Summary

Tuberculosis (TB), a multi systemic disease with myriad presentations disease with myriad presentations and manifestations, is the most common cause of infectious disease related mortality world wide the world health organization (WHO) has estimated that 2 billion people have latent TB and that globally in 2009, the disease killed 1.7million people ***(WHO, 2010)***.

Tuberculosis was probably the leading cause of death in europe and the united states in recorded history the earliest known cases of tuber culosis were discovered in ancient EGyption mummies, who suffered from tuberculosis of the spine (Pott's Disease) dating back to 8000 to 10000 BC pulmonary tuberculosis was known in the time of Hippocrates as phthisis, which is derived from the Greek for "wasting away" ***(Asensio et al., 2008)***.

The incidence of tuberculosis increased dramatically in Europe until the beginning of the 19th century, when rates peaked at 700 cases per 100.000persons annually then declined ***(Wells et al., 2007)***.

These rates fell long before the availability of chemotherapy and without the use of BCG vaccine it has long been recognized that stress in the forms of war, famine, population displacement, and crowded living and working conditions favors the spread of tuberculosis among humans and that periods of improvement in societal conditions favor its rapid decline. The influence of these and other societal conditions on tuberculosis case rates must be considered in BCG vaccine trials, which by necessity take place over prolonged time ***(Plotkin et al., 2004)***.

Increased risk of acquiring active disease occurs with HIV infection, IV drug abuse, alcoholism, D.M, silicosis immunosuppressive therapy cancer of the head and neck, hematologic malignancies,end stage renal disease, intestinal by pass surgery or mastectomy, chronic malabsorption syndromes, and low body weight, the risk is also higher in infants younger than 5 years ***(Verhagen et al., 2011)***.

Globally, more than 1 in 3 individuals in infected with tubercle bacillus, on estimated 9.27 million incident TB cases were reported internationally in 2007, an increase from 9.24 million in 2006, However, although the total number of cases increased the number of cases per capita decreased from a global peak of 142 cases per100.000 in 2004 to 139 cases per 100.000 in 2007 ***(WHO, 2010)***.

BCG is a vaccine against tuberculosis that is prepared from a strain of the attenuated live bovine tuberculosis bacillus, the bacilli have retained enough strong antigencicity to become a somewhat effective vaccine for the prevention of human tuberculosis at best the BCG vaccine is 80% effective in preventing tuberculosis for a duration of 15 years however, its protective effect appears to vary according to geography ***(Fine et al., 1999)***.

The most controversial aspect of BCG is the variable efficacy found in different clinical trials that appears to depend on geography trials conducted in the UK have consistently shown a protective effect of 60-80% but those conducted else where have shown no protective effect and efficacy appears to fall the closer one gets to the equator ***(Colditz et al., 2005)***.

The duration of protection of BCG is not clearly known. The MRC (Medical research council) study showed protection waned to 59% after 20 years ***(Aronson, 2004)***.

BCG seems to have its greatest effect in preventing military TB or TB meningitis, for which reason, it is still extensively used even in countries where efficacy against pulmonary tuberculosis is negligible ***(Rodrigues et al., 2008)***.

The reasons for the variable efficacy of BCG indifferent countries are difficult to under stand and discussed at length in WHO.

1- Back ground frequency of exposure to tuberculosis.
2- Genetic variation in BCG strains.
3- Genetic variation in population.
4- Inter ference by non tuberculous mycobacteria.
5- Inter ference by concurrent parasitic infection.
6- Exposure to utra violet light.

(Pack et al., 2008)

Tuberculosis the main use of BCG is for vaccination against tuberculosis it is recommended the BCG vaccination be given intra dermally by a nurse skilled in the technique ***(WHO, 2004)***.

WHO recommended BCG be given to all children born in endemic for TB.

- United states never used mass immunization of BCG but for detection and treatment of latent tuberculosis.
- United kingdom introduced universal BCG immunization to all school children at the age of 13 and all neonates born into high risk groups.

Other uses:

1- leprosy.
2- Buruli ulcer
3- Cancer immuno therapy.
4- Diabetes type I.
5- Interstitial cystitis.
6- Multiple sclerosis.
7- Parkinson's disease.

BCG is widely used and the safety of this vaccine has not been a serious issue until recently ***(Weir, 2008)***.

The medical center of Benha city was chosen for the study location this medical center was a warded the golden star of quality management.

Subjects of the study or the study population consisted of 200 infants that were brought to the medical center for BCG and polio vaccination (Zero dose) during the period October 2011 Until febreuary 2011.

The vaccine involved in the study was one BCG vaccine SSI (Danish, 1331).

Enrollment were took place over a period of 2 months at the time of this first contact. These participants enrolled in the study were given an appointment for follow up visit or phone call on the day of subsequent vaccination.

Adverse events following BCG vaccine.

1- Mild adverse events in 90-95% of vaccine recipients BCG causes aspecific lesion that starts as apapule two or more weeks after vaccination. This then becomes ulcerated and heals after several months leaving a scar.

* Mild reactions are mostly local with or without regional manifestations

* limited lupoid reaction, keloids and renal tuberculous lupus.

- Axillary or cervical lymphadenitis, when larger than 1.5 cm in diameter.
- Local and regional superlative lymphadenitis.

2- Severe adverse events:

- osteitis may occur as BCG complication.
- Tuberculous meningitis due to BCG has been described, but this is also exceptional.
- Generalized infection due to BCG vaccination has also been reported, some times being fatal systemic BCG itis is arecognized but rare consequence of BCG vaccination, and traditionally has been seen in children with sever immune deficiencies in addition, the follow up form allowed for recording other unanticipated events reported by the partici pants.
- Data base for the study was designed using the statistical analysis program spss 11.0 followed by data entry and data analysis.
- The total 200 infants were successfully followed up with (7.5%) adenitis, 5% abscess and 1% ulcer incidence reports of adverse events 175 (87.5%) infants showed local reactogenicity to the BCG vaccine and scar formation stages.