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**Supplementary Table S1.** Univariate regression model of IPSS-QoL scores rated between “mostly dissatisfied” and “unhappy” (N=627)

| Variable   | Average values of each categories | Coefficient (as continuous)<br>[Note: same as Table 2] | Coefficient when considering difference of average values** | Coefficient (as categorized)<br>[Note: same as Table 2] |
|--|-----------------------------------|--|---|---|
| <b>Total IPSS<br/>(as continuous value)</b>                | *                                 | 0.130  |   |   |
| c2 (≥20 vs ≤19)  | c2 (24.95 vs 13.24)               |  | 1.52 (=0.13*(24.95-13.24))                                  | 1.380   |
| c3 (15 - 26 vs ≤14)  | c3 (20.49 vs 9.95)                |  | 1.37 (=0.13*(20.49-9.95))                                   | 1.162   |
| c3 (≥27 vs ≤14)  | c3 (29.48 vs 9.95)                |  | 2.54 (=0.13*(29.48-9.95))                                   | 3.261   |
| <b>Total ICIQ-MLUTS/severity<br/>(as continuous value)</b> | *                                 | 0.135  |   |   |
| c2 (≥19 vs ≤18)  | c2 (24.00 vs 12.87)               |  | 1.5 (=0.135*(24.00-12.87))                                  | 1.330   |
| c3 (16 - 25 vs ≤15)  | c3 (20.07 vs 11.08)               |  | 1.21 (=0.135*(20.07-11.08))                                 | 0.977   |
| c3 (≥26 vs ≤15)  | c3 (29.20 vs 11.08)               |  | 2.45 (=0.135*(29.20-11.08))                                 | 2.828   |
| <b>Total ICIQ-MLUTS/bother<br/>(as continuous value)</b>   | *                                 | 0.037  |   |   |
| c2 (≥62 vs ≤61)  | c2 (82.92 vs 33.44)               |  | 1.83 (=0.037*(82.92-33.44))                                 | 1.625   |
| c3 (22 - 80 vs ≤21)  | c3 (50.67 vs 11.82)               |  | 1.44 (=0.037*(50.67-11.82))                                 | 1.606   |
| c3 (≥81 vs ≤21)  | c3 (96.10 vs 11.82)               |  | 3.12 (=0.037*(96.10-11.82))                                 | 3.706   |

\* See Table 2

\*\* Coefficient for categorized value derived from continuous value coefficients (0.130, 0.135 and 0.037 for IPSS, ICIQ-MLUTS/severity and ICIQ-MLUTS/bother, respectively)

c2: Comparing ranges of scores in both categorized groups when distinguishing 2 groups (i.e. categorizing as mild or severe). The cut-off point predicting QoL impact (IPSS-QoL of <5 vs. ≥5) was 20 for IPSS, 19 for ICIQ-MLUTS/severity and 62 for ICIQ-MLUTS/bother. c3: Comparing ranges of scores in each categorized group, when distinguishing 3 groups (i.e. categorizing as mild, moderate or severe). Cut-off points are given in results section

ICIQ-MLUTS: International Consultation on Incontinence Questionnaires Male Lower Urinary Tract Symptoms; IPSS: International Prostate Symptom Score

**Supplementary Table S2.** The change of global QoL derived from IPSS-QoL (A) and bother derived from ICIQ-MLUTS bother scores (B1; voiding LUTS, B2; post voiding LUTS and B3; storage LUTS) associated with LUTS following surgery for those men who underwent surgery during the trial.

A. IPSS-QoL score

|          |          | No. of pts | Change of score at 18 months |                 |                  |
|----------|----------|------------|------------------------------|-----------------|------------------|
|          |          |            | Improvement                  | No change       | Worse            |
| baseline | 0        | 0          | 0                            | 0               | 0                |
|          | <b>1</b> | <b>2</b>   | <b>1 (50%)</b>               | <b>1 (50%)</b>  | <b>0</b>         |
|          | <b>2</b> | <b>14</b>  | <b>7 (50%)</b>               | <b>1 (7.1%)</b> | <b>6 (42.9%)</b> |
|          | 3        | 46         | 36 (78.3%)                   | 4 (8.7%)        | 6 (13%)          |
|          | 4        | 50         | 43 (86%)                     | 2 (4%)          | 5 (10%)          |
|          | 5        | 97         | 86 (88.7%)                   | 9 (9.3%)        | 2 (2.1%)         |
|          | 6        | 54         | 48 (88.9%)                   | 6 (11.1%)       | 0                |
| Total    |          | 263        | 221                          | 23              | 19               |

