## Supplementary Materials

**Title:**

Treatment Patterns with Mirabegron and Antimuscarinics for Overactive Bladder: A Prospective, Registry Study in Taiwan and South Korea (FAITH)

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## SUPPLEMENTAL METHODS

### Inclusion and Exclusion Criteria

To be included in the study, patients needed to be aged at least 18 years, have been diagnosed with overactive bladder (OAB) symptoms (with or without urgency incontinence) by a treating healthcare professional, and have had symptoms for at least 3 months prior to study enrollment. They needed to be about to initiate monotherapy with mirabegron or any antimuscarinic therapy for OAB symptoms, prescribed as part of routine clinical practice, which was the first course of any treatment for OAB, initiation after a lapse of treatment, or switch from one drug to another. They must also have provided informed consent. OAB was defined as urinary urgency, with or without urinary incontinence, usually with frequency and nocturia, with no proven infection or other obvious pathology [1]. Lapse of treatment was defined as the discontinuation of any OAB drug for more than 30 days (defined as the day after the last day of the prior supply to the next dispensing date).

Patients were excluded if they were receiving more than one medication (including Chinese herbal medicine) for OAB; were participating in clinical trials for OAB; had undergone surgery for OAB; had mixed incontinence, where stress incontinence was the predominant form as determined by the investigator; had been treated with onabotulinum toxin A, sacral neuromodulation, percutaneous tibial nerve stimulation, external beam radiation, stents, surgery, or intermittent catheterization prior to or at the time of enrollment; were at risk of acute urinary retention in the opinion of the investigator; had neurologic conditions associated with OAB symptoms; or had hypersensitivity and contraindication(s) to mirabegron and antimuscarinics.

**Enrollment**

Enrollment occurred over a 15-month period (July 2018 to September 2019). Patients were invited to participate in the study only after the decision had been made by the physician to prescribe mirabegron or any antimuscarinic as monotherapy and prior to the commencement of treatment. Enrolled patients who consented were categorized into the mirabegron group or the antimuscarinics group and were followed until week 22–26, even if they discontinued treatment earlier. Efforts were made to recruit approximately 50% of the eligible patients into each group, based on currently observed trends in prescription patterns in the participating countries.

**Data Collection, Endpoints, and Analysis**

No additional clinic visits or examinations, laboratory tests, or procedures were mandated or recommended as part of this study. If a patient failed to attend the routine visit, the participating investigator should have collected information on the treatment, health status, and reason for missing the routine visit via telephone consultation.

Clinical data elements were collected from information routinely recorded in medical records or were prospectively recorded by the investigator or patients for the purposes of the study. Data in medical records collected in routine clinical practice and source documents included, but were not limited to, hospital or medical records (inclusive of any reports or investigations completed as part of routine clinical practice); serious adverse event report forms; patient-reported outcome documents/questionnaires (OAB Symptom Score, Overactive Bladder Questionnaire: Short Form, treatment satisfaction visual analog scale, and OAB Bladder Assessment Tool); and the healthcare resource utilization worksheet.

The analysis time points were at visit 1 and 2. Wider windows were used for the analysis compared with the assessment windows: visit 1, day 2–153; and visit 2, day 154–183.

**REFERENCE**

1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn. 2002;21(2):167-78.

