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| Table 2. Signal strength of reports of elagolix at the Preferred Term (PT) level in the FAERS database. | | | | | | |
| SOC | Preferred terms (PTs) | Elagolix cases reporting PT | ROR (95%two-sided CI) | PRR (χ2) | IC (IC025) | EBGM (EBGM05) |
| Surgical and medical procedures | Hysterosalpingo-oophorectomy | 4 | 337.68(118.08-965.64) | 337.23(1167.92) | 8.2(0.95) | 293.85(102.76) |
|  | Intra-uterine contraceptive device insertion | 3 | 325.51(97.04-1091.89) | 325.19(848.38) | 8.15(0.43) | 284.66(84.86) |
|  | Laparoscopic surgery | 7 | 194.77(89.95-421.76) | 194.32(1240.4) | 7.48(1.92) | 179.11(82.72) |
|  | Oophorectomy | 18 | 171.75(106.24-277.64) | 170.72(2825.35) | 7.31(3.47) | 158.88(98.28) |
|  | Hysterectomy | 77 | 66.84(53.14-84.08) | 65.16(4730.93) | 5.99(4.84) | 63.37(50.38) |
|  | Salpingo-oophorectomy unilateral | 3 | 56.03(17.81-176.25) | 55.97(158.09) | 5.77(0.32) | 54.66(17.38) |
|  | Salpingectomy | 3 | 44.97(14.34-141.08) | 44.93(126.36) | 5.46(0.3) | 44.08(14.05) |
|  | Endometrial ablation | 3 | 40.93(13.06-128.28) | 40.89(114.69) | 5.33(0.29) | 40.19(12.82) |
|  | Medical procedure | 6 | 16.81(7.52-37.56) | 16.78(88.39) | 4.06(1.23) | 16.66(7.46) |
|  | Surgery | 120 | 12.96(10.79-15.56) | 12.48(1264.68) | 3.63(3.27) | 12.42(10.34) |
|  | Gastric bypass | 3 | 10.01(3.22-31.12) | 10(24.19) | 3.32(0.01) | 9.96(3.2) |
| Social circumstances | Menopause | 19 | 45.38(28.78-71.56) | 45.1(803.5) | 5.47(3.2) | 44.24(28.06) |
|  | Partner stress | 3 | 27.9(8.93-87.16) | 27.87(76.79) | 4.78(0.24) | 27.55(8.82) |
| Reproductive system and breast disorders | Endometriosis | 256 | 386.41(336.98-443.1) | 353.6(77930.31) | 8.26(6.97) | 306.19(267.03) |
|  | Ovulation disorder | 3 | 359.78(106.41-1216.43) | 359.42(926.05) | 8.28(0.43) | 310.54(91.85) |
|  | Ovulation pain | 9 | 306.69(152.79-615.59) | 305.77(2410.26) | 8.08(2.38) | 269.68(134.36) |
|  | Endometrial atrophy | 3 | 253.18(76.76-835) | 252.92(677.51) | 7.83(0.41) | 227.73(69.05) |
|  | Adenomyosis | 15 | 206.72(121.72-351.08) | 205.69(2802.3) | 7.56(3.2) | 188.73(111.12) |
|  | Pelvic adhesions | 4 | 175.33(63.37-485.08) | 175.1(642.97) | 7.35(0.92) | 162.67(58.8) |
|  | Premenstrual dysphoric disorder | 3 | 122.07(38.19-390.19) | 121.95(341.57) | 6.86(0.37) | 115.8(36.23) |
|  | Adnexa uteri pain | 12 | 87.62(49.17-156.12) | 87.27(985.65) | 6.39(2.73) | 84.09(47.19) |
|  | Endometrial disorder | 5 | 78.08(32-190.55) | 77.96(367.27) | 6.24(1.26) | 75.41(30.9) |
