Visual Analogue Scale and Expanded Prostate Cancer Index Composite-26 in the Evaluation of Urinary Continence Recovery After Three-Dimensional Laparoscopic Radical Prostatectomy, a Single-Center Prospective Registered Study

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OBJECTIVE To assess the correlation between the Visual Analogue Scale (VAS) and the Expanded Prostate Cancer Index Composite (EPIC)-26 in the evaluation of urinary continence (UC) recovery after 3-dimensional laparoscopic radical prostatectomy (3D-LRP).

METHODS 105 men underwent 3D-LRP in Seinäjoki Central Hospital Finland between November 2018 and February 2021. VAS forms and EPIC-26 questionnaires were used to assess UC preoperatively and at 6 weeks, 3-, 6-, 9-, 12-, 15-, 18-, 21-, and 24 months postoperatively.

On the VAS form, the patient put a mark on the 10 cm long horizontal line in place, which described his experienced degree of UC (0 cm; fully incontinent—10 cm; fully continent). The scores for the urinary incontinence domain of EPIC-26 (UI-EPIC-26) were calculated and transformed to a scale of 0-100. Spearman´s rank correlation coefficient was used to evaluate the correlation between the VAS and UI-EPIC-26.

RESULTS A total of 915 VAS forms and 909 EPIC-26 questionnaires were evaluable. UC improved significantly during the first year but not after that. The medians for UI-EPIC-26 and VAS were 50.8 (0-100) and 7.2 cm (0-10 cm) at 3 months, 76.8 (14.5-100) and 8.7 cm (1.7-10 cm) at 12 months and 79.6 (8.25-100) and 9.0 cm (2.7-10 cm) at 24 months. The correlation coefficient (95% confidence interval) between VAS and UI-EPIC-26 preoperatively, at 12 months and at 24 months was 0.639 (0.505-0.743), 0.807 (0.716-0.871), and 0.831 (0.735-0.894), respectively ($P < 0.001$).

CONCLUSION The VAS can be utilized as an easy-to-use alternative to the EPIC-26 when evaluating UC recovery after 3D-LRP. UROLOGY 177: 103–108, 2023.

Prostate cancer (PCa) is the second most common cancer in men globally and 1 out of 8 men will be diagnosed with PCa during his lifetime.[1,2] Radical prostatectomy (RP) is the primary curative treatment for men under 75-years of age with clinically significant localized PCa.[3] Despite advances in surgical techniques for RP, treatment-related functional adverse effects, especially urinary incontinence (UI) and erectile dysfunction can have a major negative impact on a patient´s Health Related Quality of Life (HRQoL). Due to good general survival after RP, patients' HRQoL may be compromised by these functional problems for years or even decades.[4–7]

Quality control (QC) for RP-related HRQoL has changed dramatically during the evolution of RP. The Expanded Prostate Cancer Index Composite-26 (EPIC-26) has become a widely used patient-reported outcome instrument that measures HRQoL among PCa survivors across 5 disease-specific domains: UI, urinary obstruction and irritation, bowel-related symptoms, sexual dysfunction, and hormonal symptoms[7–11].

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However, the EPIC-26 can be cumbersome in a daily clinical practice setting because it requires approximately 10 minutes to complete. Some patients need help in filling out complex questionnaires, which can lead to misinformation. Domain scores are calculated using an algorithm, and scores are transformed to a linear 0-100 scale in which higher scores indicate better outcomes in each domain,[13] but interpretation can be challenging, especially when determining clinically relevant thresholds.[11,12]

An ideal QC tool for outpatient clinics should be reliable, easy to use, and interpret for both the patient and medical staff. We recently reported a retrospective study in which a strong correlation between the Visual Analogue Scale (VAS) and both the UI- and sexual dysfunction domain of EPIC-26 was demonstrated after 3-dimensional laparoscopic radical prostatectomy (3D-LRP), but the evaluation was performed nearly 3 years after the operation.[14] The aim of the present investigation was to test the feasibility of using the VAS in the evaluation of urinary continence (UC) recovery among patients undergoing 3D-LRP in a prospective study.

