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EFFICACY AND QUALITY OF LIFE BENEFITS OF BIOLOGICS IN CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

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CONCLUSION

- This systematic literature review and meta-analysis demonstrates that adding biologics to SOC significantly enhances efficacy and QoL in CRSwNP patients compared to SOC alone, thus reducing the dependence on systemic corticosteroids

INTRODUCTION

- Chronic rhinosinusitis with nasal polyps (CRSwNP) is an inflammatory condition which negatively impact the quality of life (QoL) marked by symptoms including sinus infections that keep coming back, facial pain or pressure, impaired sense of smell, and congestion in the nasal cavity
- Topical or intranasal corticosteroids are the standard of care (SoC) treatment for CRSwNP along with biologics which are quite helpful in treating CRSwNP
- FDA approved biologics specifically address the underlying inflammation and immune response associated with CRSwNP by targeting key proteins involved in the disease's pathogenesis, for treating CRSwNP

OBJECTIVE

- To compare the efficacy and QoL of biologics as an add-on treatment with SoC i.e., corticosteroids, to SoC alone in adult patients with CRSwNP

METHODS

- Key biomedical databases (EMBASE® and MEDLINE®) including bibliographic searching of published SLR/meta-analysis (MA) were conducted to identify randomized controlled trials (RCTs) assessing biologics in adult patients with CRSwNP
- The predefined key inclusion and exclusion criteria used for the selection of studies is depicted in **Figure 1.** Two independent reviewers performed screening and data collection, followed by a quality control check by a third reviewer, adhering to PRISMA guidelines. Influence plots were generated to determine the studies contributing to high heterogeneity
- STATA17.0 software was used to calculate the weighted mean difference (WMD) from the mean change from the baseline score of Nasal polyp score (NPS) and Sino-nasal outcome test score (SNOT-22) after 24 ± 4 weeks and 52 ± 4 weeks of treatment

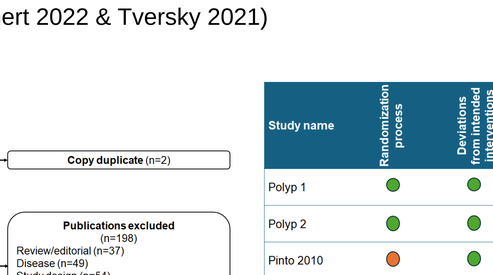

Figure 1: Eligibility criteria for selection of studies

RESULTS

- Of 378 screened publications, nine RCTs met the inclusion criteria involving a total of 1,952 patients (sample size ranged between 14 to 448). A PRISMA diagram for the screening process is presented in **Figure 2**
- The majority of studies (n=7) were found to have low risk of bias, whereas two studies had some concerns over randomization process (**Table 1**)
- The biologics assessed across the included studies were as follows:
  - **Omalizumab** (n=3, POLYP-1, POLYP-2, & Pinto 2010)
  - **Dupilumab** (n=2, LIBERTY NP SINUS-24 & SINUS-52)
  - **Mepolizumab** (n=2, Bachert 2017 & SYNAPSE), and
  - **Benralizumab** (n=2, Bachert 2022 & Tversky 2021)

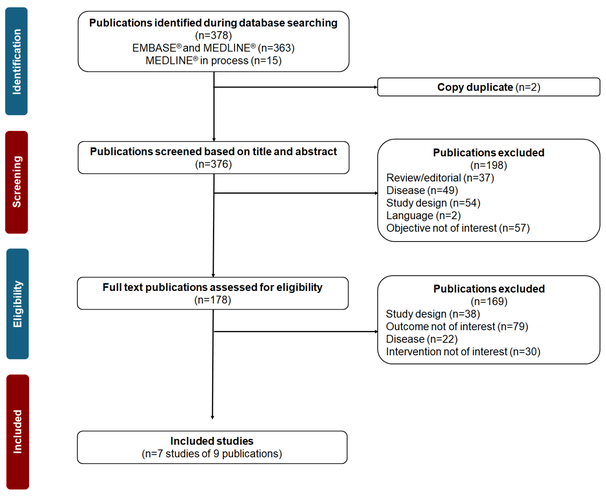

Figure 2: PRISMA flow of studies in the SLR

Study name	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Assessor's overall Judgement
Polyp 1	Low	Low	Low	Low	Low	Low
Polyp 2	Low	Low	Low	Low	Low	Low
Pinto 2010	Some concerns	Low	Low	Low	Low	Some concerns
Bach 2017	Low	Low	Low	Low	Low	Low
LIBERTY NP SINUS 24	Low	Low	Low	Low	Low	Low
LIBERTY NP SINUS 52	Low	Low	Low	Low	Low	Low
Tversky 2021	Some concerns	Low	Low	Low	Low	Some concerns
Bach 2022	Low	Low	Low	Low	Low	Low
SYNAPSE	Low	Low	Low	Low	Low	Low