|  | Dyspareunia | 29 | 71.28(49.17-103.33) | 70.6(1930.29) | 6.1(3.91) | 68.51(47.26) |
|  | Ovarian cyst ruptured | 11 | 56.98(31.29-103.76) | 56.78(588.13) | 5.79(2.51) | 55.42(30.44) |
|  | Uterine pain | 6 | 56.78(25.24-127.75) | 56.67(320.18) | 5.79(1.53) | 55.32(24.59) |
|  | Haemorrhagic ovarian cyst | 5 | 56.16(23.11-136.48) | 56.07(263.93) | 5.77(1.22) | 54.74(22.53) |
|  | Polymenorrhoea | 20 | 53.66(34.39-83.72) | 53.31(1003.2) | 5.7(3.33) | 52.11(33.4) |
|  | Amenorrhoea | 87 | 52.67(42.46-65.34) | 51.17(4188.07) | 5.65(4.73) | 50.07(40.36) |
|  | Abnormal uterine bleeding | 18 | 51.78(32.41-82.72) | 51.47(871.29) | 5.65(3.18) | 50.36(31.52) |
|  | Dysmenorrhoea | 84 | 49.23(39.55-61.29) | 47.89(3779.01) | 5.55(4.65) | 46.92(37.69) |
|  | Uterine enlargement | 5 | 43.18(17.81-104.68) | 43.11(201.86) | 5.4(1.19) | 42.33(17.46) |
|  | Menopausal symptoms | 15 | 37.75(22.63-62.95) | 37.56(525.25) | 5.21(2.82) | 36.97(22.17) |
|  | Ovarian disorder | 5 | 36.66(15.14-88.75) | 36.6(170.39) | 5.17(1.16) | 36.03(14.88) |
|  | Menstrual disorder | 41 | 34.49(25.29-47.05) | 34.04(1295.87) | 5.07(3.83) | 33.55(24.6) |
|  | Premenstrual syndrome | 5 | 34.13(14.1-82.6) | 34.08(158.17) | 5.07(1.14) | 33.59(13.88) |
|  | Intermenstrual bleeding | 27 | 33.86(23.12-49.6) | 33.57(840.93) | 5.05(3.44) | 33.09(22.59) |
|  | Pelvic pain | 60 | 29.17(22.56-37.73) | 28.61(1579.91) | 4.82(3.95) | 28.27(21.86) |
|  | Metrorrhagia | 26 | 28.27(19.17-41.69) | 28.04(669.83) | 4.79(3.28) | 27.71(18.79) |
|  | Menorrhagia | 48 | 27.03(20.29-36) | 26.61(1170.15) | 4.72(3.74) | 26.31(19.75) |
|  | Heavy menstrual bleeding | 40 | 25.73(18.81-35.22) | 25.41(927.93) | 4.65(3.57) | 25.14(18.37) |
|  | Ovarian mass | 3 | 22.78(7.3-71.09) | 22.76(61.81) | 4.49(0.21) | 22.55(7.23) |
|  | Endometrial thickening | 3 | 22.49(7.21-70.15) | 22.46(60.93) | 4.48(0.21) | 22.25(7.13) |
|  | Infertility | 4 | 21.1(7.88-56.52) | 21.08(75.8) | 4.38(0.68) | 20.89(7.8) |
|  | Vulvovaginal dryness | 11 | 21.06(11.62-38.18) | 20.99(207.52) | 4.38(2.15) | 20.81(11.48) |
|  | Ovarian cyst | 30 | 19.89(13.86-28.54) | 19.7(528.13) | 4.29(3.13) | 19.54(13.61) |
|  | Uterine spasm | 4 | 16.85(6.3-45.09) | 16.83(59.13) | 4.06(0.62) | 16.71(6.25) |
|  | Breast cyst | 3 | 10.22(3.28-31.78) | 10.21(24.81) | 3.35(0.01) | 10.17(3.27) |
|  | Polycystic ovaries | 4 | 9.53(3.57-25.45) | 9.51(30.36) | 3.24(0.42) | 9.48(3.55) |
|  | Uterine haemorrhage | 6 | 8.54(3.83-19.04) | 8.52(39.69) | 3.09(0.91) | 8.49(3.81) |
|  | Breast tenderness | 6 | 8.38(3.76-18.7) | 8.37(38.8) | 3.06(0.9) | 8.34(3.74) |