MATERIALS AND METHODS

Study Population

A total of 105 consecutive men who underwent 3D-LRP at the Seinäjoki central hospital in Finland between November 2018 and February 2021 were enrolled in this prospective study. The median age at surgery was 63 years (range, 46-75).

Collection of Data on Incontinence

Before the operation, patients completed the validated Finnish language paper version of the EPIC-26 questionnaire, along with the VAS form, to assess preoperative continence. The VAS form was a 10 cm horizontal line, on which the patients were asked to place a single mark based on their experienced degree of continence. Marking on the right end of the scale indicated the patient felt that their UC was normal (10 cm), whereas marking on the left end indicated total incontinence (0 cm). The marks on the VAS lines were measured using a ruler to an accuracy of 0.1 cm (min 0 cm, max 10 cm). The scores for the UI domains of the EPIC-26 were calculated using the University of Michigan scoring instructions, and the multi-item scores were transformed to a 0-100 scale on which a higher score indicates a better outcome.[13]

After the surgery, the patients were sent the same questionnaires at regular intervals, first at 6 weeks and then at 3, 6, 9, 12, 15, 18, 21, and 24 months postoperatively. The patients answered all the questionnaires on the same date, at home, without the presence of medical staff, and then returned the completed questionnaires to the hospital via mail. The maximum follow-up time was 24 months, so each patient completed, at most, 10 VAS forms and 10 EPIC-26 questionnaires. The data collection were terminated in December 2022.

The patients were monitored during subsequent control visits, which occurred at 3, 12, and 24 months postoperatively. At the control visits, patients were categorized into 4 groups based on self-reported urinary continence: continent (no pads), single daytime safety pad (night-time continent and most of the day), 2 or more pads (pads during daytime but night-time continent), or totally incontinent (pads during both on daytime and night-time).

Statistical Analysis

Spearman´s rank correlation coefficient was used to evaluate the correlation between the incontinence VAS and UI domain of EPIC-26 (UI-EPIC-26). Statistical significance was considered when P value was ≤0.05. The McNemar test was used when continence recovery during the first and second years was evaluated. The statistical analyses were performed with SPSS statistical software (IBM SPSS Statistics, Version 27; IBM Co., Armonk, New York, USA).

RESULTS

A total of 915 responses to VAS forms and 909 responses to EPIC-26 questionnaires were evaluable for analyses. The median number of returned questionnaires (VAS and EPIC-26) per patient was 9 (range: 1-10). The number of comparable (same patient and survey date) VAS and UI-EPIC-26 measurements was 901, making the overall response rate 87%. Two patients filled out only the preoperative surveys.

The medians for VAS and UI-EPIC-26 and Spearman's rank correlation coefficients are described in Table 1. The preoperative median for the UI-EPIC-26 was 95.2 points (35.5-100) and that for the VAS was 9.4 cm (4.9-10 cm). The

Table 1. Medians for the Visual Analogue Scale (VAS) and the Urinary Incontinence domain of the Expanded Prostate Cancer Index Composite (UI-EPIC-26) and Spearman´s rank correlation coefficients. Cohort of 105 Finnish men with prostate cancer treated with 3D-laparoscopic radical prostatectomy.

