Novartis, AbbVie, Amgen, BMS, Crescendo, Genentech, Janssen, Lilly, Merck, Pfizer, UCB, D. van der Heijde Consultant for: AbbVie, Amgen, Astellas, AstraZeneca, BMS, Boehringer Ingelheim, Celgene, Daiichi, Eli Lilly, Galapagos, Janssen, Merck, Novartis, Pfizer, Roche, Sanofi Aventis and UCB, Employee of: Imaging Rheumatology BV, C. Karki Employee of: Corrona, LLC, M. Liu Employee of: Corrona, LLC, R. Pandurengan Employee of: Corrona, LLC, Y. Park Employee of: Novartis, J. Greenberg Shareholder of: Corrona, LLC, Consultant for: Lilly, Genentech, Janssen, Novartis, Pfizer, Employee of: Corrona, LLC

DOI: 10.1136/annrheumdis-2017-eular.1530

THU0387 THE CLINICAL IMPORTANCE OF THE THYROID NODULES DURING TUMOR NECROSIS FACTOR-ALPHA INHIBITOR THERAPY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS

R. Terlemez[1], K. Akgün[2], D. Palamar[2], H. Sarı[2]. *[1]Physical medicine and rehabilitation, Şişli Hamidiye Etfal Research and Training Hospital; [2]Physical medicine and rehabilitation, Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey*

Background: TNF is a pivotal regulator of inflammation and the cytokine system. Besides this, there is no doubt that TNF has a major role in cancer biology. TNF has a dual defensive and offensive role in carcinogenesis (1). TNF-blocking treatment has led to improvements in the management of inflammatory diseases.Even though their efficacy as anti-inflammatory drugs is well-proven, there are some concerns about the adverse effects of anti-TNF therapy (2). Basic research suggests that the evaluation of infections and malignancy as major adverse effects should be performed effectively (3). However, some studies conducted so far have dubious notions that anti-TNF therapy increases the risk of cancer (3,4).
Objectives: Objective: The clinical importance of the thyroid nodules in patients with axial spondyloarthritis (ax-SpA) rests with the need to exclude thyroid malignancy. The aim of this study is to assess the risk of thyroid malignancy in ax-SpA patients receiving anti-TNF therapy.
Methods: From September 2015 until December 2015, 70 patients diagnosed with ax-SpA according to ASAS criteria, were included in the research. Forty of the patients had received anti-TNF therapy, and 30 of the patients were anti-TNF naive. A clinician from the Physical Medicine and Rehabilitation clinic performed ultrasonography on all patients to screen for thyroid nodule(s). If thyroid ultrasonography revealed an abnormal finding, the patient was referred to a radiologist.
Results: The mean (SD) age was 38±9.87 years; % 75.7 of the patients were male. None of the demographic differences between the groups were statistically significant. Fifteen of the forty patients that received anti-TNF therapy and eleven of the thirty anti-TNF naive patients had thyroid nodule(s). Four patients from the anti-TNF group underwent fine needle aspiration biopsy, and two of them were diagnosed with papillary thyroid carcinoma. None of the nodules in anti-TNF naive patients required biopsy. When compared to the normal population, the standardized incidence ratio (SIR) was found to be increased in both male (SIR: 2.03% 95 CI: 1.9 to 18) and female (SIR: 2.7% 95 CI: 2.6 to 24) cases.
Conclusions: We see a mild increase in thyroid malignancies in ax-SpA patients that received anti-TNF therapy. Consequently, the thyroid gland should also be taken into consideration while screening for malignancy before anti-TNF therapy.
References:

[1] Wajant, Harald. The role of TNF in cancer. Death Receptors and Cognate Ligands in Cancer. Springer Berlin Heidelberg, 2009. 1–15.
[2] Dixon, W. G., et al. Influence of anti-tumor necrosis factor therapy on cancer incidence in patients with rheumatoid arthritis who have had a prior malignancy: results from the British Society for Rheumatology Biologics Register. Arthritis care & research 62.6 (2010): 755–63.
[3] Bongartz, Tim, et al. Anti-TNF antibody therapy in rheumatoid arthritis and the risk of serious infections and malignancies: systematic review and meta-analysis of rare harmful effects in randomized controlled trials. Jama 295.19 (2006): 2275–85.
[4] Askling, Johan, et al. Risks of solid cancers in patients with rheumatoid arthritis and after treatment with tumour necrosis factor antagonists. Annals of the rheumatic diseases 2005;64:1421–6.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.1013

THU0388 EFFICACY AND SAFETY OF ADALIMUMAB IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: RESULTS FROM THE 28-WEEK OPEN-LABEL PERIOD OF THE ABILITY-3 STUDY