B1. Voiding LUTS in ICIQ-MLUTS bother scores

| Slow stream |                | No. of pts | Score at 18 months |                |             |
|-------------|----------------|------------|--------------------|----------------|-------------|
|             |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline    | Low (0-4)      | 66         | 59 (89.4%)         | 7 (10.6%)      | 0           |
|             | Moderate (5-7) | 51         | 43 (84.3%)         | 6 (11.8%)      | 2 (3.9%)    |
|             | High (8-10)    | 92         | 73 (79.3%)         | 14 (15.2%)     | 5 (5.4%)    |
|             |                |            | 175                | 27             | 7           |

| Straining |  | No. of pts | Score at 18 months |                |             |
|-----------|--|------------|--------------------|----------------|-------------|
|           |  |            | Low (0-4)          | Moderate (5-7) | High (8-10) |

| baseline |                | No. of pts | Score at 18 months |                |             |
|----------|----------------|------------|--------------------|----------------|-------------|
|          |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
|          | Low (0-4)      | 101        | 95 (94.1%)         | 6 (5.9%)       | 0           |
|          | Moderate (5-7) | 51         | 44 (86.3%)         | 7 (13.7%)      | 0           |
|          | High (8-10)    | 38         | 29 (76.3%)         | 4 (10.5%)      | 5 (13.2%)   |
|          |                |            | 168                | 17             | 5           |

B2. Post voiding LUTS in ICIQ-MLUTS bother scores

| PMD      |                | No. of pts | Score at 18 months |                |             |
|----------|----------------|------------|--------------------|----------------|-------------|
|          |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline | Low (0-4)      | 98         | 83 (84.7%)         | 7 (7.1%)       | 8 (8.2%)    |
|          | Moderate (5-7) | 44         | 34 (77.3%)         | 5 (11.4%)      | 5 (11.4%)   |
|          | High (8-10)    | 72         | 43 (59.7%)         | 9 (12.5%)      | 20 (27.8%)  |
|          |                |            | 160                | 21             | 33          |

| Sensation of incomplete emptying |                | No. of pts | Score at 18 months |                |             |
|----------------------------------|----------------|------------|--------------------|----------------|-------------|
|                                  |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline                         | Low (0-4)      | 84         | 77 (91.7%)         | 7 (8.3%)       | 0           |
|                                  | Moderate (5-7) | 49         | 44 (89.8%)         | 3 (6.1%)       | 2 (4.1%)    |
|                                  | High (8-10)    | 77         | 55 (71.4%)         | 8 (10.4%)      | 14 (18.2%)  |
|                                  |                |            | 176                | 18             | 16          |

B3. Storage LUTS in ICIQ-MLUTS bother scores

| Nocturia |                | No. of pts | Score at 18 months |                |             |
|----------|----------------|------------|--------------------|----------------|-------------|
|          |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline | Low (0-4)      | 60         | 52 (86.7%)         | 7 (11.7%)      | 1 (1.7%)    |
|          | Moderate (5-7) | 55         | 46 (83.6%)         | 6 (10.9%)      | 3 (5.5%)    |
|          | High (8-10)    | 101        | 66 (65.3%)         | 13 (12.9%)     | 22 (21.8%)  |

164                      26                      26

| Increased daytime frequency |                | No. of pts | Score at 18 months |                |             |
|-----------------------------|----------------|------------|--------------------|----------------|-------------|
|                             |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline                    | Low (0-4)      | 82         | 74 (90.2%)         | 7 (8.5%)       | 1 (1.2%)    |
|                             | Moderate (5-7) | 60         | 48 (80%)           | 9 (15%)        | 3 (5%)      |
|                             | High (8-10)    | 72         | 47 (65.3%)         | 7 (9.7%)       | 18 (25%)    |
|                             |                |            | 169                | 23             | 22          |

| Urgency  |                | No. of pts | Score at 18 months |                |             |
|----------|----------------|------------|--------------------|----------------|-------------|
|          |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline | Low (0-4)      | 63         | 54 (85.7%)         | 8 (12.7%)      | 1 (1.6%)    |
|          | Moderate (5-7) | 56         | 43 (76.8%)         | 10 (17.9%)     | 3 (5.4%)    |
|          | High (8-10)    | 97         | 64 (66%)           | 16 (16.5%)     | 17 (17.5%)  |
|          |                |            | 161                | 34             | 21          |