Time	VAS Median cm (min-max) [n]	UI-EPIC-26 Median Points (min-max) [n]	Spearman Correlation Coefficient (95% Confidence Interval)
Baseline	9.4 (4.9-10 cm) [105]	95.2 (35.5 -100) [105]	0.639 (0.505-0.743); *P*-value < 0.001
6 weeks	6.6 (0-10 cm) [96]	38.6 (0-100) [94]	0.823 (0.742-0.881); *P*-value < 0.001
3 months	7.2 (0-10 cm) [99]	50.8 (0-100) [99]	0.831 (0.756-0.855); *P*-value < 0.001
6 months	8.2 (0-10 cm) [99]	65.9 (0-100) [98]	0.807 (0.722-0.868); *P*-value < 0.001
9 months	8.4 (0.2-10 cm) [97]	71.4 (0-100) [97]	0.830 (0.753-0.885); *P*-value < 0.001
12 months	8.7 (1.7-10 cm) [88]	76.8 (14.5-100) [90]	0.807 (0.716-0.871); *P*-value < 0.001
15 months	8.7 (1.2-10 cm) [90]	75.8 (14.5-100) [91]	0.816 (0.729-0.877); *P*-value < 0.001
18 months	8.7 (2.8-10 cm) [87]	75.7 (8.25-100) [84]	0.845 (0.766-0.898); *P*-value < 0.001
21 months	8.6 (2-10 cm) [86]	76.0 (8.25-100) [83]	0.841 (0.761-0.896); *P*-value < 0.001
24 months	9.0 (2.7-10 cm) [68]	79.6 (8.25-100) [68]	0.831 (0.735-0.894); *P*-value < 0.001
n total	915	909	

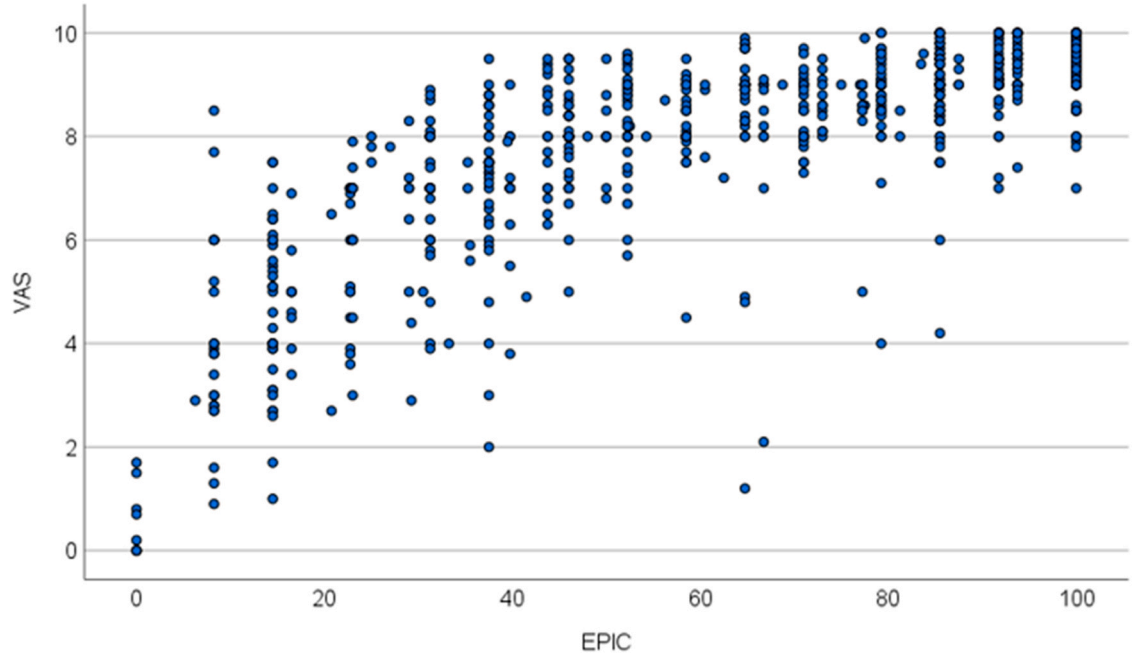

Figure 1. Scatterplot of the results of the comparable Visual Analogue Scales and urinary incontinence domains of EPIC-26 (n 901). Cohort of 105 Finnish men with prostate cancer treated with 3D-laparoscopic radical prostatectomy.

correlation coefficient between the UI-EPIC-26 and incontinence VAS was 0.639 (95% confidence interval (CI) 0.505–0.743, *P*-value < 0.001). The correlation coefficients between the VAS and UI-EPIC-26 were > 0.8 at every time point after the operation (*P*-value < 0.001), as described in Table 1. These correlations are depicted in the scatterplot shown on Figure 1.

