'To switch or not to switch': the missing piece in the puzzle of biosimilar literature?

We read with great interest the paper from Glintborg and coauthors 'To switch or not to switch' reporting biosimilar etanercept switching in Denmark.[1]

In the Danish Biologic (DANBIO) cohort, patient treated with originator etanercept (Enbrel) were informed of a mandatory switch to SB4. However, the 25 mg pen or a powder-based preparation of original etanercept (OE) were still available. At 1 year after this decision, the authors reported that only 79% of patients had switched to SB4 and 21% remained treated with the originator biologic.

In westernised countries, biologics therapies take a high toll on healthcare systems. With their 20%–50% lower costs, biosimilars' wide diffusion are therefore a necessity in order to provide sustainable healthcare to patients with chronic inflammatory rheumatic diseases. While the use of biosimilar in patient initiating a treatment is a simple subject, switching from originator to biosimilar and the strategy to do it (shared decision vs mandatory switch) has been a hot topic of debate in the rheumatology community.[2–5]

Two strategies for the use of biosimilars can be differentiated in patients already treated with an originator: mandatory switch or physician–patient shared decision. Physician–patient shared decision has been favored by rheumatology scientific societies, by an international consensus group and by patients association.[6–8] Indeed, real-life studies reporting the acceptance of the switch from OE to SB4 in case of shared decision together with an optimised communication strategy have reported acceptance rates of 92%–99%.[9 10] Outside an improved acceptance rate of physician–patient decision, there are reasonable evidence suggesting that forcing the switch on a patient is likely to increase the risk of *nocebo* effect, with negative effect on the patient and on physician–patient relationship (reviewed by Kravvaviti).[11] This *nocebo* effect might, at best, mandate a reswitch to the originator, therefore, a failure of the switching strategy. In the worst case (if the originator is not available anymore), the patient will be switched to another (possibly originator) biologic, leading to an avoidable exhaustion of therapeutic options, a weakening of the patient–physician relationship and increased healthcare costs. Considering this body of evidence, we believe that Glintborg's study was the missing piece in the puzzle of the biosimilars literature, demonstrating that a mandatory switch is probably not the most efficient strategy for the wide diffusion of biosimilar in chronic rheumatic diseases and reinforcing the evidence of the necessity of a shared physician–patient decision as recommended by many.

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