| Urgency UI |                | No. of pts | Score at 18 months |                |             |
|------------|----------------|------------|--------------------|----------------|-------------|
|            |                |            | Low (0-4)          | Moderate (5-7) | High (8-10) |
| baseline   | Low (0-4)      | 88         | 79 (89.8%)         | 6 (6.8%)       | 3 (3.4%)    |
|            | Moderate (5-7) | 35         | 23 (65.7%)         | 8 (22.9%)      | 4 (11.4%)   |
|            | High (8-10)    | 85         | 53 (62.4%)         | 11 (12.9%)     | 21 (24.7%)  |
|            |                |            | 155                | 25             | 28          |

Table 1. Patient characteristics in the analysis set (N=627)

|              |                  | Number of patients | Mean $\pm$ SD     | Median (Min - Max)   |
|--------------|------------------|--------------------|-------------------|----------------------|
| Age          |                  | 627                | 67.4 $\pm$ 9.0    | 68 (30-91)           |
| Uroflowmetry | Q <sub>max</sub> | 598                | 12.4 $\pm$ 7.3    | 11.0 (1.4 – 58.3)    |
|              | Voided volume    | 604                | 250.3 $\pm$ 142.3 | 224.0 (7.0 - 947.0)  |
|              | PVR              | 603                | 136.4 $\pm$ 148.1 | 100.0 (0.0 - 1600.0) |
| IPSS-QoL     |                  | 627                | 4.1 $\pm$ 1.3     | 4 (0 - 6)            |
| IPSS         |                  | 627                | 18.8 $\pm$ 7.1    | 19 (1 - 35)          |
| ICIQ-MLUTS   | Symptom severity | 627                | 18.1 $\pm$ 6.8    | 18 (3 - 40)          |
|              | Bother           | 627                | 52.3 $\pm$ 29.2   | 51 (0 – 130)         |

SD: standard deviation; Q<sub>max</sub>: maximum flow rate; PVR: post-void residual urine; IPSS-QoL: International Prostate Symptom Score Quality of Life; IPSS: International Prostate Symptom Score; ICIQ-MLUTS: International Consultation on Incontinence Questionnaires Male Lower Urinary Tract Symptoms.

Table 2. Univariate regression model of IPSS-QoL scores rated between “mostly dissatisfied” and “unhappy” (N=627)

| Variable                               | Coefficient  | Lower CI     | Upper CI     | P value          | AIC            |
|--|--------------|--------------|--------------|------------------|----------------|
| Age                                    | -0.009       | -0.027       | 0.009        | 0.318            | 867.377        |
| Q <sub>max</sub>                       | 0.003        | -0.019       | 0.025        | 0.780            | 828.399        |
| Voided volume                          | -0.001       | -0.003       | 0            | 0.021            | 832.351        |
| PVR                                    | 0            | -0.001       | 0.002        | 0.433            | 835.651        |
| <b>Total IPSS*</b>                     | <b>0.130</b> | <b>0.104</b> | <b>0.159</b> | <b>&lt;0.001</b> | <b>762.002</b> |
| c2 (≥20 vs ≤19)                        | 1.380        | 1.05         | 1.716        | <0.001           | 798.494        |
| c3 (15 - 26 vs ≤14)                    | 1.162        | 0.756        | 1.586        | <0.001           | 755.457        |
| c3 (≥27 vs ≤14)                        | 3.261        | 2.572        | 4.033        |                  |                |
| <b>Total ICIQ-<br/>MLUTS/severity*</b> | <b>0.135</b> | <b>0.107</b> | <b>0.165</b> | <b>&lt;0.001</b> | <b>762.99</b>  |
| c2 (≥19 vs ≤18)                        | 1.330        | 1.001        | 1.665        | <0.001           | 803.266        |
| c3 (16 - 25 vs ≤15)                    | 0.977        | 0.612        | 1.351        | <0.001           | 768.34         |
| c3 (≥26 vs ≤15)                        | 2.828        | 2.203        | 3.523        |                  |                |
| <b>Total ICIQ-MLUTS/bother*</b>        | <b>0.037</b> | <b>0.03</b>  | <b>0.044</b> | <b>&lt;0.001</b> | <b>732.015</b> |
| c2 (≥62 vs ≤61)                        | 1.625        | 1.279        | 1.979        | <0.001           | 778.136        |
| c3 (22 - 80 vs ≤21)                    | 1.606        | 1.041        | 2.240        | <0.001           | 736.026        |
| c3 (≥80 vs ≤21)                        | 3.706        | 2.968        | 4.517        |                  |                |