|  | Vaginal haemorrhage | 45 | 8.37(6.23-11.24) | 8.26(286.43) | 3.04(2.44) | 8.23(6.13) |
|  | Vulvovaginal pain | 5 | 5.73(2.38-13.79) | 5.72(19.43) | 2.51(0.43) | 5.71(2.37) |
|  | Galactorrhoea | 4 | 5.58(2.09-14.89) | 5.57(14.97) | 2.48(0.14) | 5.56(2.08) |
|  | Premature menopause | 7 | 59.37(28.01-125.84) | 59.23(390.61) | 5.85(1.8) | 57.76(27.25) |
|  | Hypomenorrhoea | 11 | 45.69(25.13-83.08) | 45.53(469.68) | 5.48(2.45) | 44.65(24.56) |
|  | Oligomenorrhoea | 9 | 44.28(22.87-85.73) | 44.15(372.38) | 5.44(2.14) | 43.33(22.38) |
|  | Menstruation delayed | 16 | 14.16(8.65-23.18) | 14.09(193.44) | 3.81(2.32) | 14.01(8.56) |
|  | Menstruation irregular | 20 | 11.03(7.1-17.15) | 10.97(180.42) | 3.45(2.29) | 10.92(7.03) |
| Product issues | Product packaging difficult to open | 4 | 5.76(2.16-15.38) | 5.76(15.68) | 2.52(0.16) | 5.74(2.15) |
| Investigations | Laparoscopy | 7 | 285.2(129.88-626.25) | 284.54(1758.06) | 7.98(1.94) | 253.04(115.23) |
| Injury, poisoning and procedural complications | Procedural haemorrhage | 4 | 5.87(2.2-15.67) | 5.86(16.1) | 2.55(0.17) | 5.85(2.19) |
|  | Post procedural complication | 11 | 4.06(2.25-7.35) | 4.05(25.25) | 2.02(0.87) | 4.05(2.24) |
|  | Maternal exposure during pregnancy | 82 | 3.9(3.13-4.86) | 3.82(171.97) | 1.93(1.6) | 3.82(3.07) |
| General disorders and administration site conditions | Cyst rupture | 10 | 81.56(43.36-153.42) | 81.3(765.78) | 6.3(2.43) | 78.53(41.75) |
|  | Haemorrhagic cyst | 3 | 51.79(16.48-162.72) | 51.73(145.95) | 5.66(0.31) | 50.61(16.11) |
|  | Adhesion | 8 | 38.04(18.9-76.57) | 37.94(283.02) | 5.22(1.92) | 37.33(18.55) |
|  | General symptom | 15 | 32.25(19.35-53.75) | 32.09(445.62) | 4.98(2.75) | 31.66(18.99) |
|  | Surgical failure | 3 | 12.12(3.89-37.71) | 12.11(30.41) | 3.59(0.07) | 12.05(3.87) |
|  | Cyst | 23 | 9.22(6.11-13.91) | 9.16(166.58) | 3.19(2.21) | 9.12(6.05) |
|  | Crying | 43 | 8.85(6.55-11.97) | 8.74(294.07) | 3.12(2.49) | 8.71(6.44) |
|  | Adverse drug reaction | 125 | 7.58(6.34-9.07) | 7.31(682.23) | 2.87(2.56) | 7.29(6.09) |
|  | Unevaluable event | 48 | 3.83(2.88-5.1) | 3.79(98.7) | 1.92(1.46) | 3.78(2.84) |
|  | Pain | 396 | 3(2.7-3.33) | 2.73(457.31) | 1.45(1.31) | 2.73(2.46) |
| Skin and subcutaneous tissue disorders | Umbilical haemorrhage | 4 | 186.07(67.11-515.92) | 185.82(679.82) | 7.43(0.92) | 171.87(61.99) |

*ROR, reporting odds ratio; CI, confidence interval; PRR, proportional reporting ratio; χ 2, chi-squared; IC, information component; EBGM, empirical Bayesian geometric mean*