Objectives: In this study, we compared the efficacy of IGU in elderly group with the non-elderly group.

Methods: 190 patients who were able to continuously administer IGU more than three months was included. Cases were divided into two groups. Group A (75 years or older) includes 57 patients, and Group B (younger than 75 years) includes 133 patients. The patients background, the use of methotrexate (MTX) and glucocorticoid, the change of serum CRP, and the DAS28-ESR (before, 6, 12, and 24 months) as an evaluation of the disease activity were compared between two groups. The study protocol was approved by our institutional review board. All the patients were required to give written informed consent.

Results: The average age at the beginning of IGU was 79.9 ± 4.1 years old in Group A, and 59.9 ± 10.6 years old in Group B. The average disease duration was 14.8 ± 16.5 year in Group A and 8.5 ± 10.6 year in Group B ($p < 0.01$). Although the rate of concomitant use of MTX was significantly lower in Group A (Group A; 28.1%, Group B; 56.4%), the averaged dose of MTX did not show difference between groups (7.0 and 8.4 mg/week, respectively). Group A showed significantly higher rate of concomitant use of glucocorticoid (56.1%, and 36.1%, respectively), but the averaged dose of glucocorticoid did not show a difference between groups (4.3 and 3.6 mg/day, respectively). Similarly, the rate of concomitant use of NSAIDs did not have a difference in two groups. Group A showed significantly higher serum CRP at the beginning of the IGU (Group A; 2.0 mg/dl, Group B; 1.2 mg/dl), but there was no difference after six months. In both groups, serum CRP was significantly decreased when compared at the beginning of IGU. After six months of IGU administration, both groups showed good clinical performance with DAS28-ESR, more than 60% of the cases showed remission or low disease activity. No difference of DAS28-ESR scores between two groups was observed after six months.

Conclusion: From the results of this study, the efficacy of IGU for elderly patients was confirmed and did not show differences with non-elderly people. IGU is an inexpensive drug with enough efficacy and thought to be possible substitute for cases with insufficient reaction with other DMARDs.

References:

- [1] Nozaki Y, et al. Modern Rheumatology 1439-7595, 2019.
- [2] Yoshikawa A, et al. Mod Rheumatol 28: 227-234, 2018.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.2639

AB0352

CONSENSUS STATEMENT: USE OF JAKINIB THERAPY IN IMMUNE MEDIATED INFLAMMATORY DISEASES.

P. Nash¹, A. Kerschbaumer², D. Van der Heijde³, J. S. Smolen². ¹Griffith University, School of Medicine, Brisbane, Australia; ²University of Wien, Wien, Austria; ³Leuven University, Leuven, Netherlands

Background: Janus kinase inhibitor therapy is approved for use in a variety of Immune mediated inflammatory diseases.

Objectives: With 4 agents approved & 1 in development, it is timely to undertake a systematic literature review (SLR) of evidence across indications for efficacy, safety & management issues.

Methods: Existing data was evaluated by a steering committee & subsequently by a 25 person expert committee leading to a consensus statement to assist the clinician once the decision had been made to commence a Jakinib. The Committee included patients, rheumatologists, gastroenterologist, haematologist, dermatologist & infectious disease specialists. SLR of Medline, Embase, Cochrane, abstracts from 2018 EULAR & ACR congresses & Epistemonikos identified 1,178 RA & PsA, 128 SLE, & 1339 "other indications" unique references meeting criteria that included randomized & open label clinical trials, registries, phase 4 trials, & meta-analyses. Warnings from regulators issued after the end of the SLR search date were taken into consideration. Cochrane risk of bias tool was used.

Results: General principles included (1) shared decision making, (2) adherence to T2T principles, (3) reference to disease specific product information & (4) reference to country/region specific treatment algorithms. Mode of action & indications are discussed & consensus was reached on pre-treatment screening, contra-indications, monitoring, treatment dose, co-medications & adverse effects (see Table 1.), with 80-100% agreement. A research agenda was formulated to update the review as new information becomes available.

