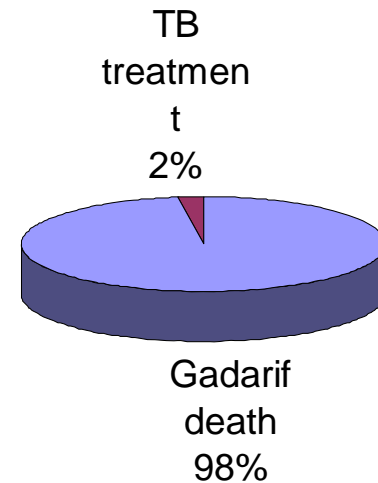


TB treatment at the time of death

TB RX at time of death in Kassala

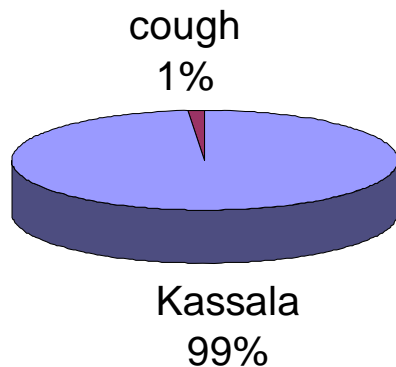


TB treatment Gadarif

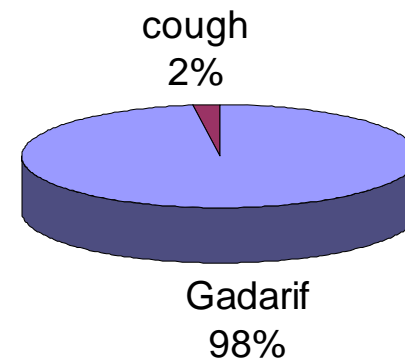


Cough rates in Kassala and Gadarif

cough rate in Kassala



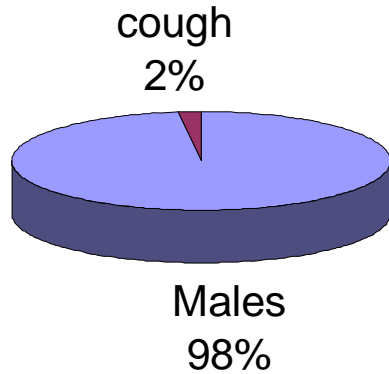
Cough rate in Gadarif



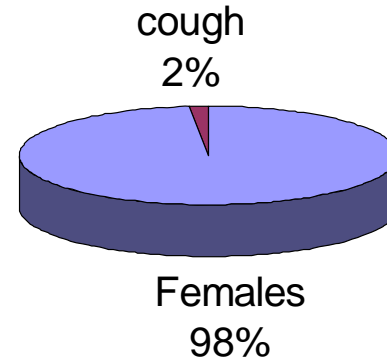


Cough rate among gender

cough rate among males

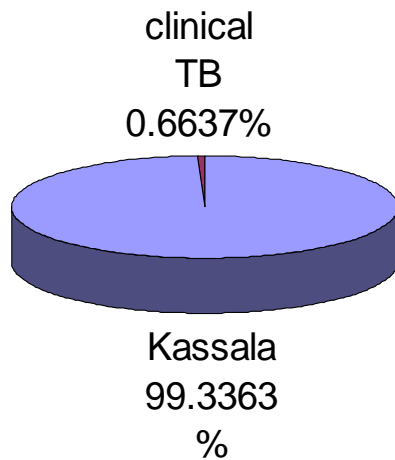


Cough rate among females

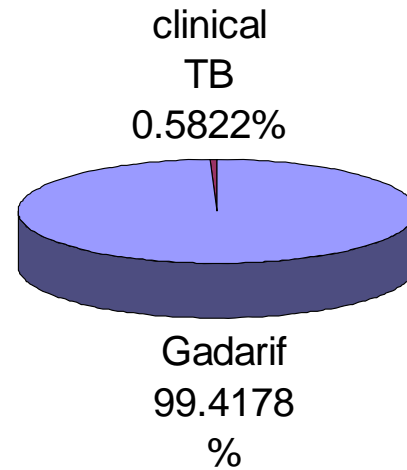


Clinical TB in Kassala and Gadarif

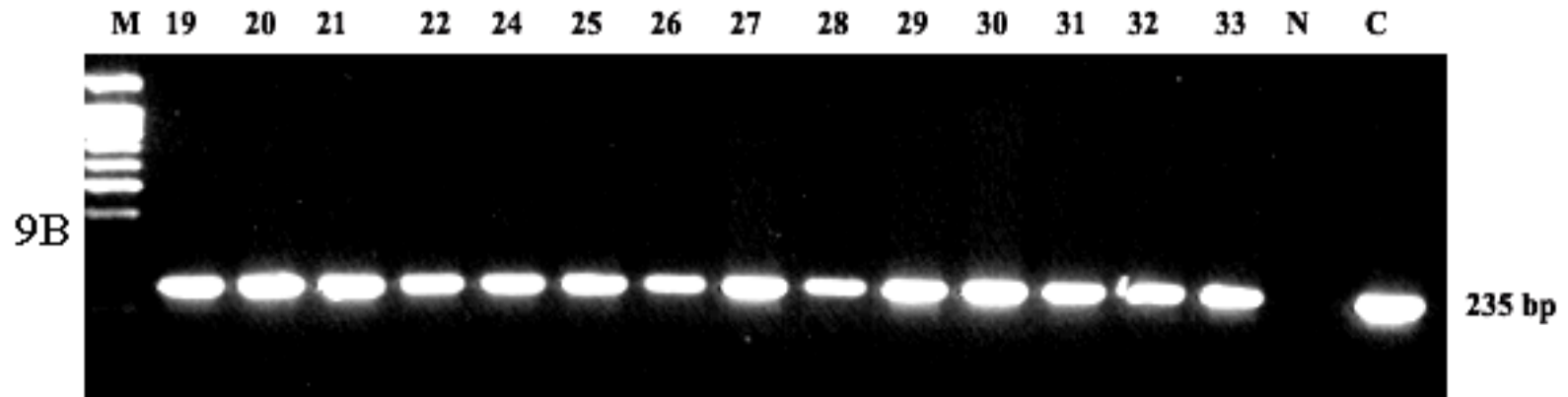
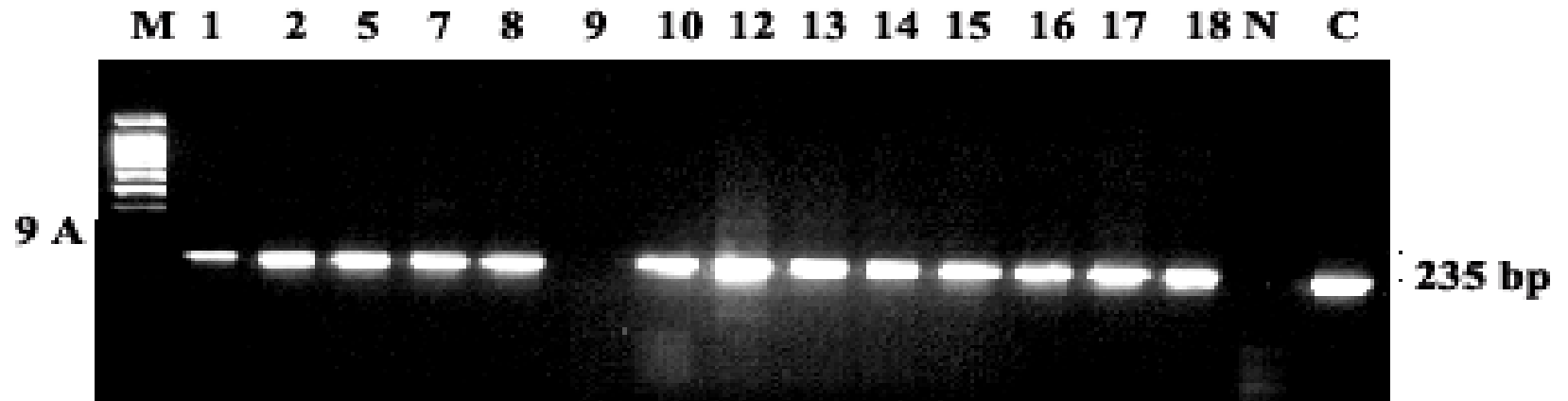
Kassala



Gadarif



PCR Characterization of isolates



Treatment seeking and default rate

Behavior	%
Seek treatment	>60% after 6 months cough
Traditional healer	>60%
Stigma	>80%
Free diagnosis	<80%
compliance	<70%



Discussion & Conclusions



- Two epidemiological patterns exist in eastern Sudan.
- Similar TB endemicity rates were determined in the two states.
- Low TB/ HIV coinfections were reported.
- The NTB reports = 10% of the TB rate detected in this study.
- Pulmonary TB cause higher mortality in Kassala than Gadarif.
- There is an urgent need for improvement of TB diagnostics and management protocols.
- The study area could serve as a suitable TB clinical trial site.

Collaborators

- Prince Leopold Institute of Tropical Medicine:
- Professor Patrick Van der Styft
- Dr. Greet Dieltiens
- Kassalla Faculty of Medicine
- Kassalla State Ministry of Health
- Gadarif Ministry of Health
- Central Health Laboratory
- Federal Ministry of Health
- National TB control Program

Thank You