The Clinical Global Impressions: a widely used instrument in psychiatry

Benedetto Vitiello

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Disclosure

Benedetto Vitiello, M.D.

- Professor of Child and Adolescent Neuropsychiatry, University of Turin, Italy

  - I do not have any financial conflict of interest with the content of this presentation
Aims

• To review the main characteristics of the Clinical Global Impression (CGI) scales

• To discuss its strength and limitations in child psychiatry
Clinical Global Impression Scales

Of the clinician, by the clinician, for the clinician

- CGI were developed as simplified global measures
- Meant to reflect the clinician’s overall impression of a patient’s condition
- As a way of quantify clinically relevant information
CGI-improvement scale

- 1 = Very much improved—a very substantial positive change
- 2 = Much improved—notably better with significant reduction of symptoms, but some symptoms remain
- 3 = Minimally improved—slightly better with little or no clinically meaningful reduction of symptoms. Very little change in basic clinical status, level of care, or functional capacity
- 4 = No change—symptoms remain essentially unchanged
- 5 = Minimally worse—slightly worse but may not be clinically meaningful;
- 6 = Much worse—clinically significant increase in symptoms and diminished functioning
- 7 = Very much worse—severe exacerbation of symptoms and loss of functioning
CGI - Severity

- 1 = Normal—not at all ill, symptoms of disorder not present
- 2 = Borderline mentally ill—subtle or suspected pathology
- 3 = Mildly ill—clearly established symptoms with minimal, if any, distress or difficulty in social and occupational function
- 4 = Moderately ill—overt symptoms causing noticeable, but modest, functional impairment or distress;
- 5 = Markedly ill—intrusive symptoms that distinctly impair social/occupational function or cause intrusive levels of distress
- 6 = Severely ill—disruptive pathology that affects behavior and function
- 7 = Among the most extremely ill patients—pathology drastically interferes in many life functions; may need hospital care
## Efficacy Index

<table>
<thead>
<tr>
<th>Therapeutic effect</th>
<th>Side effects</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Marked</td>
<td>01</td>
</tr>
<tr>
<td>Moderate</td>
<td>05</td>
</tr>
<tr>
<td>Minimal</td>
<td>09</td>
</tr>
<tr>
<td>Unchanged or worse</td>
<td>13</td>
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</tbody>
</table>
CGI-S and CGI-I

- Good internal consistency and concurrent validity
- Correlation with symptom-specific rating scales: 0.4-.07
- Primary outcome measure in clinical trials for a variety of conditions
  - major depression, social phobia, post-traumatic stress disorder, panic disorder, binge-eating disorder, bipolar, etc.
In general, good concordance between CGI and symptom rating scales

- Leucht & Engel (2006) re-analyzed the databases of four comparative effectiveness trials of antipsychotics in adults with schizophrenia (n=1,205)
  - Similar effect sizes on BPRS and on CGI-S
CGI-Improvement

- Often dichotomized
  - Very much improved (1) or much improved (2) → IMPROVED
  - Minimally improved (3), no change (4), or worse (5-7) → NOT IMPROVED

- Forcing a clinical decision to:
  - Continue treatment as effective
  - Discontinue treatment as ineffective
Risperidone (n=49) vs. placebo (n=52) for irritability in autism

Risperidone (n=49) vs. placebo (n=52) for irritability in autism CGI-defined improvement rate
TADS, 2004

Mean CDRS Score - Adjusted

Stage I Assessments

Baseline Week 6 Week 12

COMB FLX CBT PBO
Treatment Response: Week 12

- COMB: 71%
- FLX: 61%
- CBT: 43%
- PBO: 35%
Symptomatic remission (CDRS $\leq 28$) rate at 3 months (Kennard et al. 2006)
Level of functioning (CGAS ≥ 70)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Percent</th>
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<tbody>
<tr>
<td>COMB (N=107)</td>
<td>34.6</td>
</tr>
<tr>
<td>Fluoxetine (N=109)</td>
<td>20.2</td>
</tr>
<tr>
<td>CBT (N=111)</td>
<td>13.5</td>
</tr>
<tr>
<td>Placebo (N=112)</td>
<td>18.7</td>
</tr>
</tbody>
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CGI in clinical trials

- Often used as secondary outcome measure, together with a specific symptom rating scale

- At times, combined with a specific symptom rating scale to form a primary outcome measure
  - Responder: CGI=1 or 2 + >25% decrease in hyperactivity scores (RUPP Network, 2005)
Methylphenidate in preschoolers with ADHD (PATS): parallel-design clinical trial (Abikoff et al 2007)

- N=114
- Age 3-5 y
- Dx: ADHD-combined or hyperactive type
- Parallel-group design
  - Methylphenidate (mean 14 mg/d) vs. placebo
- Double-blind
- 4-weeks
PATS parallel-design clinical trial (N=114): secondary outcomes (Abikoff et al 2007)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>ES</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWAN Total ADHD Parent (n=86)</td>
<td>0.43</td>
<td>NS</td>
</tr>
<tr>
<td>SWAN Total ADHD Teacher (n=64)</td>
<td>0.32</td>
<td>NS</td>
</tr>
<tr>
<td>ECI depression Parent (n=61)</td>
<td>0.55*</td>
<td>.02</td>
</tr>
<tr>
<td>CGI-Severity (n=114)</td>
<td>0.73</td>
<td>.001</td>
</tr>
</tbody>
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*Worse on medication
Disease-specific modifications of the CGI

- Application of anchor points to the CGI scores

- The anchor points direct and limit the scoring to the target symptoms of the specific disorder of the study
CGI-BP

Spearing MK, Post RM, Leverich GS, Brandt D, Nolen W.

Modification of the Clinical Global Impressions (CGI) Scale for use in bipolar illness (BP): the CGI-BP.

Psychiatry Res. 1997;73(3):159-71
Improvement rate in the Treatment of Early Age Mania (TEAM) (N=279) (Geller et al., 2012)

- Valproate: 24%
- Risperidone: 69%
- Lithium: 36%
## CGI

### Strengths
- Global: overall index
- Transdiagnostic
- Widely used
- Quick to rate
- Low burden on patient’s and clinician’s time
- Convenient for use in practical trials

### Limitations
- Global: lack specificity
- Needs clinical expertise and appropriate knowledge of the patient situation
- Not explanatory