Table 1. A. Pre-treatment screening

1. Patient history, examination
2. Routine Laboratory testing: FBC diff LFTs Renal function, lipids at wk 12
3. Hepatitis Bs Ag & Ab, core Ab & Hep C ab, & HIV in high risk individuals.
4. TB screening as per national guidelines
5. Assess & update vaccination status
6. Consider VTE risk factors – prior history, familial VTE, use of Cox2 inhibitors
- B. Monitoring
 1. FBC diff LFTs mth 1, & mth 3 with lipids, repeat periodically
 2. Annual skin examination
 3. Evaluated response using validated disease specific measures of disease activity – be aware ESR/CRP may be reduced independently of reduction in disease activity or infection
- C. Contra-indications (consult label & warnings)
 1. Severe active (or chronic) infection, including tuberculosis and opportunist infections
 2. Current malignancies
 3. Pregnancy & lactation
 4. Severe organ dysfunction eg severe hepatic disease (Child-Pugh C) or severe renal disease
 5. Allergy to Jak inhibitor
 6. History of VTE (relative contra-indication, careful consideration +/- anticoagulation)

Table 2.

- D. Adverse Effects.
 1. Serious infections including opportunist infections, TB, Herpes Zoster, are increased. The risk is lowered with reduction or elimination of concomitant corticosteroid
 2. Rates of malignancy do not appear elevated although the risk of NMSC may be elevated
 3. Lymphopenia, neutropenia, elevated liver transaminases, & lipid changes have been noted
 4. An increased risk of VTE has been reported in a safety trial of tofacitinib & in the placebo-controlled trial period of baricitinib in RA patients
 5. Elevations of CPK noted but have been rarely associated with clinical events
 6. Elevations of creatinine noted but not associated with renal failure or hypertension

Conclusion: The consensus provides an assessment of evidence for efficacy & safety of an important therapeutic class with guidance on practical management issues.

Acknowledgments: Unrestricted grants were provided by Abbvie & Lilly with no input into the planning & development of the recommendations, nor influence or attendance at the meeting nor review of the abstract, with full disclosures from participants & the opportunity to declare any feelings of conflict of interest.

Disclosure of Interests: Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi,

UCB, Andreas Kerschbaumer Paid instructor for: Celgene, Speakers bureau: Andreas Kerschbaumer has received lecture fees from Bristol-Myers Squibb, Gilead, Merck Sharp and Dohme and Pfizer., Désirée van der Heijde Consultant of: AbbVie, Amgen, Astellas, AstraZeneca, BMS, Boehringer Ingelheim, Celgene, Cytone, Daiichi, Eisai, Eli-Lilly, Galapagos, Gilead Sciences, Inc., Glaxo-Smith-Kline, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda, UCB Pharma; Director of Imaging Rheumatology BV, Josef S. Smolen Grant/research support from: AbbVie, AstraZeneca, Celgene, Celltrion, Chugai, Eli Lilly, Gilead, ILTOO, Janssen, Novartis-Sandoz, Pfizer Inc, Samsung, Sanofi, Consultant of: AbbVie, AstraZeneca, Celgene, Celltrion, Chugai, Eli Lilly, Gilead, ILTOO, Janssen, Novartis-Sandoz, Pfizer Inc, Samsung, Sanofi

DOI: 10.1136/annrheumdis-2020-eular.2790

AB0353

COMPARATIVE STUDY OF PATIENT BACKGROUND AND TREATMENT OUTCOME BY BARICITINIB DOSE UNDER REAL CLINICAL CONDITIONS.

T. Nishiume¹, N. Takahashi¹, T. Kojima¹, S. Asai¹, K. Terabe¹, N. Ishiguro¹.

¹Nagoya University Hospital, Orthopedic Surgery, Nagoya city, Japan

Background: Baricitinib (BAR) is one of the Janus kinase (JAK) inhibitors, which mainly inhibits JAK1 and JAK2 and has an anti-inflammatory effect on rheumatoid arthritis (RA). In Japan, it is necessary to use different doses of BAR depending on the RA patient's estimated glomerular filtration rate (eGFR). The RA-BEACOM and RA-BUILD trials reported the treatment effects by BAR dose at 24 weeks and concluded that there was no difference in DAS (disease activity score) 28CRP between BAR 2mg and 4mg. The patient background treated in these double-blind RCTs is uniform even at different BAR doses. There is uncertainty about the difference in the therapeutic effects of BAR dose under the real clinical setting where the patient background differs from that of the trial patients.

Objectives: To compare patient backgrounds and treatment outcome by Baricitinib dose under real clinical setting.

