

A randomized controlled trial of a phytotherapeutic compound containing *Boswellia Serrata* and Bromeline for Seasonal Allergic Rhinitis complicated by Upper Airways Recurrent Respiratory Infections

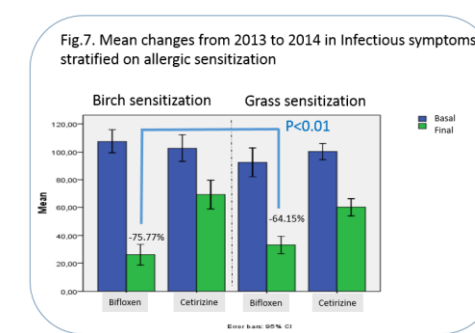
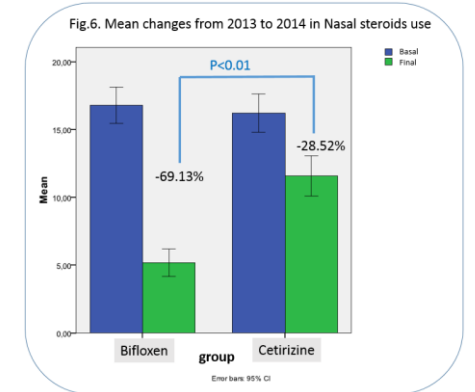
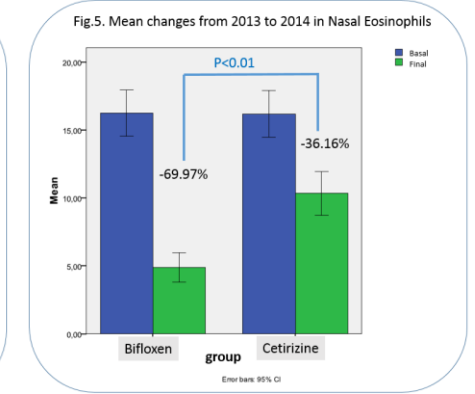
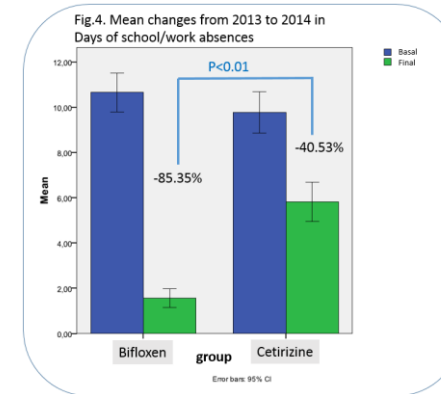
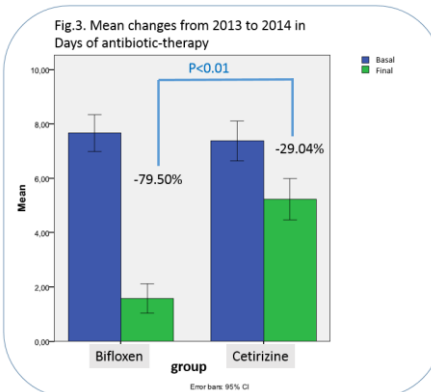
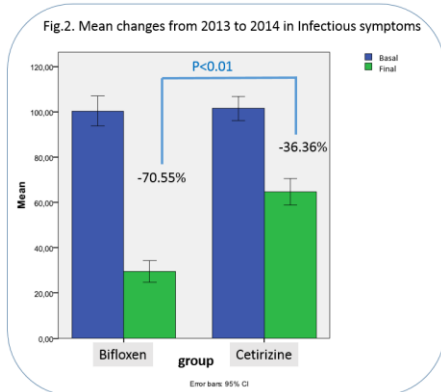
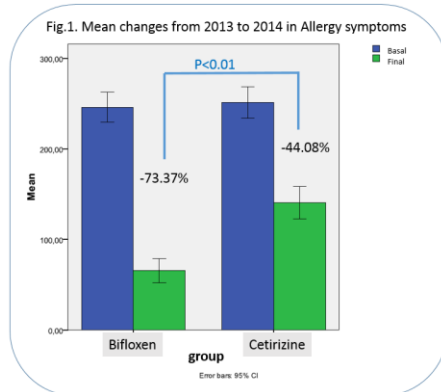
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Rationale

Phytotherapeutic compound containing *boswellia serrata* and bromeline (Biflofen orosoluble) has natural antiflogistic properties with pronounced action on 5-lipoxygenase and thromboxane synthetase. Its clinical effect in seasonal allergic rhinitis (SAR) complicated by recurrent upper airways respiratory infections (RRI) was assessed in this investigation.

Methods

- This randomized open controlled trial recruited 150 patients (5-59 years-old) allergic to birch or grass pollen with upper RRI.
- During a first pollen season (2013) of antiallergic treatment wash-out (only on demand nasal steroids admitted), the monthly average seven allergy symptoms (nasal itching, sneezing, rhinorrhea, nasal congestion, cough, wheezing, dyspnea), symptoms of upper airways infections (nasal purulent draining, frontomaxillary headache, purulent expectorate, pharyngodynia, otalgia), days of antibiotic therapy, days of work/school absence due to the disease, use of nasal steroids, nasal eosinophils (at the end of season) were calculated and compared to those of the subsequent season (2014).
- Patients were randomly assigned to two groups, receiving daily treatment with phytotherapeutic compound (Biflofen) or cetirizine, and nasal steroids were admitted as rescue medications.
- Data were collected through patients' diary and monthly means were calculated to estimate a global mean score for the whole period.
- The analyses of intra-group (Wilcoxon test) and between-group (T-test and Mann-Whitney test) differences were carried out, with subgroup analysis (ANOVA and post-hoc LSD Fisher test) based on four balanced blocks stratified on allergen sensitization and treatment.



Results

The study was concluded by 132 patients (n.68 phytotherapy, n.64 controls). All groups improved in all outcomes from baseline to the second season (p<0.05).

From 2013 to 2014 the improvement achieved by the phytotherapeutic agent :

- is statistically significant, independent of the allergic sensitization, and superior to that of cetirizine in terms of allergy symptoms (fig.1), days of antibiotic therapy (fig.3), days of school/work absences (fig.4), nasal eosinophilic infiltration (fig.5), recourse to topic corticosteroids (fig.6);
- is statistically significant, higher in birch-sensitized patients, and superior to that of cetirizine in infectious symptoms (fig.2, 7).
- No serious adverse events occurred.

Conclusions

This is the first controlled trial showing a large benefit of a **boswellia serrata** and **bromeline** compound in Seasonal Allergic Rhinitis complicated by Recurrent Respiratory Infections.