Urinary continence improved significantly during the first year but not after that. The median UI-EPIC-26 and VAS scores at 6 weeks and 12 and 24 months were 38.6 (0-100) and 6.6 cm (0-10 cm), 76.8 (14.5-100) and 8.7 cm (1.7-10 cm), and 79.0 (8.25-100) and 8.9 cm (2.7-10 cm), respectively. Continence recovery during the first 2 years after 3D LPR based on the VAS and UI-EPIC-26 is presented in Figures 2 and 3.

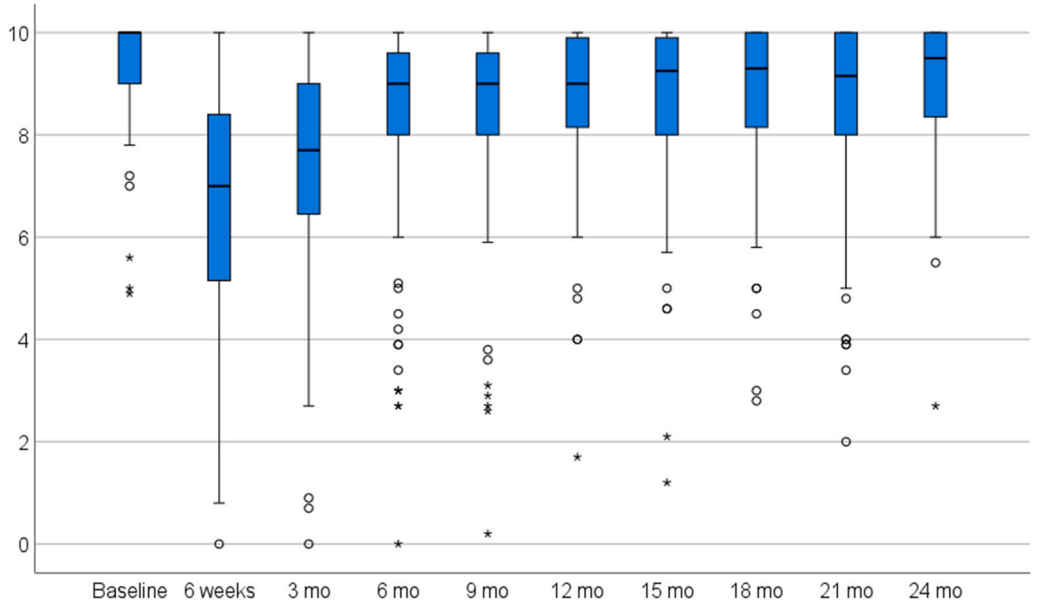

Figure 2. Continence recovery during the first 2 years after 3D-LPR using the Visual Analogue Scale. Cohort of 105 Finnish men with prostate cancer treated with 3D-laparoscopic radical prostatectomy.