**Supplemental Table S1** List of independent ethics committees and institutional review boards

| **Taiwan** |
|---|
| Research Ethics Committee, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, No. 707, Sec. 3, Chung-Yang Rd., Hualien 97002, Taiwan, R.O.C. |
| Research Ethics Committee, China Medical University & Hospital, Taichung, Taiwan, 2 YuDe Road, Taichung, 40447, Taiwan, R.O.C. |
| Chang Gung Medical Foundation Institutional Review Board, 199, Tung Hwa North Road, Taipei, Taiwan, 10507, R.O.C. |
| Institutional Review Board, Taipei Veterans General Hospital, 201 Shih-Pai Road, Sec.2, Taipei, Taiwan 11217, R.O.C. |
| Kaohsiung V.G.H. Institutional Review Board, No.386, Dazhong 1st Rd., Zuoying Dist., Kaohsiung City 81362, Taiwan, R.O.C. |
| **South Korea** |
| IRB of Seoul National University Hospital, IRB department, Biomedical Research Institute of Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul, 03080, South Korea |
| IRB of Samsung Medical Center, IRB department, 81, Irwon-ro, Gangnam-gu, Seoul, South Korea |
| IRB of Asan Medical Center, IRB department, Asan Institute for Life Sciences Building, 88, Olympic-ro 43gil, Songpa-gu, 05505, Seoul, South Korea |
| IRB of Ajou University Hospital, IRB department of Ajou University Hospital, 164, World Cup-ro, Yeongtong-gu, Suwon, 16499, South Korea |
| IRB of Hallym University Kangnam Sacred Heart Hospital, IRB department of Hallym University Kangnam Sacred Heart Hospital, 12, Siheung-daero 187-gil, Yeongdeungpo-gu, Seoul, South Korea |
| IRB of Severance Hospital, IRB department of Yonsei University Health System, 50-1 Yonsei-ro, Seodaemun-gu, Seoul, 03722, South Korea |
| IRB of Hanyang University Guri Hospital, IRB department of Hanyang University Guri Hospital, 153, Gyeongchun-ro, Guri-si, Gyeonggi-do, South Korea |
| IRB of Daejeon Eulji Medical Center, Eulji University, IRB department of Eulji University Hospital, Dunsanseo-ro 95, Seo-gu, Daejeon 35233, South Korea |
| IRB of Gachon University Gil Medical Center, IRB department of Gachon University Gil Medical Center, 16, Dokjeom-ro 29beon-gil, Namdong-gu, Incheon, South Korea |

*R.O.C.* Republic of China

**Supplemental Table S2** Association between baseline variables and time to treatment change in the mirabegron initiator group (univariate analysis)

| | *n* (%) | Estimate | SE | Chi-square *p* value | HR | 95% CI | Wald *p* value |
|---|---|---|---|---|---|---|---|
| Mirabegron *N* = 409 | | | | | | | |
| Baseline age, years | 409 (100.0) | − 0.01 | 0.01 | 0.027 | 0.99 | 0.97–1.00 | 0.027 |
| Sex | 409 (100.0) | | | | | | 0.075 |
| Male | 180 (44.0) | − 0.32 | 0.18 | 0.075 | 0.72 | 0.51–1.03 | |
| Female | 229 (56.0) | Reference | | | | | |
| Previous OAB medication | 409 (100.0) | | | | | | 0.238 |
| Yes | 102 (24.9) | 0.23 | 0.19 | 0.238 | 1.26 | 0.86–1.83 | |
| No | 307 (75.1) | Reference | | | | | |
| Type of OAB | 408 (99.8) | | | | | | 0.322 |
| Wet | 177 (43.4) | 0.17 | 0.18 | 0.322 | 1.19 | 0.84–1.68 | |
| Dry | 231 (56.6) | Reference | | | | | |
| Severity of OAB | 407 (99.5) | | | | | | 0.011 |
| Mild | 111 (27.3) | − 0.56 | 0.26 | 0.034 | 0.57 | 0.34–0.96 | |
| Moderate | 244 (60.0) | − 0.70 | 0.23 | 0.003 | 0.50 | 0.31–0.79 | |
| Severe | 52 (12.8) | Reference | | | | | |
| CCI score | 409 (100.0) | | | | | | 0.083 |
| None (0) | 35 (8.6) | 0.43 | 0.32 | 0.180 | 1.54 | 0.82–2.90 | |
| Mild (1–2) | 104 (25.4) | 0.54 | 0.23 | 0.017 | 1.71 | 1.10–2.66 | |
| Moderate (3–4) | 127 (31.1) | 0.13 | 0.23 | 0.567 | 1.14 | 0.72–1.80 | |
| Severe (≥ 5) | 143 (35.0) | Reference | | | | | |

*CCI* Charlson Comorbidity Index, *CI* confidence interval, *HR* hazard ratio, *OAB* overactive bladder, *SE* standard error

**Supplemental Table S3** Association between baseline variables and time to treatment change in the mirabegron initiator group (multivariate analysis)

