ComorBidities And Disease Manifestations in Ankylosing Spondylitis (BAD AS): An analysis of US claims databases.

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**Background:** Patients with ankylosing spondylitis, a multi-system immune-mediated chronic inflammatory disease, have experienced reduction in signs and symptoms, improvement in physical function and quality of life with the advent of biologic treatment such as tumor necrosis factor inhibitors (TNFi). Whether TNFi have altered the incidence of comorbidities in AS is not known.

**Methods:** Three commercial insurance claims databases – Multi-Payer Claims Database (MPCD) (2007-2010), Truven Marketscan (2010-2014), and the U.S. Medicare Fee-for-Service Claims data (2006-2014) – were searched to assess disease manifestations and comorbidities (total 13 categories: including cardiac, neurological, kidney, lung diseases, fracture, disease manifestations such as uveitis, psoriasis, and inflammatory bowel disease, infections (hospitalized and opportunistic), hematologic malignancy, solid tumors, and non-melanoma skin cancer (basal & squamous cell) in three groups of AS patients: those managed with either no therapy or prescription non-steroidal anti-inflammatory drugs (NSAIDs), those given conventional disease modifying anti-rheumatic drugs (DMARDS), and those using TNFi. Entry criteria were a rheumatologist’s diagnosis of AS, six-months of pre-diagnosis insurance coverage, and (for drug-specific exposures) administration of AS exposures of interest after the AS diagnosis. For the estimation of the incidence of comorbidities, data collection ended at the earliest of date of death, loss of medical or pharmacy coverage, end of study period, first outcome occurrence, or treatment discontinuation. Samples of the non-AS general population in Medicare was used as comparator.

**Results:** Total number of people included in three databases is ≈ 40 million. The age & sex standardized prevalence of AS was XX. The prevalence of comorbidities and the incidence rates of outcome of interest by treatment exposures stratified by each data source are shown in Table 1. Multivariable adjusted hazard ratios (HR) of outcomes of interest for TNFi compared with HR for NSAIDs being 1 are shown in Table 1 (Cox regression).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | MPCD Database | | | | Marketscan Database | | | | Medicare Database | | | | Pooled TNFi HR |
|  | Prev | Incidence rate | | | Prev | Incidence rate | | | Prev | Incidence rate | | |  |
|  |  | NS | DM | TNF |  | NS | DM | TNF |  | NS | DM | TNF |  |
| UC |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cr |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Uv |  |  |  |  |  |  |  |  |  |  |  |  |  |
| PsO |  |  |  |  |  |  |  |  |  |  |  |  |  |
| PsA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| AR |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MI |  |  |  |  |  |  |  |  |  |  |  |  |  |
| CE |  |  |  |  |  |  |  |  |  |  |  |  |  |
| PF |  |  |  |  |  |  |  |  |  |  |  |  |  |
| IgA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| NS |  |  |  |  |  |  |  |  |  |  |  |  |  |
| VF |  |  |  |  |  |  |  |  |  |  |  |  |  |
| NVF |  |  |  |  |  |  |  |  |  |  |  |  |  |

(NS: NSAIDs, DM: DMARDS, TNF: TNF inhibitors, Inciden: incidence, Prev: prevalence, UC: ulcerative colitis, Cr: Crohn’s disease, Uv: uveitis, PsO: psoriasis, PsA: psoriatic arthritis, AR: aortic regurgitation, MI: myocardial infarction, CE: cauda equine syndrome, PF: pulmonary fibrosis, IgA: IgA nephropathy, NS: nephrotic syndrome, VF: vertebral fractures, NVF: non-vertebral fractures)

**Conclusion**: Patients with AS on TNF inhibitors have lower incidence of most of the disease manifestations (uveitis, IBD) and comorbidities, compared to those treated with NSAIDs alone.