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Drop in biological initiation for patients with psoriasis during the COVID-19 pandemic

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Dear Editor, Biologics have become the backbone of treatment for chronic inflammatory diseases, including psoriasis. Postapproval studies allowed for a better understanding of their safety profile, demonstrating a favourable risk–benefit ratio despite an increased risk of infection, and especially an increased risk of bacterial infection with anti-tumour necrosis factor (TNF) agents.[1,2] In the context of the COVID-19 pandemic, all experts agree that discontinuing biological therapy is not recommended.[3] However, we hypothesized that the pandemic may have modified the first initiation of biological therapy for patients with psoriasis. Indeed, in France, many patients experienced difficulties accessing healthcare during and after the first lockdown (from March to May 2020) owing to the COVID-19 pandemic.[4] Therefore, we studied changes in the dispensation of biologics for psoriasis in France during 2020.

The design of this study has been previously described elsewhere.[5] We conducted a French nationwide cohort study based on health administrative data from the French National Health Insurance database (SNDS-PMSI). The study was approved by the French data protection agency Commission Nationale de l'Informatique et des Libertés (regulatory decision DE-2015-165). All adults (aged ≥ 18 years) with psoriasis registered between 1 January 2015 and 31 December 2020 were eligible for inclusion. Psoriasis was defined as having at least two prescriptions of topical vitamin D derivatives (ATC D05AX, the recommended first-line treatment for psoriasis) within a 2-year period (a definition commonly used in previous studies).[4] All healthcare users who had a prescription for any of the following biological medications for psoriasis were included: etanercept, infliximab, adalimumab, certolizumab (anti-TNF); ustekinumab [anti-interleukin (IL)-12/23]; secukizumab, ixekizumab, and brodalumab (anti IL-17) or guselkumab (anti IL-23). New users of biologics were defined as those who had fulfilled a first prescription of any of the available biologics listed above, after 1 year without any biologics. We assessed the number of healthcare users with psoriasis per month who were treated with biologics and the number of new users of biologics per month who initiated treatment with a biologic over time. Lastly, we compared the numbers of both healthcare users with psoriasis treated with biologics and new users of biologics in 2020 with those of the previous years (from 2015 to 2019).

From 2015 to 2020, a total of 45 580 healthcare users with psoriasis were users of biologics [mean (SD) age 44·8 (13·8) years; male patients 52·9%]; 28 441 (62·4%) of these patients were biologic-naïve and had initiated treatment with a first biologic. From 2015 to 2020, the number of healthcare users with psoriasis treated with biologics was constant over time (Figure 1a), whereas the number of new biologic users dramatically decreased during the first lockdown (from March to May 2020) (Figure 1b). Dispensing of first biologics decreased by up to 57% from March to May compared with 2019. During the rest of 2020, the number of new biologic users remained lower than expected with a second more pronounced decrease during the second lockdown (October to December 2020).

This study highlights a marked decrease of up to 57% in the initiation of biologics for healthcare users with psoriasis during the COVID-19 pandemic in France compared with 2019, which was not compensated for after the lockdown ended, whereas

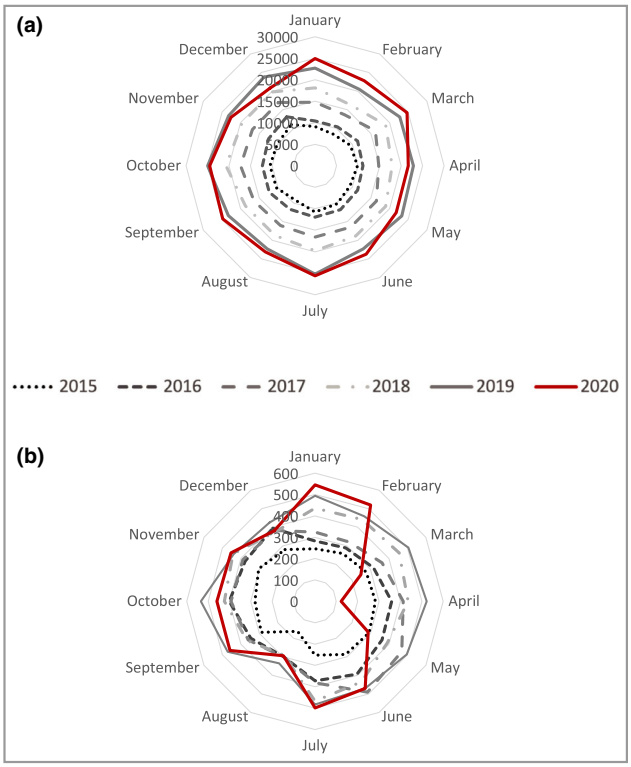

Figure 1 Radar plot. (a) Number of healthcare users with psoriasis treated with biologics per month from 2015 to 2020. (b) Number of new biologic users per month from 2015 to 2020.

patients with psoriasis who were already being treated with biologics continued to maintain their treatment.

