APPENDIX XI:

SARAA TB GUIDELINES

TB Guidelines

Consensus statement re anti TB therapy / prophylaxis policy

These guidelines are to be seen in the context of use of anti TNF drugs where used in South Africa.

Recommendations

1. Ensure the appropriate indications for use
2. Unique problems faced in the South African Situation.
   a. Exposure - All of us exposed to tuberculosis at some time
   b. Latency – It is crucial to determine the latency status pre use of TNF blockers. Data suggests that in immuno-compromised patients, treatment with prophylaxis can reduce TB by 70% when patients are compliant. Definition and diagnosis of the LATENT state. This Implies treatment is essential
      i. Assessment of Latency
         a. Mantoux - the most essential component
            • Equal or More than 5mm = positive (induration.) = latent.
            • To do even in people on treatment with anti TNF at present (but untested as yet.)
            • All new patients to be tested BEFORE anti TNF Rx
            • In pediatrics -If at baseline a negative test is recorded, then we advise retest every 12 months, as this tests for exposure.
            • In adults no data is available re retest. Therefore in adults it is not considered mandatory for a retest.
      b. CXR – The main role is especially to hunt for active disease.
 ii. Treatment choice for latency:
   a. INH – RIF combined - The benefit may last longer – in HIV patients, benefit is observed for up to 3 years.
   b. INH alone - protected for 1 year in HIV patients.
      • CDC guidelines - Advise INH at least 6 months minimum 9 months desirable.
      • Combination Rifampicin – INH for 3 months, is advised in certain circumstances only. This applies where early initiation of therapy considered absolutely vital i.e. with aggressive disease.
c. **Duration of treatment.**
   - See clause (a) and (b).

d. **Time to start TNF after latency treatment started**
   - Information limited. No data available
   - recommend full treatment but practitioner judgement allowed vs. activity of disease
   - INH – RIF regimen may be more useful here as shorter regimen.

e. **Monitoring of prophylaxis treatment.**
   - Concerns regarding treatment of latent status
   - Hepatotoxicity – more significant in methotrexate co therapy.
     i. **Liver function testing**
        1. ALT at baseline. Minimum testing - MONTHLY if baseline abnormal. 1% of INH patients will get increase in enzymes. Monitor Levels of ALT
           a. If >3 x with symptoms – stop
           b. If > 5 times without symptoms – stop.
        2. **Education of patient regarding symptoms to suggest toxicity – i.e. nausea, vomiting, upper quadrant pain, dark urine..etc.**
           - Drug resistance - not considered a problem if TB Rx becomes required.
     iii. **Repetition of screening program**
          a. There is no evidence in adults of benefit to rescreening the MANTOUX –.

c. **Active disease**
   i. **Must exclude in all cases...as there is absolute contraindication to TNF Rx.**
   ii. **To determine if active TB is present**
      a. If there is a history of previously treated TB – ensure no active disease. Anti TNF Rx is allowed if the patient had > 6 months of full therapy, or the disease was in the distant / remote past. Role for empirical latency treatment in these cases is unclear as there is no data available.
b. **Diagnosis of active disease:**
   - CXR: If abnormal.
   - Symptoms: Cough > 2 weeks
   - Sputa if obtainable – plus culture (4 weeks.)

iii. **Treatment in disease whilst on TNF.**
   a. **Diagnosis and Treatment in Patients with TNF drug Rx in situ.**
      - Vigilance.
      - Beware of atypical disease / presentation.
      - Extra pulmonary.
      - Unusual histology - poor granuloma formation.
      - STOP TNF drug.
      - No reintroduction until TB therapy completed.

3. **Ongoing vigilance in all patients on therapy is required at all times- even if MANTOUX negative**