Registries

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What is a registry?

• non-interventional research program is a coordinated effort to collect information directly from physicians and patients who are at least 18 years of age or older and have been diagnosed with an immune-mediated disease, such as psoriasis and psoriatic arthritis.

• this is how the corrona defines itself
In general registries collect data about a particular disease and track the course of patients on various therapies.
India does not have a psoriasis registry and not all can access one of the many registries in the world—even doctors
Advantages of a registry

• Unbiased real time data
• information on the disease
• help in making decisions
• tracks side effects of medications so patients and doctors can make better choices
• Tracking and incorporation of various studies in registries helps to identify the early signs of adverse effects and also failure of therapy
• Replaces biased websites indulging in promotional material
Most important, psoriasis registries can track trends in disease epidemiology

This helps in precision medicine
All information collected for the registry is kept confidential. Complete details about how your information is protected is described in the consent form.
Who is participating—eg corrona

• 50,000 patients from different states across the US and Canada, and include a mix of academic, private, and hospital affiliated clinical sites
variety of local, national, and international patient registries collect longitudinal data on (systemic) psoriasis treatment

publications reflect the main registry objectives of safety and effectiveness

with additional therapy-related investigations being addressed as well

combination of data from these registries will involve many methodological challenges

To gain comparability and combinability of cohorts and data across registries, further harmonization of data collection is demanded.

Review of U.S. Registries for Psoriasis

- identified 6 psoriasis patient registries in the United States
- important information about the safety, efficacy, and long-term effects of systemic therapies
- primary objectives of a patient registry are to collect and provide “real-world” epidemiological data about specific diseases, determine the safety and efficacy of certain treatments, and to detect particular subgroups of patients with optimal risk/benefit ratio for a specific treatment
- data can be utilized in cost/benefit analyses by evaluating patient outcomes and the associated costs of care
safety profile of adalimumab remains unchanged—why?

• ESPRIT is an ongoing 10-year international, post-marketing observational registry evaluating the long-term safety and effectiveness of adalimumab.

• Menter et al published an initial 5-year report to provide an update on the incidence of treatment-emergent adverse events (TEAEs) in this patient registry.

• Serious TEAE was 4.3/100PY, with infection being the most common.

• The mortality rate was lower than the expected mortality rate in the general population.

• Based on this initial report, the safety profile of adalimumab remains unchanged and is consistent with previous report.
• observed efficacy of adalimumab appeared promising at five-year follow-up
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<thead>
<tr>
<th>Study type</th>
<th>Registry studies</th>
<th>Clinical trials</th>
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<td>Advantages</td>
<td>Offers a realistic representation of clinical practice. Ability to observe patients over a longer period of time. Provides ongoing surveillance of any delayed side-effects, especially rare adverse events. Data is publicly available. Less rigorous inclusion and exclusion criteria, resulting in larger patient enrollment.</td>
<td>Randomization to intervention groups reduces the incidence of bias and confounding factors. Outcomes during exposure intervals can be monitored and recorded. Cohorts are very homogenous prior to treatment. Demonstrates cause and effect of an intervention.</td>
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Shorter period of observation  
Ethical issues may arise regarding distribution of treatment  
Study environments may not represent realistic clinical practice  
Side effects in certain patient populations may go unnoticed because of rigorous inclusion and exclusion criteria  
Patients are less sick so may not be generalizable to the typical disease population |
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Thank you

Dr Murlidhar Rajagopalan