Table 54. Patient characteristics–haloperidol versus risperidone

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Janicak et al. 2001**90 | ***Study design***: RCT  ***Registration #:*** NR  ***Study population:*** Bipolar  ***DSM Classification:*** DSM–IV  ***Study period:*** NR  ***Number of centers:*** Multicenter (n=3)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** yes (4–6d)  ***Run-in phase performed:*** no  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** bipolar subtype/manic phase, had not received depot antipsychotics or fluoxetine in the 4 weeks before  ***Main exclusion criteria:*** A Dx of alcohol or substance abuse within 6 months of admission, hypersensitivity to haloperidol or risperidone | ***G1:***  ***Age (mean±SD):*** 41.80 ± NR  ***Males (n(%)):*** 59/185 (31.9%)  ***Ethnicity:*** Caucasian 61/185 (33%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 41.90 ± NR  ***Males (n(%)):*** 63/175 (36%)  ***Ethnicity:*** Caucasian 70/175 (40%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–17mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1–6mg/d  ***Intervals:*** BID |
| **Sachs et al. 2002**128 | ***Study design***: RCT  ***Registration #:*** NR  ***Study population:*** Bipolar  ***DSM Classification:*** DSM–IV  ***Study period:*** NR  ***Number of centers:*** Multicenter (NR)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** no  ***Run-in phase performed:*** no  ***Followup period:*** 3 wks | ***Main inclusion criteria:*** bipolar disorder and at least 1 prior manic episode  ***Main exclusion criteria:*** alcohol or substance abuse | ***G1:***  ***Age (mean±SD):*** 42.70 ± 12.38  ***Males (n(%)):*** 30/53 (56.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 41.20 ± 10.92  YMRS (mean±SD): 27.30 ± 5.82  ***G2:***  ***Age (mean±SD):*** 41.40 ± 10.82  ***Males (n(%)):*** 26/52 (50.0%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD):  42.50 ± 10.82  YMRS (mean±SD): 28.00 ± 5.77 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 3–12mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–6mg/d  ***Intervals:*** BID |

**Table 54. Patient characteristics–haloperidol versus risperidone (continued)**

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Segal et al. 1998**133 | ***Study design***: RCT  ***Registration #:*** NR  ***Study population:*** Bipolar  ***DSM Classification:*** DSM–IV  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** South Africa  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** no  ***Run-in phase performed:*** no  ***Followup period:*** 28 days | ***Main inclusion criteria:*** bipolar with acute manic episode  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 29.50 ± NR  ***Males (n(%)):*** 5/15 (33.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 15.20 ± NR  CGI (mean±SD): 3.60 ± NR  GAS (mean±SD): 40.20 ± NR  ***G2:***  ***Age (mean±SD):*** 34.3 ± NR  ***Males (n(%)):*** 2/15 (13.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD):  17.60 ± NR  CGI (mean±SD): 4.000 ± NR  GAS (mean±SD): 33.80 ± NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 10mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 6mg/d  ***Intervals:*** BID |

**Table 54. Patient characteristics–haloperidol versus risperidone (continued)**

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Smulevich et al. 2005**138 | ***Study design***: RCT  ***Registration #:*** NR  ***Study population:*** Bipolar  ***DSM Classification:*** DSM–IV  ***Study period:*** NR  ***Number of centers:*** Multicenter  ***Setting:*** Mixed  ***Country:*** International  ***Financial support:*** Industry (Johnson & Johnson)  ***Washout period performed:*** yes (3 days)  ***Run-in phase performed:*** no  ***Followup period:*** 12 wks | ***Main inclusion criteria:*** bipolar I disorder; Hx of at least one documented manic or mixed episode; met DSM–IV criteria for a current manic episode.  ***Main exclusion criteria:*** Schizoaffective disorder; rapid cycling bipolar disorder; borderline or antisocial personality disorder; recent substance abuse or dependence; poor antimanic response to antipsychotic monotherapy | ***G1:***  ***Age (mean±SD):*** 38.50 ± 12.20  ***Males (n(%)):*** 83/154 (53.9%)  ***Ethnicity:*** Caucasian 95/154 (65.9%)  ***BL symptom scores:*** BPRS (mean±SD): 32.50 ± 7.30  CGI-S (mean±SD): 3.70 ± 0.80  YMRS (mean±SD): 31.30 ± 6.50  ***G2:***  ***Age (mean±SD):*** 41.30 ± 13.10  ***Males (n(%)):*** 78/144 (54.2%)  ***Ethnicity:*** Caucasian 102/154 (66.2%)  ***BL symptom scores:*** BPRS (mean±SD):  32.30 ± 7.80  CGI-S (mean±SD): 3.80 ± 0.80  YMRS (mean±SD): 32.10 ± 6.90 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–12mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1–6mg/d  ***Intervals:*** NR |

AP = antipsychotic; BID = Twice daily; BL = baseline; BPRS  = Brief Psychiatric Rating Scale; ; CGI  = Clinical Global Impression; d = day; DSM = Diagnostic and Statistical Manual of Mental Disorders; FGA = first-generation antipsychotic; GAS = Global Assessment Scale; mg = milligram; n = number; NR = not reported; RCT = randomized controlled trial; SD = standard deviation; SGA = second-generation antipsychotic; Sz = schizophrenia; wk = week; YMRS = Young Mania Rating Scale; yr = year