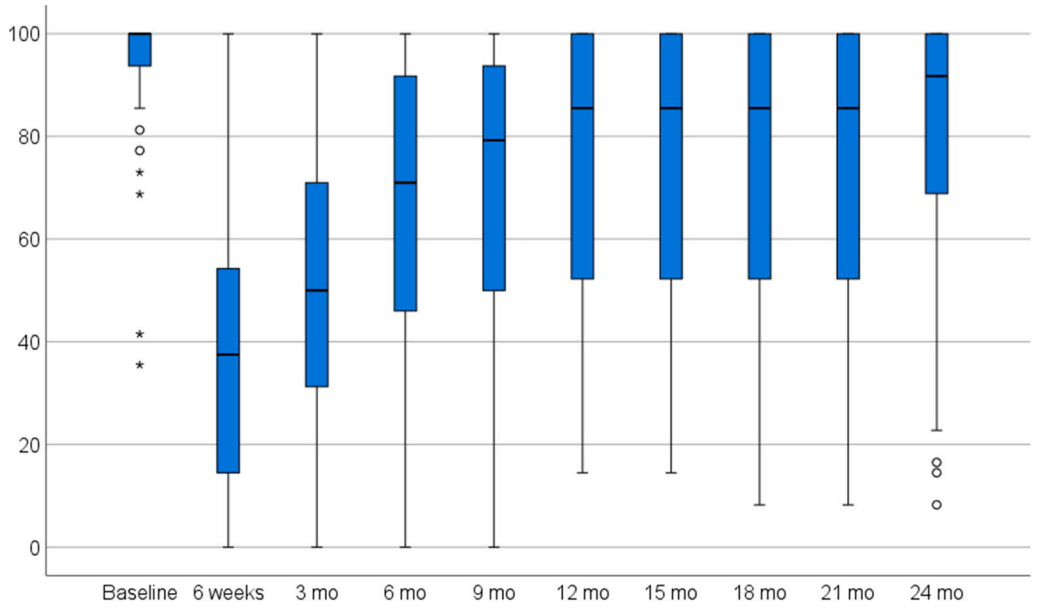

Figure 3. Continence recovery during the first 2 years after 3D-LPR using the urinary incontinence domain of the EPIC-26. Cohort of 105 Finnish men with prostate cancer treated with 3D-laparoscopic radical prostatectomy.

According to the patients' self-reports, the overall continence rate (no pads) was 24.8% at 3 months, 64.1% at 12 months, and 65.1% at 24 months. If good post-prostatectomy continence is defined as ≤1 pad per day, the corresponding continence rates were 58.4%, 86.4%, and 88.8%, respectively.

DISCUSSION

This prospective single-center clinical trial was conducted to investigate the correlation between the validated but laborious EPIC-26 and the simple VAS form in the evaluation of UC recovery after radical prostatectomy and to explore whether the correlation differs depending on timing in relation to the operation. Over 900 completed VAS forms, along with EPIC-26 questionnaires from 105 operated patients, were collected, so the response rate for returned questionnaires in this study was high, at 87%.

We found a significant correlation between the VAS and UI-EPIC-26 during the entire follow-up time, suggesting that the VAS offers a reliable method via which to evaluate patients' experience of UC after RP. These results support our previous findings of a strong postoperative correlation between the VAS and UI-EPIC-26.[13] However, in the preoperative period, the basis correlation between VAS and UI-EPIC-26 was not as strong as postoperatively. Interestingly, when analyzing patients' individual scores, a few patients had estimated their preoperative continence on the VAS form to be much lower than the full 10 cm, even if they achieved the maximum score on the UI-EPIC-26. This reflects the bias that is associated with subjective measures, such as patient-reported outcome measures.

As expected, the worst UC was observed immediately after the operation, and the most significant UC recovery occurred during the first postoperative year. Our functional results, indicating that 64.5% of the patients were using no pads and 86.4% were using, at most, 1 pad per day 1 year after surgery, are in accordance with other studies.[15,16] The final degree of postoperative UC is usually achieved within 1 year after RP. Although additional improvement in continence after 1 year is unlikely, contrary reports also exist. Jeong et al found that about half of the patients who were incontinent at 1 year became continent between years 1 and 2 after the operation, with a patient's age and severity of incontinence at 1 year being the strongest factors leading to a late recovery.[17] We could not, however, confirm this, as no significant change in the continence rate was noted during the second postoperative year.

The main limitation of this study is that VAS is not currently a validated assessment instrument among urological indications. To our knowledge, this is the first prospective study that validates VAS in the evaluation of UC recovery at several measurement points and over a relatively long follow-up time after RP. In addition to our previous study,[14] there is only sparse literature on VAS usage in the evaluation of urinary symptoms among males. Tiwari et al noted that, when evaluating lower-urinary-tract symptoms, the VAS was correlated strongly with maximal urinary flow rate, voided volume, and International Prostate Symptom scores (IPSS).[18] In a study by Ushijima et al, the VAS was found to be significantly better at identifying a patient's main complaint as compared to IPSS.[19] Okihara et al used the VAS to evaluate lower-urinary-tract symptoms in patients

undergoing brachytherapy; the VAS reflected the change in HRQoL more precisely than the IPSS.[20]

