Efficacy and Safety of 23-Valent Pneumococcal Vaccine for Patients with Autoimmune Inflammatory Rheumatic Diseases

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Abstract: Backgrounds: Comorbid infections have significant impact on morbidity and mortality, especially in autoimmune rheumatic diseases. Prevention of infection is an integral part of supervision of these patients. The aim of our study is investigating the clinical efficacy, immunogenicity, and safety of a 23-valent pneumococcal vaccine in patients with autoimmune inflammatory rheumatic diseases.
Methods: The investigation enrolled 133 patients (102 women and 31 men, aged 23–76 years), including 79 patients with rheumatoid arthritis (RA), 16 patients with scleroderma systematica (SDS), 7 – with dermatomyositis/polymyositis (DM/PM), and 31 people without systemic inflammatory rheumatic diseases (a control group) who had a recent history of 2 and more cases of lower respiratory tract infections (bronchitis, pneumonia). When included, all the patients with RA received anti-inflammatory therapy with methotrexate (MTX) (n = 52), leflunomide (LEF) (n = 14), or MTX + tumor necrosis factor-α (TNF-α) inhibitors (n = 13). A single 0.5-ml dose of the 23-valent pneumococcal vaccine Pneumo-23 (Sanofi Pasteur) was administered subcutaneously during continuous MTX or LEF therapy for the underlying disease or 3–4 weeks before the use of a TNF-α inhibitor. During control visits (1 and 3 months and 1 year after administration of the vaccine), the patients underwent physical examination and routine clinical and laboratory studies. Levels of pneumococcal antibodies of the capsular polysaccharide in the serum were measures in 102 patients using enzyme-linked immunosorbent assay (ELISA) with commercial kits VaccZymeTM Anti-PCP IgG Enzyme Immunoassay Kit (The Binding Site Group Ltd, Birmingham, UK).
Results: No clinical and radiological symptoms of pneumonia were recorded in any case during a 12-month follow-up. The RA and control groups showed a more than 2-fold increase in anti-pneumococcal antibody levels 1 year after vaccination ($p < 0,001$). The vaccine was well tolerated by 90 (68%) patients. 37 (28%) patients were observed to have pain, cutaneous swelling and hyperemia and 6 (4%) had subfebrility. As these reactions had no casual relationship with current RA therapy, and fully resolved within 24 hours without additional treatment, no therapy modification was required. There were neither episodes of AIRD exacerbation nor new autoimmune disorders during the follow-up.
Conclusion: The findings suggest that 23-valent pneumococcal vaccine shows a good clinical efficacy, adequate immunogenicity, and good tolerability in the patients with autoimmune inflammatory rheumatic diseases.

Key words: Vaccination, rheumatoid arhritis, pneumoccocal infections, autoimmune inflammatory rheumatic diseases, comorbid infection