Methods: 113 RA patients taking BAR who were registered in the Nagoya University Orthopedic Surgery Multicenter Study (TBCR) were included in this study. Patient characteristics (such as age, illness duration, combined anti-rheumatic drugs, eGFR) and DAS28CRP, clinical and simplified disease activity index (SDAI, SDAI respectively) up to 24 weeks were compared between BAR 2mg and 4mg groups. The continuation rates, including the discontinuation due to ineffectiveness and adverse events (AEs), were also compared between the two groups. For these comparisons, Student's t-test and Pearson's chi-square test, Kaplan-Meier survival curve were used. Missing data due to discontinuation of BAR was complemented by LOCF method and analyzed statistically. The significance level was set to less than 0.05.

Results: There were 39 subjects (8 males and 31 females) in BAR2mg group and 74 patients (17 males and 57 females) in BAR4mg group. There was a significant difference in mean age (73.5 vs. 62.3 years old, $p < 0.001$), average eGFR (65.1 vs 84.8 ml / min / 1.73m², $p < 0.001$), methotrexate (MTX) use rate (28 vs 58%, $p < 0.01$), average MTX dose (3.0 vs 5.5mg, $p < 0.01$), glucocorticoid (GC) use rate (51.3 vs 33.8%, $p < 0.01$) between the two groups (Table). DAS28CRP improved from week 0 (3.2 vs 3.5) to week 24 (2.5 vs 2.4), and no significant difference was observed between the two groups at each time point (Fig. 1-A). The same was true for CDAI and SDAI (Fig. 1-B, -C). The rate of DAS28CRP remission and low disease activity was not significantly different at 24 weeks (0.64 vs. 0.69, Fig. 1-D). The same was true for CDAI and SDAI (Fig. 1-E, -F). Kaplan-Meier analysis showed that there was no difference in discontinuation rate due to ineffectiveness in the two groups. The same was true for the discontinuation rate due to AEs (Figure 2-B, -C). The total continuation rate including discontinuation due to ineffectiveness and AEs was significantly lower in BAR2mg group (0.691 vs 0.843, $p < 0.05$, Fig. 2-A).

Conclusion: BAR2mg group under real clinical setting was older and had lower eGFR than BAR4mg group. Although the treatment effect for 24 weeks was similar, safety management was considered more important because the discontinuation rate due to AEs tended to be higher in BAR2mg group.

References:

- Taylor PC, (2017) The New England journal of medicine. 376(7), 652.
- Takeuchi T, Ann Rheum Dis 2019;78:171–178.
- Keystone EC, Ann Rheum Dis 2015;74:333–340

Table. Clinical characteristics of the BAR2mg group and the BAR4mg group

	BAR2mg (n=39)	BAR4mg (n=74)	p value
Age, years old	73.5±9.7	62.3±12.6	<0.001
Female	31(79)	57(77)	0.767
Disease duration, year	13.7±11.3	14.2±15.4	0.857
Stage(1/2/3/4)	6/17/8/8	15/24/14/21	0.473
ACPA >4.5U/ml	29(74.4)	59(79.7)	0.629
eGFR, ml/min/1.73m ²	65.1±27.7	84.8±23.2	<0.001
MTX use, mg/week	3.03±4.83	5.54±5.48	0.018
MTX use	11(28.2)	41(55.4)	0.003
GC dose, mg/day	1.91±2.36	1.32±2.20	0.191
GC use	20(51.3)	25(33.8)	0.007
DAS28CRP	3.42±1.04	3.52±13.0	0.689
CDAI	12.6±7.6	15.1±10.9	0.222
SDAI	14.7±9.7	16.2±11.4	0.279

Values are the mean±SD or the number (%).

Figure 1

n.s.: not significant Pearson's chi-square test

Figure 2

Disclosure of Interests: Tsuyoshi Nishiume: None declared, Nobunori Takahashi Speakers bureau: AbbVie, Asahi Kasei, Astellas, Bristol-Myers Squibb, Chugai, Daiichi-Sankyo, Eisai, Eli Lilly, Janssen, Mitsubishi Tanabe, Ono, Pfizer, Takeda, and UCB Japan, Toshihisa Kojima Grant/research support from: Chugai, Eli Lilly, Astellas, Abbvie, and Novartis, Consultant of: AbbVie, Speakers bureau: AbbVie, Astellas, Bristol-Myers Squibb, Chugai, Daiichi-Sankyo, Eli Lilly, Janssen, Mitsubishi Tanabe, Pfizer, and Takeda, Shuji Asai Speakers bureau: AbbVie, Astellas, Bristol-Myers