This study has also other limitations. The number of patients included in this study was relatively low. However, both questionnaires were collected preoperatively, as well as at 6 weeks and 3, 6, 9, 12, 15, 18, 21, and 24 months postoperatively, making over 900 comparisons possible. It must be remembered that patients filled out both forms at home without the presence of medical staff, which can be considered a strength of this study. Unfortunately, we have not collected any structured feedback from our patients during the follow-up time regarding the usefulness and patients´ experiences of completing the VAS. However, feedback in the outpatient clinic has been encouraging.

Although we found a strong correlation between the VAS and UI-EPIC-26 for UC after 3D-LRP, we should determine what can be considered a clinically important VAS value when evaluating UC because the VAS value is still a numerical measurement, like the EPIC-26. Litwin has stated that prostate cancer-related patient-reported outcome measures must cover both function and discomfort in independent domains.[21] Also, HRQoL is highly subjective and cannot directly be measured by any instrument. Despite Litwin´s statement, to keep the questionnaire as simple as possible we used only 1 "overall" VAS line, which included both function and the discomfort of UI, to evaluate UC recovery after RP. However, it would be interesting to compare UI-EPIC-26 function scores to a "Function-VAS" and discomfort scores to a "Discomfort-VAS."

More studies are needed to define clinically significant VAS thresholds and to explore their use in other indications, such as in the evaluation of patients' satisfaction with pharmacological and surgical therapies. Ideally, the VAS could represent a helpful and easy assessment tool for use in the quick monitoring of functional outcomes during control visits. More consistent QC could lead to better communication between patients and clinicians and thus help in improving the overall quality of care.

Conclusion

The VAS can be considered an easy and reliable instrument via which to evaluate urinary continence recovery after radical prostatectomy.

Declaration of Competing Interest

Teemu Murtola is paid consultant to Astellas, Amgen, Janssen-Cilag, Novartis, Sanofi, Recordati, Pfizer and Ferring. He reports receiving speaker's bureau honoraria from Astellas, Amgen, Janssen-Cilag, Merck and Pfizer. He reports congress participation at expense of Sanofi, Orion, and Pfizer. Remaining authors declare no conflict of interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2023.04.021.

