Table E.21. Characteristics of single-cohort observational studies with adverse events

| Author, Year | Study Country, Study Design, Type of Study (Efficacy/ Effectiveness), Study Settings | Type of Anxiety/Severity (CGI) | Intervention and Comparisons (N of Patients) | Characteristics of Interventions (Psychotherapy: Components, Delivery Model)/Pharm: Drug) Intensity, Duration (Weeks)) | Patient Characteristics Mean Age (Range) , Male (%), Race/Ethnicity, Comorbidity, Household Income, Parent Education, Family Dysfunction/Stressor, Treatment Sequence, Insurance, History of Maltreatment) | Length of Follow up (Weeks) |
| --- | --- | --- | --- | --- | --- | --- |
| Biederman, 1987189 | United States Case series/case report  Outpatient | GAD, PD with agoraphobia, PD without agoraphobia, SAD, SoP | Clonazepam,  (N=3) | 1 mg/day | Age mean (years): 10 (range: 8-11)  Males: 66.6%  Caucasian: 100% | 21.5-156 |
| Birmaher, 1994190 | United States Case series Outpatient | SAD, SoP | SSRI:  Fluoxetine,  (N=21) | Mean dose of 25.7 mg/day for up to 43 weeks | Age Range: ( 11- 17) years  Male: 55%  CGI>=6: 91% | 0 |
| Chavira, 2002191 | United States Case series/case report  Outpatient | SoP, SP | SSRI: Citalopram, (N=12) | 100-40 mg/day for 12 weeks | Age mean (years): 13.42 (range: 8-17)  Males: 33.3%  Caucasian: 6%  African American: 8%  Hispanic: 16.6%  Others:25%  Mean CGI-S=4.82 | 0 |
| Chutko, 2011192 | Kazakhstan Case series Outpatient | GAD | SNRI: Adaptol,  (N=32) | 1000 mg/day for 4 weeks | Age range: 7-14 years | 0 |
| Compton, 2001193 | United States  RCT  Outpatient | SoP | SRI, SSRI: Sertraline, (N=14) | Maximum of 200 mg/day for 8 weeks | Age Range: (10-17) years  Males: 57% | 0 |
| dAmato, 1962194 | United States  Case series/case report  Outpatient | SP | Benzodiazepine: Chlordiazepoxide: (N=9) | 10-30mg/day for 1-4 weeks | Age range: 8-11 years  Males: 44% | 0 |
| Dummit, 1996195 | United States Case series/case report Outpatient | GAD, SAD, SoP, SP | SSRI: Fluoxetine (N=21) | 20-60 mg/day for 9 weeks | Age mean (years): 8.2 (range: 8-14)  Males: 24%  Caucasian: 90%  Asian: 9.5%  ODD: 5%  Learning disabilities: 14%  Enuresis: 5%  Trichotillomania: 5% | 0 |
| Fairbanks, 1997196 | United States  Case series/case report  Outpatient | GAD, PD, PD with agoraphobia, SAD, SoP | SSRI: Fluoxetine (N=18) | Oral,  20- 40mg/day (children) or 20-80mg/day (adolescents) for 9 weeks. | Age mean (years): 11.9 (range: 9-17)  Caucasian: 55%  African American: 5%  Hispanic: 5%  Other: 5%  Body Dysmorphic Disorder: 5% | 0 |
| Isolan, 2007197 | Brazil  Case series Mental health clinic | GAD, SAD, SP, SoP. | SSRI:  Escitalopram  (N= 20) | 10-20 mg/day for 12 weeks. | Age mean (years): 15 (Range 10 -17)  Male: 30% | 0 |
| Karabekiroglu, 2011198 | Turkey  Case series Outpatient | GAD,SAD, SoP, SP | SSRI:  Fluoxetine:  (N=40) | 12 weeks of treatment. | Age mean (years): 10.08 ( range: 7-17)  Male: 57%  ADHD: 7.5%, OCD : 2.5%, selective mutism: 2.5% | 0 |
| Lepola, 1996199 | Finland  Case series  Outpatient | PD with agoraphobia | SSRI: Citalopram, (N=3) | 20mg/day for 34-64 weeks | Age range: 9-16 years  Males: 66.6% | 52 |
| Mancini, 1999200 | Canada  Case series/ case report  Outpatient | SoP | SSRI: Paroxetine, (N=5) | 40 - 80 mg/day for 5-24 weeks | Age Range: 7-18 years  Males: 20%  OCD: 40%  Dysthymia: 40% | 0 |
| SNRI: Nefazodone, (N=1) | 350 mg/day for 20 weeks | Age: 15  Males: 0% |
| SSRI: Sertraline, (N=1) | 175 mg/day, | Age: 17  Males: 0%  Depression: 100%  Dysthymia: 100% |
| Masi, 2001201 | Italy  Case series  Outpatient | GAD, PD with agoraphobia, PD without agoraphobia, SAD, SoP, SP | SSRI:  paroxetine, (N=18) | Average 23.9 mg/day  Daily for 2-24 weeks | Age mean (years): 12.3 (range: 7-16)  Males: 66.6%  Depression: 22%  OCD: 22%  Tic Disorder: 11% | 0 |
| Mrakotsky, 2008202 | United States  Open-label pilot Outpatient | SoP | Tetracyclic Antidepressant: Mirtazapine, (N=18) | 15-45 mg/day for 8 weeks | Age mean (years): 12.06 (range: 8-17)  Males: 50%  ODD: 5%  Depression: 10% | 0 |
| Renaud, 1999203 | United States Case series  Outpatient | GAD, PD, SAD, SoP, SP | SSRI, (N=12) | 9 received Fluoxetine (34.4 mg/day)  2 received Paroxetine (20 mg/day)  1 received of Sertraline (125 mg/day) | Age mean (years): 12 (range: 7-17)  Males: 42%  Depression: 66.6%  Substance abuse: 8%  OCD: 8% | 26 |
| Simeon, 1987204 | Canada  Cross over study  Outpatient | GAD | Benzodiazepine: Alprazolam, (N=12) | 0.5 mg to 1.5 mg/day | Age mean (years):11.5 (Range: 8-14)  Males: 90%  Caucasian: 100% | 4 |
| Simeon, 1994205 | Canada  Case series Outpatient | GAD, SAD | Buspirone: (N=15) | NR | Age mean (years): 10 (range: (6-14)  Males: 66.6%  ADHD: 27%  Avoidant disorder: 7% | 0 |
| Zwier, 1993206 | United States  Case series/case report  Inpatient | SoP | Buspirone:  (N=1) | 20 mg/day for 52 weeks | Age: 16  Males: 100%  Caucasian 100% | 0 |

ADHD: attention deficit hyperactivity disorder, CGI: clinical global impression scale, GAD: generalized anxiety disorder, NR: not reported, OCD: obsessive compulsive disorder, ODD: oppositional defiant disorder, PD: panic disorder, SAD: separation anxiety disorder, SNRI: serotonin–norepinephrine reuptake inhibitor, SoP: social anxiety, SP: specific phobia, SRI: serotonin reuptake inhibitor, SSRI: selective serotonin reuptake inhibitor.