There are several possible explanations for these findings. First prescriptions of biologics for psoriasis in France are hospital-based prescriptions. Thus, patients may have experienced difficulties accessing biologic prescriber centres during the first lockdown. More generally, patients may have experienced difficulties accessing physicians, as we observed a decrease of up to 48% in the initiation of nonbiological treatments for psoriasis from March to May 2020 (data not shown). These results were also observed for other chronic diseases with a care reduction for newly diagnosed persons (e.g. epilepsy), whereas adherence to treatment remained stable for patients who were already being treated.[6] A decrease in the dispensation of systemic anticancer therapy delivery was also observed during the first wave of the pandemic, with a global treatment reduction of 30% (from 20% for breast cancer to 43% for colorectal cancer).[7] Another explanation could be that dermatologists prescribed fewer biological treatments because data regarding possible severe COVID-19 infection in patients treated with biologics were missing at the start of the pandemic. However, reassuring data on the absence of a higher risk of severe COVID-19 infection for patients receiving biologics became available,[8] but we still observed a lower than expected total number of new biologic users initiating a biologic after the first lockdown. On the contrary, the dispensation of systemic anticancer therapy returned to previous levels in the months following May 2020.[7] This may have been related to the underlying diseases (oncology vs. inflammatory disorders). Extra data assessing the risks for patients initiating a first biologic could help physicians and patients to continue with the initiation of biologics when needed. Ensuring continuity of psoriasis care should be an important objective in the context of current and future epidemics.

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Reporting of randomized controlled trial abstracts in dermatology journals according to CONSORT guidelines

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Dear Editor, Clinicians often read only the abstracts of studies,[1,2] so accurate and complete reporting of randomized clinical trial (RCT) abstracts is essential. The CONSORT extension for Abstracts (CONSORT-A), published in 2008,[1] aims to improve RCT abstract reporting, requiring sufficient detail for readers to assess a trial's validity, reliability and applicability. RCT abstract reporting is suboptimal in other medical specialties,[3–5] but this has not been evaluated in dermatology.

We conducted a meta-epidemiological review to assess reporting quality of RCT abstracts recently published in dermatology journals. Our protocol and supplemental results can be found at osf.io/dk2x3. We searched MEDLINE and Embase for full reports of primary-outcome parallel-group RCTs published between 1 January 2015 and 31 December 2019 in the 10 highest-impact dermatology journals (2019 Science Citation Index). Two authors (A.C.B. and M.L.M.) independently performed abstract and full-text screening. The same authors evaluated the included abstracts against the CONSORT-A checklist independently in batches of 15 until > 95% agreement was achieved, after which each RCT was abstracted by one abstractor. Disagreements were resolved through discussion or involvement of a senior author (A.M.D. or S.H.V.).

Of 2939 records identified in our search, we included 198 abstracts. The mean proportion of CONSORT-A items reported in the 198 abstracts was 42%. No abstract reported more than 13 of 18 CONSORT-A items, and the majority (68%, 134 of 198) reported less than half of the items. The most frequently reported items were title (89%, 176 of 198), eligibility criteria (89%, 177 of 198), intervention (94%, 187 of 198), objective (96%, 190 of 198) and interpretation (99%, 197 of 198). Adherence was lowest for random sequence generation (2%, three of 198), allocation concealment (1%, one of 198) and source of funding (1%, one of 198).

In a multivariable linear regression model, registered or published trial protocol [$\beta = 7{\cdot}63$, 95% confidence interval (CI) 3·91–11.4], abstract word count $\geq$ 250 words ($\beta = 13{\cdot}1$, 95% CI 9·26–16·8) and journal impact factor ($\beta = 3{\cdot}30$, 95% CI 1·71–4·89) were significantly associated with an increased proportion of items reported. Multicentre trial setting, structured abstract, publication year, funder and intervention type were not significantly associated with reporting. In a multivariable proportional odds model, abstract word limit $\geq$ 250 (OR 14·5, 95% CI 6·76–30·5), having a registered or published trial protocol (OR 5·11, 95% CI 2·52–10·4) and journal impact factor (per 1 unit increase: OR 1·91, 95% CI 1·42–2·58) were associated with increased odds of reporting a higher proportion of CONSORT-A items (Figure 1).

Consistently with studies in other fields,[3–6] we found low overall adherence to reporting items in RCT abstracts published in dermatology journals. Journals' abstract word limits appeared to strongly influence reporting, with word counts of 250 or more increasing the odds of improved reporting by a factor of 14. The CONSORT-A guideline specifies that 250–300 words should be sufficient to include all required elements.[1] Low abstract word count limitations may make it difficult for authors to adhere to reporting guidelines. Structured abstract formats were associated with increased adherence in a univariable analysis but not when controlling for other RCT-level and journal factors. We also found trial registration or having a published protocol, and higher journal impact factor to be associated with increased overall reporting of the CONSORT-A checklist. These findings are generally consistent with those reported in previous studies.[4,7]

Year of publication was not a significant predictor of overall adherence. This is consistent with findings for plastic surgery RCT abstracts evaluated over a similar study period,[3] but is in contrast to earlier studies that showed an improvement in abstract reporting following the publication of the CONSORT-A guidelines in 2008.[4] One possible explanation is that our study period was too far removed from the original CONSORT-A publication, and any improvements may have plateaued.