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Invited Commentary for BJD

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Real world effect of biologics on life quality in psoriasis

A well-planned and well-run clinical Registry is like a mine: just waiting for the surveyors to find another rich seam. Iskander et al[1] have struck more gold in the huge (and still growing) British Association of Dermatologists Biologic Interventions Register (BADBIR) dataset. Designed to monitor the realities of clinical practice, not the artificial topiary of randomised clinical trials (RCT) where tricky patients are pruned out, the study confirms that biologics produce marked improvement in quality of life (QoL). And there is not much difference between the various biologics. But if you are female, have co-morbidities, smoke and have considerable QoL impairment when starting a biologic, then you are less likely to reach a low level of QoL impairment.

The improvement in QoL recorded in the real world of this registry is less than that suggested by RCTs. Iskander et al[1] suggest that life course impairment caused by psoriasis may explain why some patients continue to experience QoL impairment despite major clinical improvement. BADBIR was set up before this concept, or the impact of disease on major life changing decisions[2] was considered, but future psoriasis registry developers might consider tracking this long-term burden. Whatever the explanation, this is another example of why guideline developers need to temper their reliance on "the highest ranking evidence" with the cold reality revealed by registries such as BADBIR.

A systematic review of biologics in psoriasis[3] concluded that ustekinumab was the most effective, followed by infliximab, adalimumab and etanercept, anticipating some aspects of the heirarchy revealed by the BADBIR study. Although not part of any planned Core Outcomes framework, the use of PASI and the Dermatology Life Quality Index (DLQI) in the majority of randomised controlled therapeutic trials in psoriasis[4] has allowed comparison,[5] illustrating the advantages of the objective of setting Core Outcome measures in psoriasis and other areas of dermatology.[6,7] There are many reasons why routine

measurement of QOL may be helpful clinically.[8] This BADBIR study further emphasises the clinical importance of the concept of "QoL impairment", which has lead to the proposal for a specific word to describe it.[9]

So what are the messages for tomorrow's clinic? Your patient's QoL will be improved by starting any of the three biologics investigated, but not by as much as was reported in previous RCTs. Using ustekinumab or adalimumab gives you a better chance of reaching "no" impairment than using etanercept. You can also now explain to patients that if they are male, have not smoked, have no co-morbidities and have low QoL impairment they are more likely to reach a state of "no" QoL impairment, though presumably this will be a rather small sub-group.

Could the authors have mined an even richer seam? For example applying the "happy" drug survival concept,[10] defined as a DLQI score < or = 5, might have revealed other clinically relevant differences between the biologics. However the BADBIR miners should be congratulated on revealing the realities of biologic therapy and be encouraged to continue to dig deep.

Conflicts of interest

AYF was a member of the British Association of Dermatologists committee that set up BADBIR. AYF is joint copyright owner of the DLQI: Cardiff University and AYF receive royalties (but not for the use of the DLQI in BADBIR). AYF has had consultancy agreements with Galderma, Novartis, Napp, Sanofi, Eli Lilly. There was no funding for this commentary.

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References

1. Iskandar IYK, Ashcroft DM, Warren RB *et al.* Comparative effectiveness of biologic therapies on improvements in quality of life in patients with psoriasis. *Br J Dermatol* 2017; XX: xx-xx

2. Bhatti ZU, Salek SM, Bolton CE *et al.* The development and validation of the Major Life Changing Decision Profile (MLCDP). *Health and Quality of Life Outcomes* 2013; **11(1):** 78.

3. Puig L, Lopez A, Vilarassa E, Garcia I. Efficacy of biologics in the treatment of moderate-to-severe plaque psoriasis: a systematic review and meta-analysis of randomized controlled trials with different time points. *J Eur Acad Dermatol Venereol* 2014; **28:** 1633- 1653.

4. Ali FM, Cueva AC, Vyas J *et al.* A systematic review of the use of quality of life instruments in randomised controlled trials of psoriasis. *Br J Dermatol* 2017; **176:** 577-593.

5. Ali FM, Cueva A, Vyas J *et al.* The impact of interventions on quality of life in psoriasis and the concept of multiple minimally clinically important difference (MCID): a systematic review. *J Invest Dermatol* 2016; **136 (95, Suppl 2):** S166.

6. Gottlieb AB, Armstrong AW, Christensen R *et al.* The International Dermatology Outcome Measures Initiative as Applied to Psoriatic Disease Outcomes: A Report from the GRAPPA 2013 Meeting. *J Rheumatol* 2014; **41:** 1227-1229.

7. Chalmers JR, Simpson E, Apfelbacher CJ *et al.* Report from the fourth international consensus meeting to harmonize **core** outcome measures for atopic eczema/dermatitis clinical trials (HOME initiative). *Br J Dermatol* 2016;**175:** 69-79.

8. Finlay AY, Salek MS, Abeni D *et al*. Why quality of life measurement is important in dermatology clinical practice. An expert-based Opinion Statement by the EADV Task Force on Quality of Life. *J Eur Acad Dermatol Venereol* 2017; **31:** 424-431.

9. Finlay AY. Quimp: a word meaning "quality of life impairment". *Acta Derm Venereol* 2017; **97**: 546-547.

10. van den Reek JM, Zweegers J, Kievit W *et al.* 'Happy' drug survival of adalimumab, etanercept and ustekinumab in psoriasis in daily practice care: results from the BioCAPTURE network. *Br J Dermatol* 2014; **171:** 1189-96.