| | *n* (%) | Estimate | SE | Chi-square *p* value | HR | 95% CI | Wald *p* value |
|---|---|---|---|---|---|---|---|
| Mirabegron *N* = 409 | | | | | | | |
| Final model *p* value | 407 (99.5) | | | | | | 0.020 |
| Baseline age, years | 409 (100.0) | − 0.01 | 0.01 | 0.577 | 0.99 | 0.97–1.02 | |
| Sex | 409 (100.0) | | | | | | |
| Male | 180 (44.0) | − 0.18 | 0.20 | 0.364 | 0.84 | 0.57–1.23 | |
| Female | 229 (56.0) | Reference | | | | | |
| Severity of OAB | 407 (99.5) | | | | | | |
| Mild | 111 (27.3) | − 0.55 | 0.27 | 0.039 | 0.58 | 0.34–0.97 | |
| Moderate | 244 (60.0) | − 0.67 | 0.24 | 0.005 | 0.51 | 0.32–0.82 | |
| Severe | 52 (12.8) | Reference | | | | | |
| CCI score | 409 (100.0) | | | | | | |
| None (0) | 35 (8.6) | 0.19 | 0.50 | 0.699 | 1.21 | 0.46–3.20 | |
| Mild (1–2) | 104 (25.4) | 0.37 | 0.30 | 0.217 | 1.45 | 0.81–2.60 | |
| Moderate (3–4) | 127 (31.1) | 0.10 | 0.25 | 0.687 | 1.11 | 0.68–1.80 | |
| Severe (≥ 5) | 143 (35.0) | Reference | | | | | |

*CCI* Charlson Comorbidity Index, *CI* confidence interval, *HR* hazard ratio, *OAB* overactive bladder, *SE* standard error

**Supplemental Table S4** Association between baseline variables and time to treatment change in the antimuscarinics initiator group (univariate analysis)

| | *n* (%) | Estimate | SE | Chi-square *p* value | HR | 95% CI | Wald *p* value |
|---|---|---|---|---|---|---|---|
| Antimuscarinics *N* = 197 | | | | | | | |
| Baseline age, years | 197 (100.0) | − 0.01 | 0.01 | 0.363 | 0.99 | 0.98–1.01 | 0.363 |
| Sex | 197 (100.0) | | | | | | 0.041 |
| Male | 83 (42.1) | − 0.49 | 0.24 | 0.041 | 0.61 | 0.38–0.98 | |
| Female | 114 (57.9) | Reference | | | | | |
| Previous OAB medication | 197 (100.0) | | | | | | 0.006 |
| Yes | 89 (45.2) | − 0.67 | 0.24 | 0.006 | 0.51 | 0.32–0.83 | |
| No | 108 (54.8) | Reference | | | | | |
| Type of OAB | 197 (100.0) | | | | | | 0.700 |
| Wet | 103 (52.3) | 0.09 | 0.23 | 0.700 | 1.09 | 0.70–1.70 | |
| Dry | 94 (47.7) | Reference | | | | | |
| Severity of OAB | 197 (100.0) | | | | | | 0.183 |
| Mild | 54 (27.4) | − 0.36 | 0.33 | 0.271 | 0.70 | 0.37–1.33 | |
| Moderate | 112 (56.9) | − 0.55 | 0.30 | 0.066 | 0.58 | 0.32–1.04 | |
| Severe | 31 (15.7) | Reference | | | | | |
| CCI score | 197 (100.0) | | | | | | 0.599 |
| None (0) | 23 (11.7) | 0.26 | 0.37 | 0.484 | 1.29 | 0.63–2.67 | |
| Mild (1–2) | 57 (28.9) | − 0.06 | 0.30 | 0.848 | 0.94 | 0.53–1.70 | |
| Moderate (3–4) | 62 (31.5) | − 0.24 | 0.30 | 0.430 | 0.79 | 0.44–1.42 | |
| Severe (≥ 5) | 55 (27.9) | Reference | | | | | |

*CCI* Charlson Comorbidity Index, *CI* confidence interval, *HR* hazard ratio, *OAB* overactive bladder, *SE* standard error

**Supplemental Table S5** Association between baseline variables and time to treatment change in the antimuscarinics initiator group (multivariate analysis)

| | *n* (%) | Estimate | SE | Chi-square *p* value | HR | 95% CI | Wald *p* value |
|---|---|---|---|---|---|---|---|
| Antimuscarinics *N* = 197 | | | | | | | |
| Final model *p* value | 197 (100.0) | | | | | | 0.014 |
| Sex | 197 (100.0) | | | | | | |
| Male | 83 (42.1) | − 0.27 | 0.26 | 0.306 | 0.77 | 0.46–1.28 | |
| Female | 114 (57.9) | Reference | | | | | |
| Previous OAB medication | 197 (100.0) | | | | | | |
| Yes | 89 (45.2) | − 0.56 | 0.26 | 0.033 | 0.57 | 0.34–0.95 | |
| No | 108 (54.8) | Reference | | | | | |

*CI* confidence interval, *HR* hazard ratio, *OAB* overactive bladder, SE standard error