\* Items in bold indicate analysis for continuous values. c2 and c3 indicate categorized values; c2: Comparing ranges of scores in both categorized groups when distinguishing 2 groups (i.e. categorizing as mild or severe). The cut-off point predicting QoL impact (IPSS-QoL of <5 vs. ≥5) was 20 for IPSS, 19 for ICIQ-MLUTS/severity and 62 for ICIQ-MLUTS/bother. c3: Comparing ranges of scores in each categorized group, when distinguishing 3 groups (i.e. categorizing as mild, moderate or severe). Cut-off points are given in results section

AIC: Akaike’s information criteria; CI: confidence interval; ICIQ-MLUTS: International Consultation on Incontinence Questionnaires Male Lower Urinary Tract Symptoms; IPSS: International Prostate Symptom Score; PVR: post-void residual urine

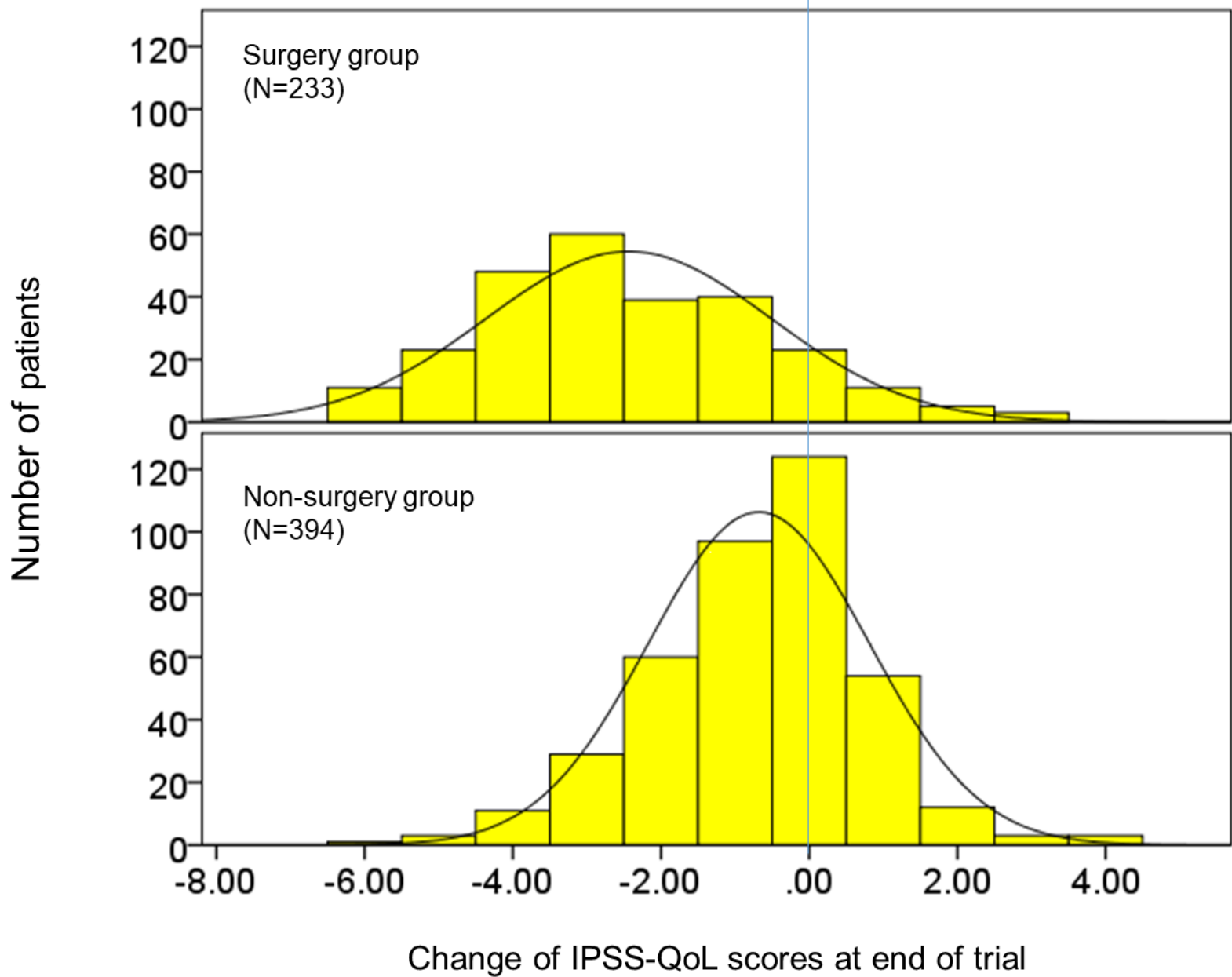
Table 3. The rankings for prevalence of severe symptoms according to symptom severity scores in IPSS and ICIQ-MLUTS and bother score in ICIQ-MLUTS

