

Current status and future perspectives of immunotherapy in Latin America and Cuba

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LATIN AMERICA - GENERAL DATA



Area: 21.069.501 km²
Population: 577.200.000.
Number of countries: 20
Most populated countries:
- Brazil: 201 millions.
- Mexico: 113.4 millions.
- Colombia: 45 millions.
- Argentina: 40.4 millions.

Allergology in LA:

- Allergology is not recognized as a full specialty in all Latin American (LA) countries.
- In almost 50% of LA countries, Allergology is at the third-level of medical care.
- Argentina, Brazil, Colombia, Mexico and Venezuela are the nations with the highest number of allergists.

Allergens & sensitizations in LA

- *Dermatophagoides pteronissynus*, *Dermatophagoides farinae*, *Lepidoglyphus*, *Euroglyphus* and *Blomia tropicalis* are the most prevalent dust mites in the region.
- Pollens are also very common in some areas, with a seasonal pattern in some countries like Argentina and Chile.
- Other important allergens are insects (cockroach) and airborne fungi.

Allergens & Immunotherapy in LA

- 90 % of LA countries use SCIT extracts from US and Europe and 50% from local providers.
- SLIT extracts are almost exclusively from Europe, but Argentina, Brazil, Cuba and Mexico prepare their local SLIT extracts.
- A small number of countries fulfill regulatory status for allergens products.
- Both SLIT and SCIT are practiced in all countries (from 1 to 5 years forward).
- The most common indications for AIT in LA are allergic rhinitis and asthma.
- In most LA countries, specific IT can be managed by non-allergists doctors.
- IT with multiple allergens is the most used modality.
- Most countries use bacterial vaccines.

Publications & research on IT

- Clinical investigation on IT in LA is still low (but increasing).
- Publications on adverse events with IT are starting to appear.
- Only 3 countries have their own guidelines on IT.
- The economical found for medical investigation in IT is still low.

Future perspectives for IT in LA

- ✓ Improvement for standardization and quality control for the production of allergen products.
- ✓ Better regulatory policies for the use of IT.
- ✓ Encourage clinical investigation for IT, especially in children and SLIT.
- ✓ Improve the regulatory status for allergens products.
- ✓ Expand IT accessibility for low-income patients.

CUBA. GENERAL DATA



Area: 110.000 Km²
Population: 11.163.934.
Number of allergists: 281.
Allergy services: 99 (≈75 % in primary care services).

Allergens & sensitizations

- It has been estimated that at least 20% of the Cuban population suffer from allergy.
- Asthma is considered a serious health problem: prevalence in general population: 9 to 15 % and increasing trend; Cuban ISAAC Study for children (see table 1).
- House dust mites are the most important allergen sources. *Dermatophagoides pteronyssinus*, *Dermatophagoides siboney* (endemic) and *Blomia tropicalis* are the most relevant.
- Other allergens: cockroaches (*Periplaneta Americana*), pollens: *Cynodon dactylon* (Bermuda grass), *Parthenium hysterophorus* (escoba amarga) and *Bidens pilosa* (yellow grass).
- Molds are also thought to be important but evidence is lacking for supporting it.

Table 1. Phase I Cuban ISAAC study. 2002-2004.

| Disease | 6-7 years | 13-14 years |
|-------------------|-----------|-------------|
| Asthma | 31.6% | 17.6% |
| Allergic rhinitis | 39.8% | 38.5% |
| Atopic dermatitis | 22.3% | 14% |

Havana Biotech pole

- There is a Biotech pole with important scientific institutions working on the application of Biotechnology into healthcare, developing and manufacturing vaccines and biopharmaceuticals products.
- This pole counts with 40 organizations, approximately 7.000 scientists and engineers and 150 research projects.
- There is a group of leading centers among them: The Center of Genetic Engineering and Biotechnology, the Center of Molecular Immunology, the Finlay Institute and the National Center of Bioproducts (BIOCEN).

Allergens & Immunotherapy

- The first registered allergen vaccines were developed in 2006: a standardized (BU) and freeze dried for SCIT.
- The sublingual version was developed in 2009.
- These vaccines are included into the group of basic medicines by the Ministry of Health.
- The IT vaccines are provided to patients free of charge.
- More than 10. 000 patients undergoing IT/year.
- In Cuba, AIT can be managed only by allergists.

Publication and research

- 3 publications on adverse events.
- 12 clinical trials on IT published at the Cuban public registry for clinical trials: <http://rpcec.sld.cu/>.
- Currently working on our own guideline for AIT management.

Future perspectives for IT in Cuba

- Work on new indications for IT (for other diseases).
- Investigate preventive effect and cost-effectiveness for current vaccines.
- Develop new products with mixed formulas for SLIT.
- Complete the phase I-II clinical study for dust mite plus adjuvant vaccine.
- Produce allergen vaccines for fungi allergy in asthmatics (Alternaria, Cladosporium) probably using recombinants allergens.
- Complete the Cuban guideline for AIT management.

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