FRI0626

SCREENING FOR TUBERCULOSIS BEFORE TNF INHIBITOR THERAPY REMAINS SUBOPTIMAL: A MULTI-SPECIALTY, REAL WORLD, NATIONWIDE EXPERIENCE IN THE UNITED STATES

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Background: Tumor necrosis factor- α inhibitors (TNFi's) effectively treat various autoimmune conditions, but drastically increase the risk of tuberculosis (TB) reactivation. Multiple international guidelines recommend screening for TB prior to initiating TNFi therapy. In the United States, this has also been incorporated into the Medicare Merit-Based Incentive Payment Systems (MIPS) quality measures, which affect physician remuneration.

Objectives: To determine the proportion of patients screened for TB prior to initiating TNFi therapy.

Table 1 Baseline Characteristics of Patients Who Initiated New TNFi Inhibitor Therapy

	Total (n = 78,088)
Age, mean $\pm$ SD years	44.8 $\pm$ 12.4
Sex	
Male	30,467 (39.0)
Female	47,621 (61.0)
Geography†	
Urban	64,937 (83.2)
Rural	11,191 (14.3)
Underlying Autoimmune Disease†‡	
Rheumatologic	39,675 (50.8)
Gastrointestinal	17,487 (22.4)
Dermatologic	13,773 (17.6)
Ophthalmologic	651 (0.8)
TNFi Inhibitor	
Adalimumab	37,576 (48.1)
Etanercept	23,210 (29.7)
Infliximab	12,810 (16.4)
Certolizumab	2,445 (3.1)
Golimumab	2,047 (2.6)
Steroids Use	
No	42,134 (54.0)
Yes	35,954 (46.0)
Prescribed non-biologic DMARD	
No	37,652 (48.2)
Yes	40,436 (51.8)
HIV	39 (0.0)
Travel#	30 (0.0)
Institutionalization	2 (0.0)
* The ages of the patients are those at the index event.	
† Some data missing, percentages calculated from number of patients with available information.	
‡ 5.5% of patients contributed to multiple categories	
# Surrogates for travel include malaria diagnosis, prophylaxis, yellow fever vaccine.	

Methods: We retrospectively analyzed patients in the Truven MarketScan Database from 2011–2015. This is the largest dataset of its kind and contains deidentified inpatient and outpatient health information on over 100 million patients. We included patients ≥ 18 years old in our cohort who were initiating TNFi therapy, based on at least 1 filled prescription. To ensure these were new TNFi starts, we excluded patients without a 6-month washout period (i.e. during which time they could not be receiving biologic DMARDs). Continuous enrollment in the database was required during the washout period and 3 months after TNFi initiation. Our primary outcome was whether patients were screened for TB during the 6-month washout period, either by interferon gamma release assays (IGRA) or tuberculin skin testing (TST). Sensitivity analysis was performed to extend the eligible screening period to 12 months pre-drug. Descriptive statistics were represented as means and medians for continuous variables and as frequencies and percentages for categorical variables.

Results: We identified 78,088 patients starting a TNFi. The mean age was 44.8 years and the cohort was 61% female. Adalimumab and Etanercept were the most common TNFi's. Regarding indication for TNFi, 50.8% of patients had a rheumatologic diagnosis, 22.4% gastrointestinal, 17.6% dermatologic, and 0.8% ophthalmic. Most patients received care from a rheumatologist, while 16.4% were managed by primary care alone. 36,918 (47.3%) were not screened for TB in the 6-month washout. By extending the pre-drug washout to 12 months, the proportion of unscreened patients improved mildly to 40.7%. 48.5% were screened by IGRA, 27% by TST, and 24.5% unknown. Steroid use, DMARD use and urban residence were associated with increased TB screening rates.

Conclusions: Screening for latent TB prior to initiating TNFi therapy was poor, such that only 52.7% received appropriate pre-drug screening. Our study population of over 78,000 patients starting a new TNFi represents nationwide, real world data across various specialties in the United States. As clinicians, these results suggest we need to improve compliance with guidelines and quality measures.

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INADVERTENT YELLOW FEVER VACCINATION OF PATIENTS WITH IMMUNE MEDIATED INFLAMMATORY DISEASE IN PRIVATE PRACTICE.

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Background: Yellow Fever (YF) is an endemic disease, in specific areas of Brazil. Since 1942, no new urban cycle cases have been observed. Yet, in early 2017, outbreaks of YF were reported in many states, outside the endemic areas, where YF was not considered a risk. Hence, new and some fatal cases have been reported including in highly populated areas close to the city of São Paulo. As it has been widely broadcasted, population searching for vaccination significantly increased and cases of inadvertent vaccination have been registered.

Objectives: To analyze the consequences of inadvertent YF primo-vaccination in patients with immune mediated inflammatory diseases (IMID).

Methods: Observational study (12/2017–01/2018). 54 rheumatologists from private practice at different areas of São Paulo included specific YF information in their patients' orientations and actively searched for IMID patients that have received YF vaccination (YFV) inputting the data in a web-based questionnaire.

Results: 56 patients received YFV; female 42 (75%), mean ($\pm$ SD) age = 56 $\pm$ 14 yr, median disease duration = 7 yr (6 months–45 yr). Diagnosis: RA (n=39; 72%), PsA (n=5), AS (n=4), 2 SLE, 3 vasculitis, 2 SS, one ReA and 2 UA. Treatment: 30 (54%) were considered under current strong immunosuppression (CE $\geq$ 20 mg, MTX $>$ 20 mg, leflunomide, tofacitinib and biologic agents (BA); 18 (32%) were on biologic agents (9 anti-TNF, 2 abatacept, 3 tocilizumab, 1 rituximab, 1 patient each secukinumab and tofacitinib). Remaining patients were receiving csDMARDs isolated or in combination, with or without low CE ($\leq$ 10 mg).

Vaccination: 54 (96%) cases were primo YFV and 43 (80%) related inadvertent YFV. Adverse events (AE): 7 patients (13%) had AE after a median of 4 days (hours–60 days); 3 of them were on BA, corresponding to 17% of the total subjects on various BA. Severity of AE: 4 patients had mild AE (local pain, vertigo, fever, headache, myalgia), in 2 of them, symptoms promptly resolved while 2 needed medical assistance (one was on tocilizumab). Of the 3 remaining cases, one had severe reaction one hour after YFV (probably anaphylaxis); Finally, 2 patients had severe AE requiring hospitalization: one had meningitis (RTX+MTX) and other (ADA+MTX), abdominal pain, myalgia, fever, headache, vertigo and increased liver enzymes. No fatal events were observed. Concerning the vaccine effect on disease activity, only 5 (9%) patients related worsening of the disease after YFV, but 2 of them also presented AE.

Conclusions: The small number of reports precludes any conclusion about rate/severity of AE and YFV in immunosuppressed rheumatic patients. Nevertheless, it emphasized the necessary awareness and careful analysis of the risk-benefit of YFV in this population. The interference of YFV on IMID disease activity seems to be marginal. On the other hand, this descriptive analysis clearly demonstrated persistence of patient's unfamiliarity with concepts of immunosuppression and its consequences, disclosing another unmet need in the management of patients with RD.

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