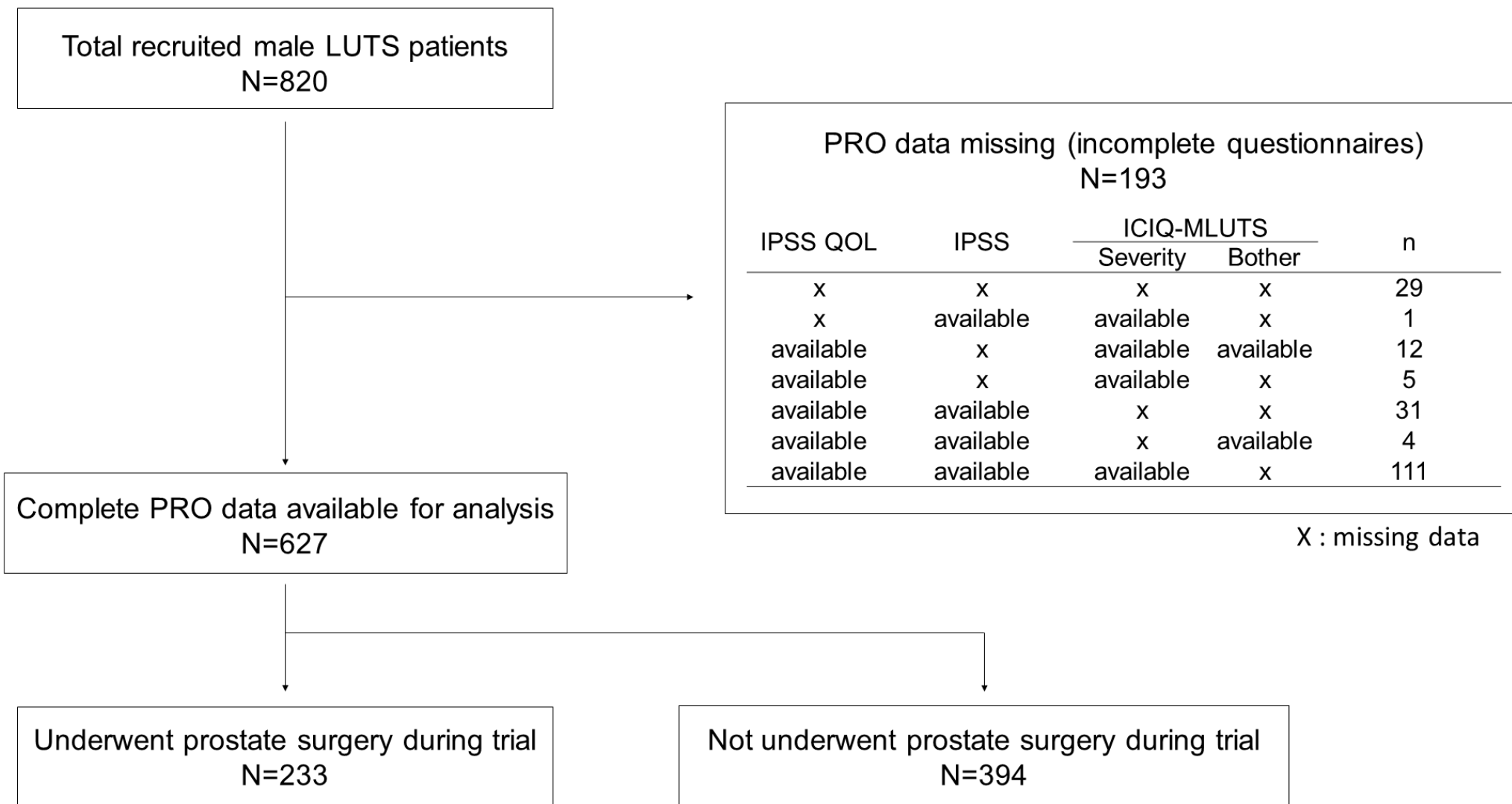
| Ranking | IPSS (N=751)                                |      | ICIQ-MLUTS                                      |      |                             |      |
|---------|---|------|---|------|-----------------------------|------|
|         |   |      | Symptom severity scores (N=739)                 |      | Bother scores (N=643)       |      |
|         | "Severe (More than half and Almost always)" | %    | "Severe (Most of the time and All of the time)" | %    | "Severe (8, 9 and 10)"      | %    |
| 1       | Weak stream                                 | 55.5 | Increased daytime frequency                     | 60.1 | Nocturia                    | 48.1 |
| 2       | Nocturia                                    | 53.0 | Weak stream                                     | 52.3 | Urgency                     | 45.7 |
| 3       | Incomplete emptying                         | 40.5 | Incomplete emptying                             | 41.8 | Urgency UI                  | 39.2 |
| 4       | Intermittency                               | 31.7 | Urgency   | 39.0 | Increased daytime frequency | 35.5 |
| 5       | Urgency                                     | 28.4 | Intermittency                                   | 37.5 | Incomplete emptying         | 35.0 |
| 6       | Delay                                       | 22.9 | Nocturia  | 26.0 | Post micturition dribble    | 33.3 |
| 7       | Increased daytime frequency                 | 18.8 | Straining                                       | 18.6 | Weak stream                 | 29.7 |

