Gadolinium Deposition: What We Know and Don’t Know, A Research Roadmap Workshop

No Evidence of Harm!

What is GDD?

What is GAP?

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Conflicts of Interest

Bayer Healthcare-Speaker Agreement.
### Open Questions for Big Data Approach

#### Dose-Dependent Effects (chronic exposure)?
- Long-Term Retention and Gd\(^{+++}\) Deposition
- Cumulative amount of deposited gadolinium
  - To reach a threshold for toxicity (if any)
- Increased Risk at threshold dose
- Time Challenges the hypotheses
  - Predictable effect
  - If any: rare events of patients with symptoms after very high cumulative doses

#### Exposure Effects (idiosyncratic reaction)?
- No Gd\(^{+++}\) Deposition
- No threshold dose (in clinical range)
- Gadolinium/GBCA - Drug Interactions
- Gadolinium/GBCA – Protein binding
- Gadolinium/GBCA and Immune system
  - Unpredictable effect
  - If any: rare events of patients with symptoms after exposure to GBCA (immune sensitization is theoretically possible)

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Big data to increase epidemiological signal to noise ratio

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**OPPORTUNITIES:**
Identifications of vulnerable patients

Differences between GBCA molecules? Large datasets with unconfounded exposure and clinical / imaging outcome

Body symptoms/signs in CNS disease patients

Neurological symptoms/signs in NON-CNS disease patients

Gadolinium tissue topographic distribution (intra / extracellular in brain, skin, bone, liver etc.) – biosamples –

**PITFALLS:**
Data validation among centers, institutions, national registries

Systematic Errors

Disease-Related Effects introduced by the pathological processes and treatments (especially in the scenario of long-term dose-dependent effects of gadolinium deposition)
International and European Gadolinium Retention Evaluation Consortia

I-GREC & E-GREC

✧ Multi-center MR image repository
✧ Gad Retention Clinical data repository
✧ Demographic registry
✧ Bio-banking repository
✧ International Database for Big data mining
✧ Gateway to resource utilization
✧ Scientific consultation of Regulatory agencies
✧ Epidemiology Resource
✧ Source of Clinical Guidelines

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