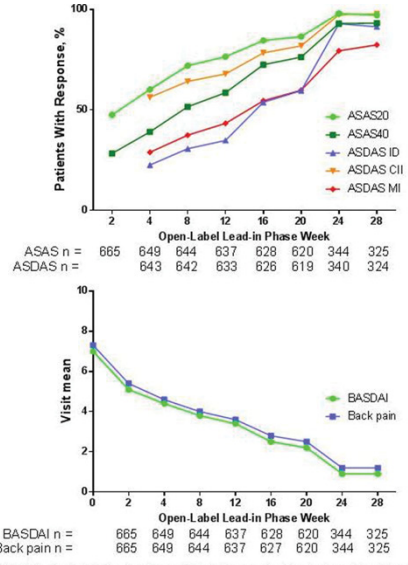
R. Landewé[1], J. Sieper[2], R. Inman[3], A.L. Pangan[4], X. Wang[4], J.K. Anderson[4]. *[1]University of Amsterdam, Amsterdam, Netherlands; [2]Charité Universitätsmedizin Berlin, Berlin, Germany; [3]Toronto Western Hospital, Toronto, Canada; [4]AbbVie, North Chicago, United States*

Background: Adalimumab (ADA) significantly improved clinical response at wk 12 vs placebo in patients (pts) with non-radiographic axial spondyloarthritis (nr-axSpA) in the ABILITY-1 study. The subsequent, ongoing ABILITY-3 study is assessing continuation vs withdrawal of ADA in nr-axSpA pts who respond to ADA.
Objectives: Evaluate the efficacy and safety of ADA during the open-label lead-in period of ABILITY-3.
Methods: ABILITY-3 has a 28-wk lead-in open-label ADA (40 mg every other wk) period; pts who achieve sustained remission (Ankylosing Spondylitis Disease Activity Score inactive disease [ASDAS ID] at wks 16, 20, 24 and 28) are randomized to double-blind placebo (withdrawal) or ADA (continuation) for 40 wks (ongoing). From wk 20–28, pts who did not achieve ASDAS ID were discontinued. Adult pts with nr-axSpA (fulfilling Assessment of SpondyloArthritis international Society [ASAS] criteria but not modified New York criteria) with objective evidence of inflammation in the sacroiliac joints or spine on MRI or elevated hs-CRP at screening; active disease at baseline (defined by ASDAS ≥2.1, BASDAI ≥4, and total back pain score ≥4); and inadequate response to ≥2 NSAIDs were eligible.
Results: Of 673 pts enrolled, 51% were women and mean BASDAI was 7.0±1.4 (Table). At wk 28, 305 (45%) pts were randomized (ASDAS ID: 33% at wk 12, 44% sustained at wk 28; nonresponder imputation) and 368 (55%) pts discontinued (not achieving sustained remission, n=300 [45%]; other reasons, n=68 [10%]). In observed analysis, 59%, 35%, and 22% of pts achieved ASAS40, ASDAS ID, and ASAS partial remission, respectively, at wk 12, similar to wk 12 data from ABILITY-1 pts with objective inflammation at baseline. The proportions of pts achieving ASAS20, ASAS40, ASDAS ID, ASDAS CII, and ASDAS MI increased, and mean BASDAI and back pain scores decreased over time (observed analysis; Figure). Adverse events (AEs) were reported by 468 pts (70%), most commonly nasopharyngitis (n=121 [18%]), upper respiratory tract infection (n=81 [12%]), and headache (n=56 [8%]); serious AEs occurred in 19 (3%) pts.

Table 1. Baseline Characteristics

Mean ± SD	(n=673)
Age	37.3±11.1
White, n (%)	651 (97)
Female, n (%)	343 (51)
Symptom duration, y	7.7±7.7
HLA-B27 positive, n (%)	515 (77)
TJC	6.5±10.4
SJC	1.9±4.0
MASES	3.4±3.5
PGA-disease activity	6.5±1.5 n=671
Patient-pain	7.4±1.7
BASDAI	7.0±1.4
ASDAS	3.6±0.8
hs-CRP	9.6±15.0
BASFI	5.3±2.2
HAQ-S	2.1±0.6

BASFI, Bath Ankylosing Spondylitis Functional Index; HAQ-S, Health Assessment Questionnaire for the Spondyloarthropathies; hs-CRP, high-sensitivity C-reactive protein; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; PGA, physician global assessment; SJC, swollen joint count; TJC, tender joint count.



BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CII, clinically important improvement; MI, major improvement.
Patients who did not achieve ASDAS ID were discontinued at week 20–28 visits.

Conclusions: Baseline disease activity was higher in ABILITY-3 pts than reported in prior trials. After 28 wks of open-label ADA therapy, disease activity improved and sustained remission was achieved in 44% of pts. Efficacy and safety in this nr-axSpA population were consistent with findings from ABILITY-1.

Acknowledgements: AbbVie funded the study and approved the abstract for submission. Medical writing support was provided by Maria Hovenden, PhD, of Complete Publication Solutions, LLC (North Wales, PA) and was funded by AbbVie.

Disclosure of Interest: R. Landewé Grant/research support from: Abbott, Amgen, Centocor, Novartis, Pfizer, Roche, Schering-Plough, UCB, and Wyeth, Consultant