References

1. Rawla P. Epidemiology of prostate cancer. *World J Oncol*. 2019;10:6389. https://doi.org/10.14740/wjon1191
2. Culp MB, et al. Recent global patterns in prostate cancer incidence and mortality rates. *Eur Urol*. 2020;77:38.
3. Mottet N, van den Bergh RCN, Briers E, et al. EAUEANM-ESTRO-ESUR-SIOG guidelines on prostate cancer-2020 update. Part 1: screening, diagnosis, and local treatment with curative intent. *Eur Urol*. 2021;79:24362. https://doi.org/10.1016/j.eururo.2020.09.042
4. Patel VR, Sivaraman A, Coelho RF, et al. Pentafecta: a new concept for reporting outcomes of robot-assisted laparoscopic radical prostatectomy. *Eur Urol*. 2011;59:702–707. https://doi.org/10.1016/j.eururo.2011.01.032
5. Hamoen EHJ, De Rooij M, Witjes JA, Barentsz JO, Rovers MM. Measuring health-related quality of life in men with prostate cancer: a systematic review of the most used questionnaires and their validity. *Urol Oncol*. 2015;33(69):e19–e28. https://doi.org/10.1016/j.urolonc.2013.10.005
6. Lardas M, Liew M, van den Bergh RC, et al. Quality of life outcomes after primary treatment for clinically localised prostate cancer: A systematic review. *Eur Urol*. 2017;72:869–885. https://doi.org/10.1016/j.eururo.2017.06.035
7. Schmidt S, Garin O, Pardo Y, et al. Assessing quality of life in patients with prostate cancer: a systematic and standardized comparison of available instruments. *Qual Life Res*. 2014;23:2169–2181. https://doi.org/10.1007/s11136-014-0678-8
8. Szymanski KM, Wei JT, Dunn RL, Sanda MG. Development and validation of an abbreviated version of the expanded prostate cancer index composite instrument for measuring health-related quality of life among prostate cancer survivors. *Urology*. 2010;76:1245–1250. https://doi.org/10.1016/j.urology.2010.01.027
9. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the expanded prostate cancer index composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. *Urology*. 2000;56(6):899–905.
10. Sibert NT, Dieng S, Oesterle A, et al. Psychometric validation of the German version of the EPIC-26 questionnaire for patients with localized and locally advanced prostate cancer. *World J Urol*. 2021;39:11–25. https://doi.org/10.1007/s00345-019-02949-7
11. Beyer B, Huland H, Feick G, Graefen M. "Expanded prostate cancer index composite" (EPIC-26): Funktionelles Behandlungsergebnis bei Patienten mit lokalisiertem Prostatakarzinom ["Expanded prostate cancer index composite" (EPIC-26): results of functional treatment in patients with localized prostate cancer]. *Urologe A*. 2015;54(11):1591–1595. https://doi.org/10.1007/s00120-015-3922-0
12. Skolarus TA, Dunn RL, Sanda MG, et al. PROSTQA consortium. minimally important difference for the expanded prostate cancer index composite short form. *Urology*. 2015;85(1):101–105. https://doi.org/10.1016/j.urology.2014.08.044
13. Sanda M.G., Wei J.T., Litwin M.S. Scoring instructions for the expanded prostate cancer index composite short form (EPIC-26). University of Michigan;2002. https://medicine.umich.edu/sites/default/files/content/downloads/Scoring%20Instructions%20for%20the%20EPIC%2026.pdf. Accessed May 23, 2023.

14. Haapiainen H, Valli J, Murtola T, Huhtala H, Kaipia A, Raitanen M. Visual Analogue Scale (VAS) in the evaluation of functional outcomes after three-dimensional laparoscopic prostatectomy. *Urology*. 2023;172:121–125. https://doi.org/10.1016/J.UROLOGY.2022.12.003. Epub 2022 Dec 19. PMID: 36549575.
15. Ficarra V, Novara G, Rosen RC, et al. Systematic review and meta-analysis of studies reporting urinary continence recovery after robot-assisted radical prostatectomy. *Eur Urol*. 2012;62(3):405–417. https://doi.org/10.1016/j.eururo.2012.05.045
16. Hagman A, Lantz A, Carlsson S, et al. Urinary continence recovery and oncological outcomes after surgery for prostate cancer analysed by risk category: results from the LAParoscopic prostatectomy robot and open trial. *World J Urol*. 2021;39(9):3239–3249. https://doi.org/10.1007/s00345-021-03662-0
17. Jeong SJ, Kim HJ, Kim JH, et al. Urinary continence after radical prostatectomy: predictive factors of recovery after 1 year of surgery. *Int J Urol*. 2012;19(12):1091–1098. https://doi.org/10.1111/j.1442-2042.2012.03106.x
18. Tiwari R, Ng MY, Neo SH, Mangat R, Ho H. Prospective validation of a novel visual analogue uroflowmetry score (VAUS) in 1,000 men with lower urinary tract symptoms (LUTS). *World J Urol*. 2019;38:1267–1273.
19. Ushijima S, Ukimura O, Okihara K, Mizutani Y, Kawauchi A, Miki T. Visual Analog Scale Questionnaire to assess quality of life specific to each symptom of the International Prostate Symptom Score. *J Urol*. 2006;176:665–671.
20. Okihara K, Ukimura O, Ushijima S, et al. Quantitative evaluation of lower urinary tract symptoms using a visual analog scale in men undergoing permanent brachytherapy. *Brachytherapy*. 2012;11:265–270.
21. Litwin MS. Measuring health related quality of life in men with prostate cancer. *J Urol*. 1994;152(5 Pt 2):1882–1887. https://doi.org/10.1016/s0022-5347(17)32407-2