Some concerns Low

Table 1: Cochrane ROB2.0 of included studies

RESULTS

- The patient's characteristics were similar across all studies except for two studies identified outliers in the box plot w.r.t. mean age (45.8 years; Pinto 2010), proportion of males (57.5%; SINUS-2), and baseline NPS (1.37; Pinto 2010) (**Figure 3**)

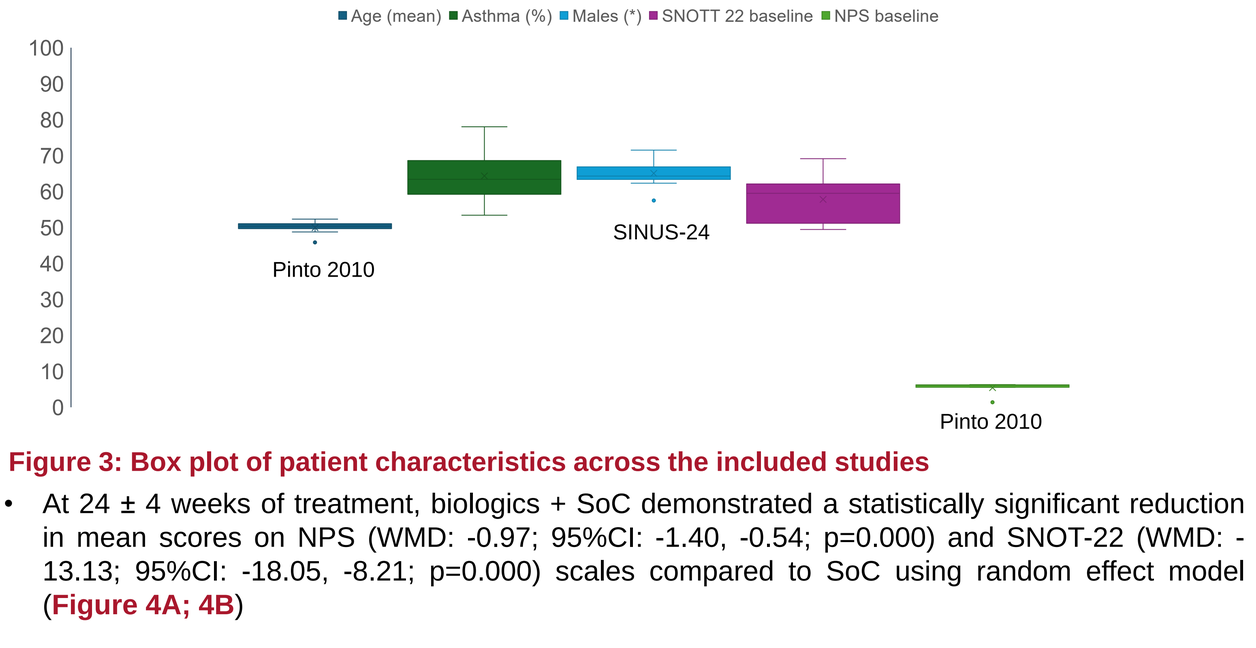

Figure 3: Box plot of patient characteristics across the included studies

- At 24 ± 4 weeks of treatment, biologics + SoC demonstrated a statistically significant reduction in mean scores on NPS (WMD: -0.97; 95%CI: -1.40, -0.54; p=0.000) and SNOT-22 (WMD: -13.13; 95%CI: -18.05, -8.21; p=0.000) scales compared to SoC using random effect model (**Figure 4A; 4B**)

