

Tables

Table 1. Maternal characteristics (prospectively ascertained cases).

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|-----------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Maternal age (N=168) ¹ : mean; median (IQR), (min/max) | 31.6; 32 (28–35), (20/44) |
| Maternal BMI ² (N=80) ¹ : mean; median (IQR), (min/max) | 24.7; 23.7 (21–27.6), (17/39.2) |
| Maternal BMI ≥25 | 37.5% (N=30/80) |
| Maternal BMI ≥30 | 16.3% (N=13/80) |
| Maternal smoking ³ (N=126) ¹ | 23.0% (N=29/126) |
| Maternal alcohol consumption ³ (N=123) ¹ | 13.8% (N=17/123) |
| GW ⁴ at 1 st TIS contact (N=175) ¹ : mean; median (IQR) | 11.2, 8+3, (6+2–14+1) |
| Treatment indication for modafinil (N=166) ¹ | |
| Narcolepsy | 63.9% (N=106/166) |
| Other sleep disorder; including hypersomnia | 20.5% (N=34/166) |
| Multiple sclerosis (MS)/fatigue in MS | 6.6% (N=11/166) |
| Other neuropsychiatric disorder | 9.0% (N=15/166) |
| Average daily modafinil dosage in mg (N=146) ¹ : mean; median (IQR), (min/max) | 229; 200 (100-300), (19/700) |
| Average daily modafinil dosage per pregnancy day in mg (N=144) ¹ : mean; median (IQR), (min/max) | 110; 65 (28-150), (0.2/604) |
| Relevant comorbidities | 41.3% (N=71/172) |
| Psychiatric and neurological disorders (N=172) ¹ | 34.9% (N=60/172) |
| Pre-existing diabetes mellitus (N=172) ¹ | 1.7% (N=3/172) |
| Gestational diabetes mellitus (N=142) ¹ | 7.7% (N=11/142) |
| Other comorbidities (N=172) ¹ | 16.3% (N=28/172) |
| Relevant concurrent medication (N=173) ¹ | |
| Any relevant concurrent medication ⁵ | 62.4% (N=108/173) |
| Teratogenic medication during 1 st trimester ⁶ | 2.9% (N=5/173) |
| Psychopharmacological medication ⁷ | 46.8% (N=81/173) |

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|-------------------------------------------|------------------|
| 2 or more psychotropic drugs | 17.3% (N=30/173) |
| Immune modulating medication ⁷ | 8.1% (N=14/173) |

¹ Study cases with sufficient information for analysis. ² Body mass index. ³ Any reported exposure during pregnancy.

⁴ Gestational week. ⁵ Any drug exposure, regardless of the trimester of pregnancy, was considered relevant, except common drugstore products, homeopathics etc. ⁶ Teratogenic co-medications were valproate (2 patients), carbamazepine, warfarin and lithium. ⁷ Any exposure, regardless of the trimester of pregnancy, was considered relevant.

Table 2. Neonatal characteristics of live born children.

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|------------------------------------------------------|-------------------------------|
| Gestational week, N=152¹ | |
| Gestational week at birth ² | 39.57 (38.6-40.6) (25.4-42.6) |
| Preterm birth, N (%) | 8 (5.3) |
| Term birth, N (%) | 144 (94.7) |
| Neonatal sex, N=149¹ | |
| Female, N (%) | 75 (50.3) |
| Male, N (%) | 74 (49.7) |
| Birth weight, N=148¹ | |
| Birth weight ² in g | 3153 (2850-3483) (595-4200) |
| Neonatal length, N=93¹ | |
| Neonatal length ² in cm | 49.5 (48-51) (35-55) |
| Neonatal head circumference, N=74¹ | |
| Neonatal head circumference ² in cm | 34 (33.75-35) (30-37) |

¹ Study cases with sufficient information for analysis, including one set of twins.

² Median, interquartile range and min/max are presented.

