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) yearsMale: 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 StatesRCTOutpatient  | SoP | SRI, SSRI: Sertraline, (N=14) | Maximum of 200 mg/day for 8 weeks | Age Range: (10-17) yearsMales: 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 yearsMales: 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 | TurkeyCase 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 | FinlandCase seriesOutpatient | PD with agoraphobia  | SSRI: Citalopram, (N=3) | 20mg/day for 34-64 weeks | Age range: 9-16 yearsMales: 66.6% | 52 |
| Mancini, 1999200 | Canada Case series/ case reportOutpatient | SoP | SSRI: Paroxetine, (N=5) | 40 - 80 mg/day for 5-24 weeks | Age Range: 7-18 yearsMales: 20%OCD: 40%Dysthymia: 40% | 0 |
| SNRI: Nefazodone, (N=1) | 350 mg/day for 20 weeks | Age: 15Males: 0% |
| SSRI: Sertraline, (N=1) | 175 mg/day,  | Age: 17Males: 0%Depression: 100%Dysthymia: 100% |
| Masi, 2001201 | Italy Case seriesOutpatient | GAD, PD with agoraphobia, PD without agoraphobia, SAD, SoP, SP | SSRI:paroxetine, (N=18) | Average 23.9 mg/dayDaily 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 StatesOpen-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 seriesOutpatient | 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 | CanadaCross over studyOutpatient | 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 | CanadaCase 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: 16Males: 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.