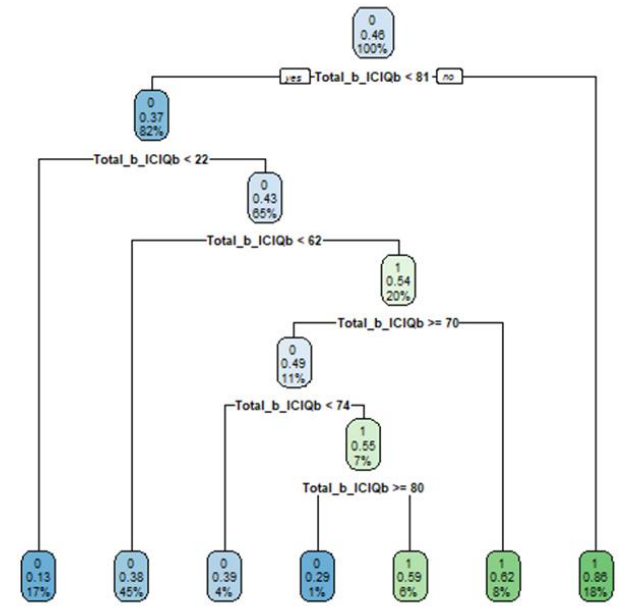
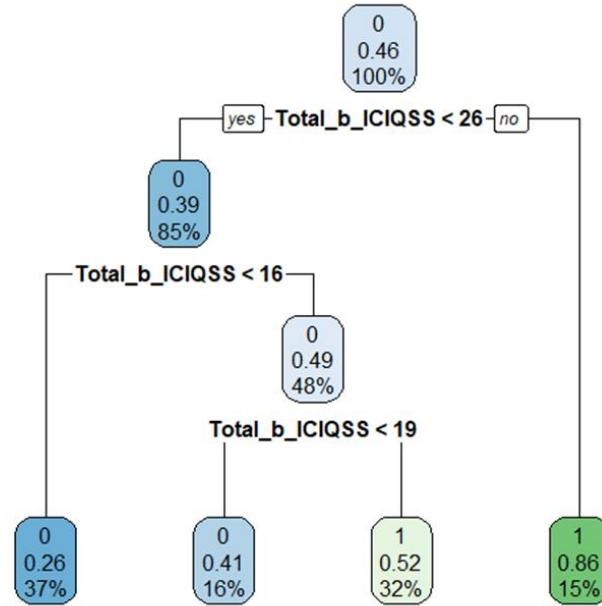
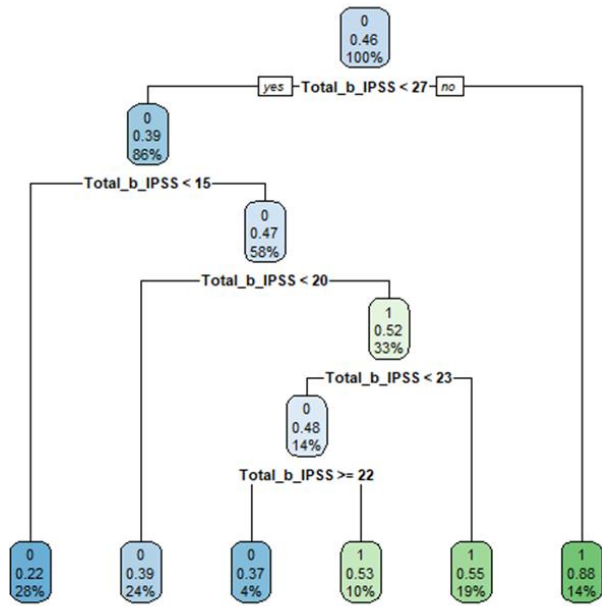