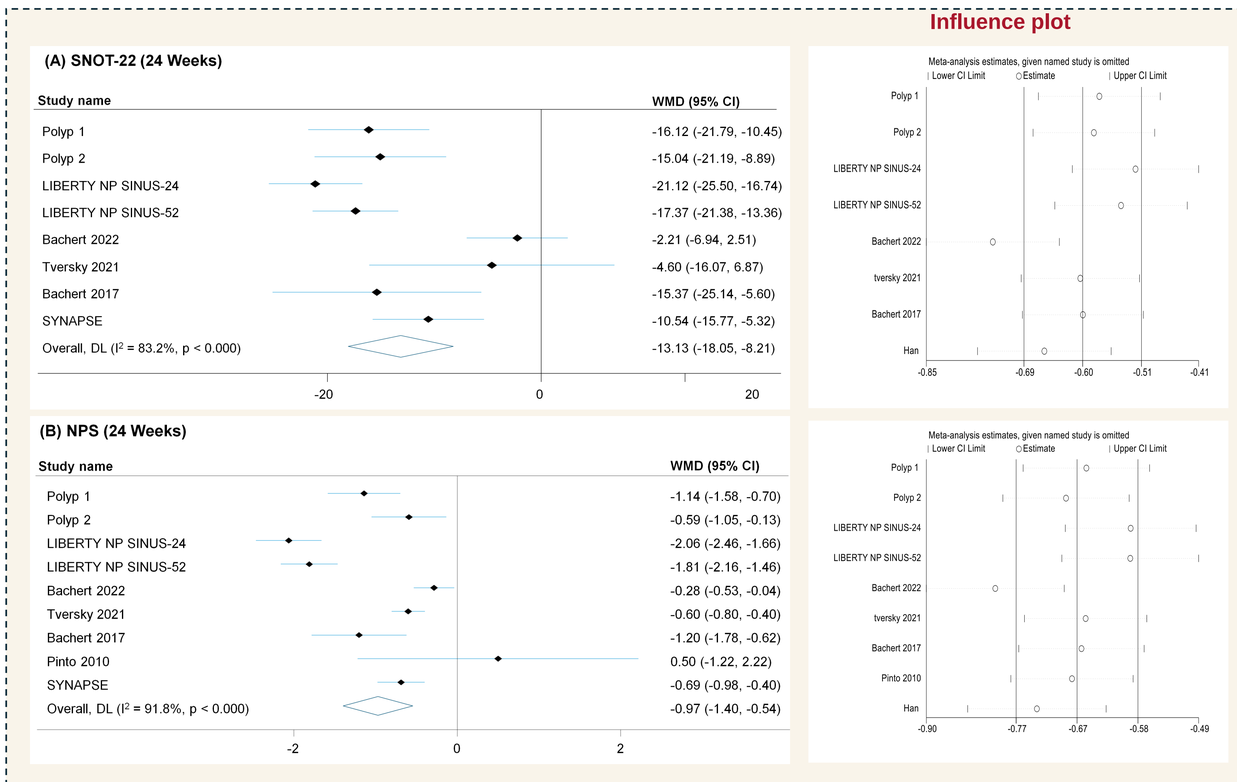

Figure 4: Meta-analysis results of (A) SNOT-22 and (B) NPS scores at 24 weeks

- Similar results were observed after 52 ± 4 weeks of treatment with biologics + SoC on NPS (WMD: -1.25; 95%CI: -2.27, -0.22; p=0.017) and SNOT-22 (WMD: -14.31; 95%CI: -21.67; -6.95; p=0.000) scales compared to SoC using random effect model (**Figure 5A; 5B**)
- Influence plot predicted no significant influence of any study on results

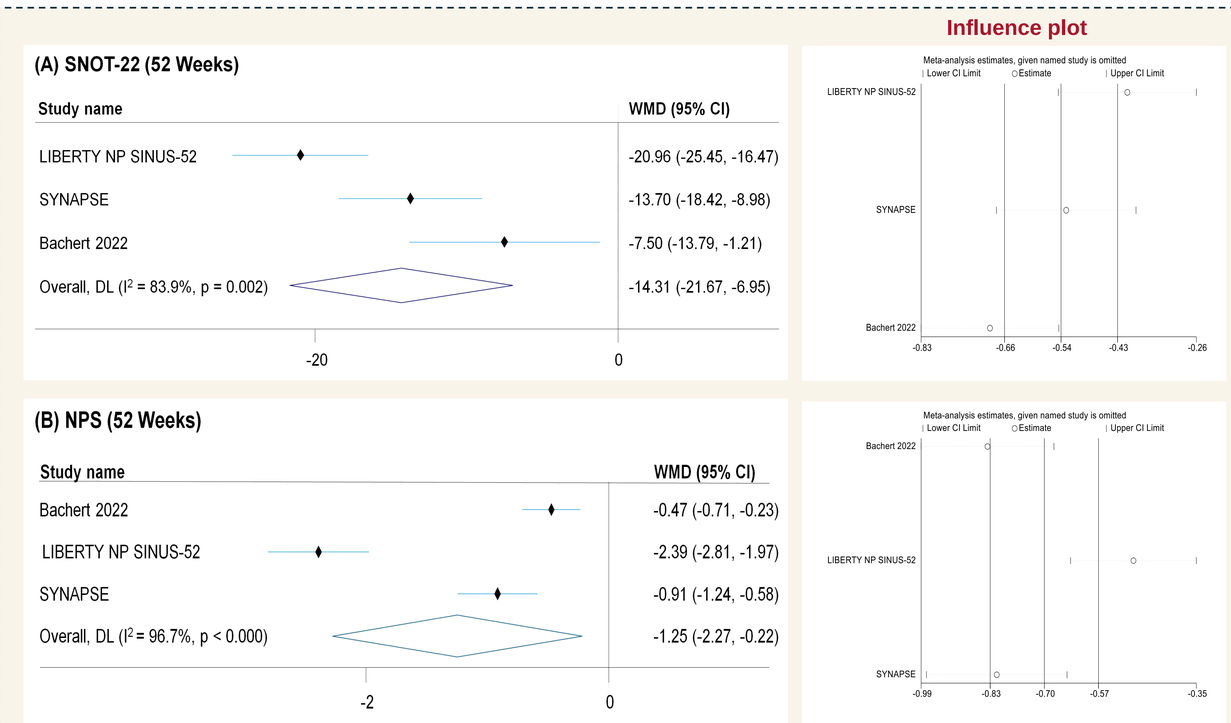

Figure 5: Meta-analysis results of (A) SNOT-22 and (B) NPS scores at 52 weeks

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Disclosures

SA, BS, PC and RD are employees of Pharmacoevidence Pvt Ltd.