Table 3. Distribution of birth weight percentiles in live births (overall and separately for all countries contributing more than ten observations to this analysis).

| | Expected proportion in % | All countries | France | Germany | Israel | Spain | Other countries ² |
|----------------------------------------------------------------------------|--------------------------|---------------|--------------|-------------|-------------|-------------|------------------------------|
| Live births overall | - | N=153 | N=71 | N=20 | N=14 | N=10 | N=38 |
| Live births with data on birth weight, sex and GW ³ at delivery | - | N=144 (94.1%) | N=64 (90.1%) | N=20 (100%) | N=14 (100%) | N=10 (100%) | N=36 (94.7%) |
| Percentile range¹ | | | | | | | |
| < 3rd | 3% | 4.2% (N=6) | 7.8% (N=5) | 0% (N=0) | 0% (N=0) | 0% (N=0) | 2.8% (N=1) |
| 3rd - 10th | 7% | 9% (N=13) | 7.8% (N=5) | 20% (N=4) | 14.3% (N=2) | 10% (N=1) | 2.8% (N=1) |
| 10th - 25th | 15% | 20.8% (N=30) | 17.2% (N=11) | 25% (N=5) | 28.6% (N=4) | 40% (N=4) | 16.7% (N=6) |
| 25th - 50th | 25% | 27.1% (N=39) | 23.4% (N=15) | 35% (N=7) | 21.4% (N=3) | 30% (N=3) | 30.6% (N=11) |
| 50th - 75th | 25% | 20.8% (N=30) | 23.4% (N=15) | 15% (N=3) | 14.3% (N=2) | 20% (N=2) | 22.2% (N=8) |
| 75th - 90th | 15% | 11.8% (N=17) | 14.1% (N=9) | 5% (N=1) | 21.4% (N=3) | 0% (N=0) | 11.1% (N=4) |
| 90th - 97th | 7% | 4.2% (N=6) | 4.7% (N=3) | 0% (N=0) | 0% (N=0) | 0% (N=0) | 8.3% (N=3) |
| ≥97th | 3% | 2.1% (N=3) | 1.6% (N=1) | 0% (N=0) | 0% (N=0) | 0% (N=0) | 5.6% (N=2) |

¹ According to reference standards for each country as listed in Table S2_SupplInfo. Percentiles were calculated according to neonatal sex and gestational week at delivery. ² All countries contributing less than ten cases to this analysis, i.e. Australia (N=4), Italy (N=2), Japan (N=5), Netherlands (N=1), Switzerland (N=5), Turkey (N=6), United Kingdom (N=9), USA (N=4). Group includes one set of twins. Since reference charts for twins were not available, percentiles for twins were calculated according to singleton reference charts. For both infants, percentiles of BW were above the median (percentile range 50th - 75th). ³ Gestational week.

Table 4. Distribution of head circumference percentiles in live births (overall and separately for all countries contributing more than ten observations to this analysis).

| | Expected proportion in % | All countries | France | Germany | Other countries ² |
|----------------------------------------------------------------------------------|--------------------------|-----------------|-----------------|----------------|------------------------------|
| Live births overall | - | N=153 | N=71 | N=20 | N=62 |
| Live births with data on head circumference, sex and GW ³ at delivery | - | N=73 (47.7%) | N=31 (43.7%) | N=19 (95%) | N=23 (37.1%) |
| Percentile range¹ | | | | | |
| < 3rd | 3% | 6.8% (N=5) | 9.7% (N=3) | 10.5% (N=2) | 0% (N=0) |
| 3rd - 10th | 7% | 8.2% (N=6) | 6.5% (N=2) | 10.5% (N=2) | 8.7% (N=2) |
| 10th - 25th | 15% | 15.1% (N=11) | 12.9% (N=4) | 26.3% (N=5) | 8.7% (N=2) |
| 25th - 50th | 25% | 24.7% (N=18) | 32.3% (N=10) | 21.1% (N=4) | 17.4% (N=4) |
| 50th - 75th | 25% | 21.9% (N=16) | 19.4% (N=6) | 21.1% (N=4) | 26.1% (N=6) |
| 75th - 90th | 15% | 16.4% (N=12) | 12.9% (N=4) | 10.5% (N=2) | 26.1% (N=6) |
| 90th - 97th | 7% | 2.7% (N=2) | 3.2% (N=1) | 0% (N=0) | 4.3% (N=1) |
| ≥ 97th | 3% | 4.1% (N=3) | 3.2% (N=1) | 0% (N=0) | 8.7% (N=2) |

¹ According to reference standards for each country as listed in Table S2. Percentiles were calculated according to neonatal sex and gestational week at delivery.² All countries contributing less than 10 cases to this analysis, i.e. Australia (N=4), Italy (N=1), Japan (N=5), Spain (N=4), Switzerland (N=3), Turkey (N=1), United Kingdom (N=2), United States (N=3). Group includes one set of twins. Since reference charts for twins were not available, percentiles for twins were calculated according to singleton reference charts. For both infants, percentiles of neonatal HC were above the median (percentile ranges 90th - 97th and >97th). ³ Gestational week.