|            |  |
|------------|--|
| AIC        | Akaike information criterion                                       |
| ICIQ-MLUTS | International Consultation on Incontinence Questionnaire Male LUTS |
| IPSS       | International Prostate Symptom Score                               |
| LUTS       | Lower urinary tract symptoms                                       |
| Qmax       | Maximum flow rate  |
| PROM       | Patient reported outcomes measures                                 |
| PMD        | Post micturition dribble   |
| PVR        | Post void residual   |
| QoL        | Quality of life  |
| ROC        | Receiver operating characteristic                                  |
| UI         | Urinary incontinence   |
| VV         | Voided volume  |

Baseline





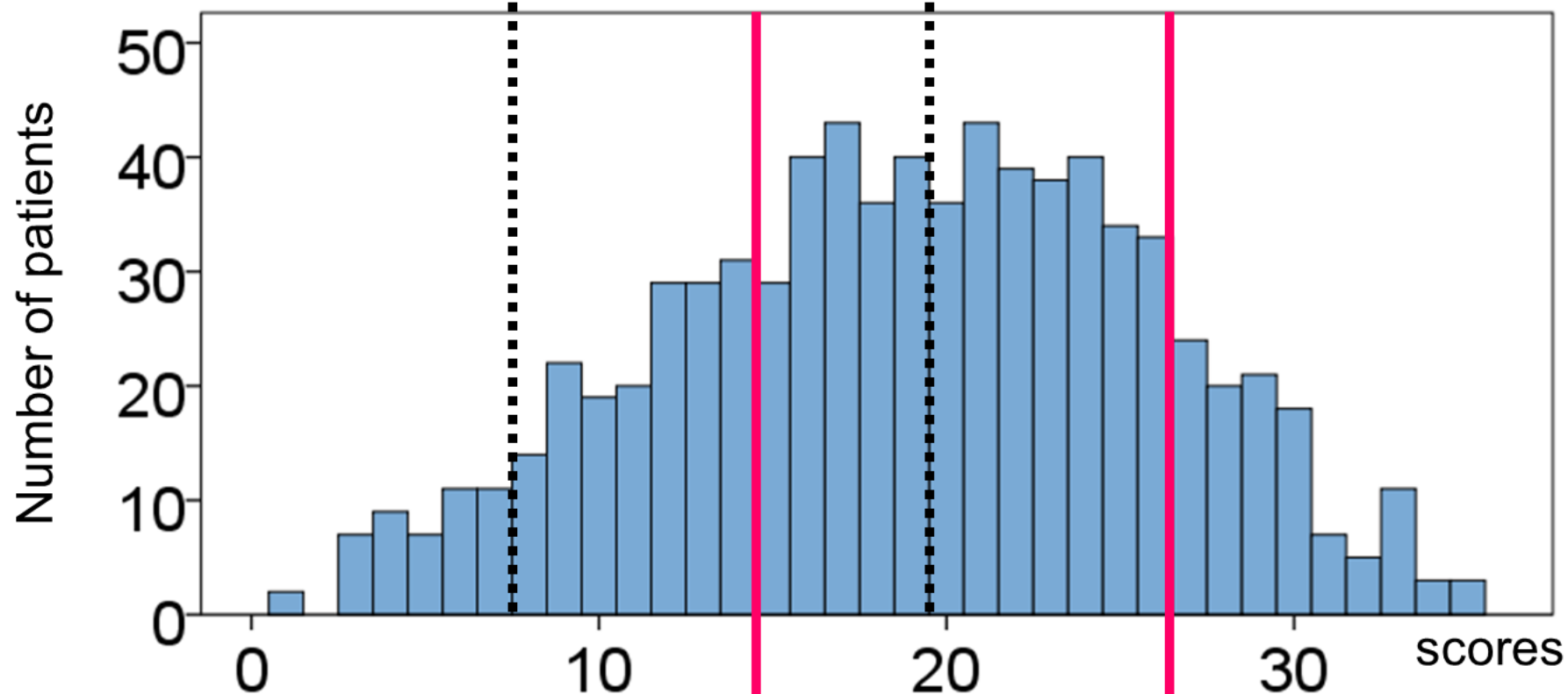


Current

mild

moderate

severe



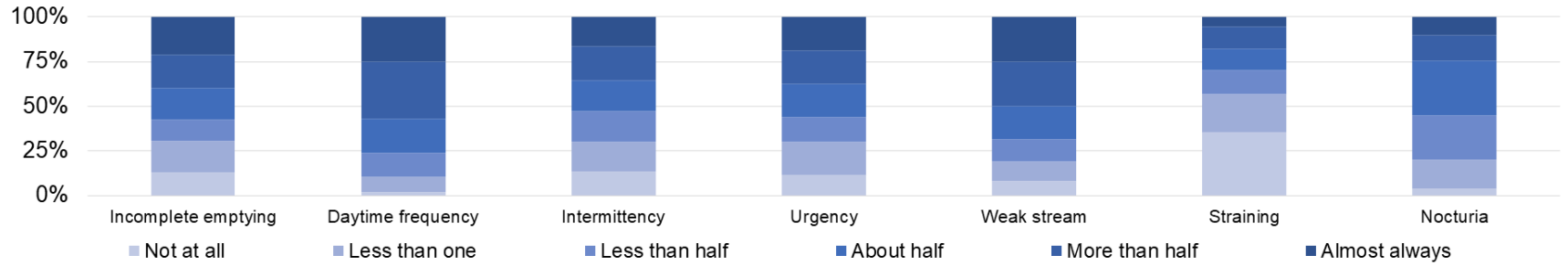
Proposed

mild

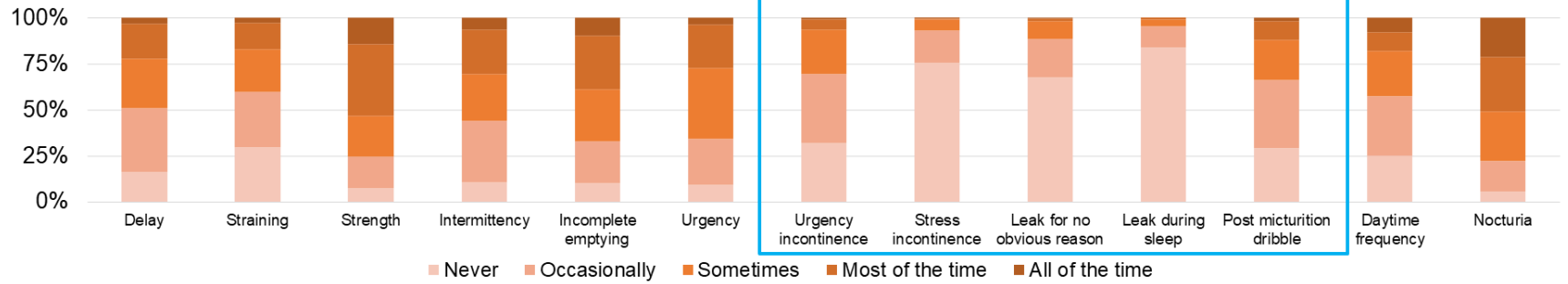
moderate

severe

A  
IPSS score (N=774)



B  
Symptom severity scores of ICIQ-MLUTS (N=756)



C  
Bother scores of ICIQ-MLUTS (N=643)

