Efficacy and Safety of a Self-Improved Continuous Bladder Irrigation Sensor Device in Patients after Transurethral Resection of the Prostate: A Prospective Study

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Purpose To explore the efficacy and safety of a self-improved continuous bladder irrigation (CBI) sensor device after transurethral resection of the prostate (TURP).

Materials and Methods: A total of 160 patients with benign prostatic hyperplasia who received TURP from June 2021 to May 2022 were selected. According to the envelope randomization method, patients were divided into a control group (80 cases) and study group (80 cases). In the control group, the speed of bladder flushing fluid was adjusted according to the clinical experience of nurses. On the basis of the control group, the self-improved CBI sensor device was used in the study group to observe the postoperative comfort and complication rate in the two groups.

Results: The comfort of patients in the study group was significantly higher than that of patients in the control group (97.50% vs. 88.75%, P = .023), and the number of postoperative complications in the control group was significantly higher than that in the study group (8.75% vs. 1.25%, P = .021). Meanwhile, the average amount of irrigation fluid in the study group was obviously lower than that in the control group (26.4 L vs. 27.8 L, P = .011). In addition, patients in the study group had a significantly shorter hospital stay than the controls (3.3 days vs. 3.6 days, P = .005).

Conclusion: Implementation of the new self-improved CBI sensor device for patients after TURP can improve their awareness regarding disease-related knowledge, alleviate their fear and anxiety, improve their compliance and comfort with treatment and nursing, and reduce the incidence of complications.

Keywords: improvement; continuous bladder irrigation; TURP; nursing; complication; comfort

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common disease in men older than 50 years of age[1]. Although BPH is not a life-threatening disease, it is a health concern and it significantly affects the quality of life of the patients [2]. Transurethral resection of the prostate (TURP) has been used as the treatment option for decades, and it has gradually become the classic surgical method for BPH[3]. Continuous bladder irrigation (CBI) is a supplementary approach for BPH management after TURP with a view to prevent clot retention, cystospasm, and hemorrhage postoperatively[4]. The key point of this operational skill is to observe the color of the irrigation fluid at any time[5]. Nurses are responsible for ensuring continuous flow of the prescribed solution during the whole procedure. However, most of these patients are older, lack awareness regarding the disease, and have poor self-care ability, which increases the occurrence of postoperative complications and affects the postoperative rehabilitation effect[6]. At the same time, observation of the irrigation fluid by nurses is mostly a subjective assessment, which relies on experience with individual differences[7]. This difference can easily cause contradictions between doctors and patients and between doctors and nurses, and it can even cause severe complications, such as cystospasm, urinary tract blockage, and secondary bleeding[8]. Therefore, there is an urgent need to solve the problem of how one can quickly and accurately evaluate the color of CBI fluid. Some scholars believe that after routine bladder flushing, a urine drainage bag is used to collect the patient's urine; and then the nurse compares it through the bladder flushing color card[9,10], and carries out the corresponding follow-up operations according to the color of the urine released. However, the overall efficiency of this method is low. When the light changes, the contrast effect may be affected. The error is large, and the production is more complex. Therefore, in order to achieve a better control of the flow rate of irrigation fluid and reduce inappropriate flow rate-related adverse effects, we aimed to design an automatic flow rate controller device for bladder irrigation equipped with a wireless sensor and evaluate its clinical efficacy in patients after TURP. The report is presented below.

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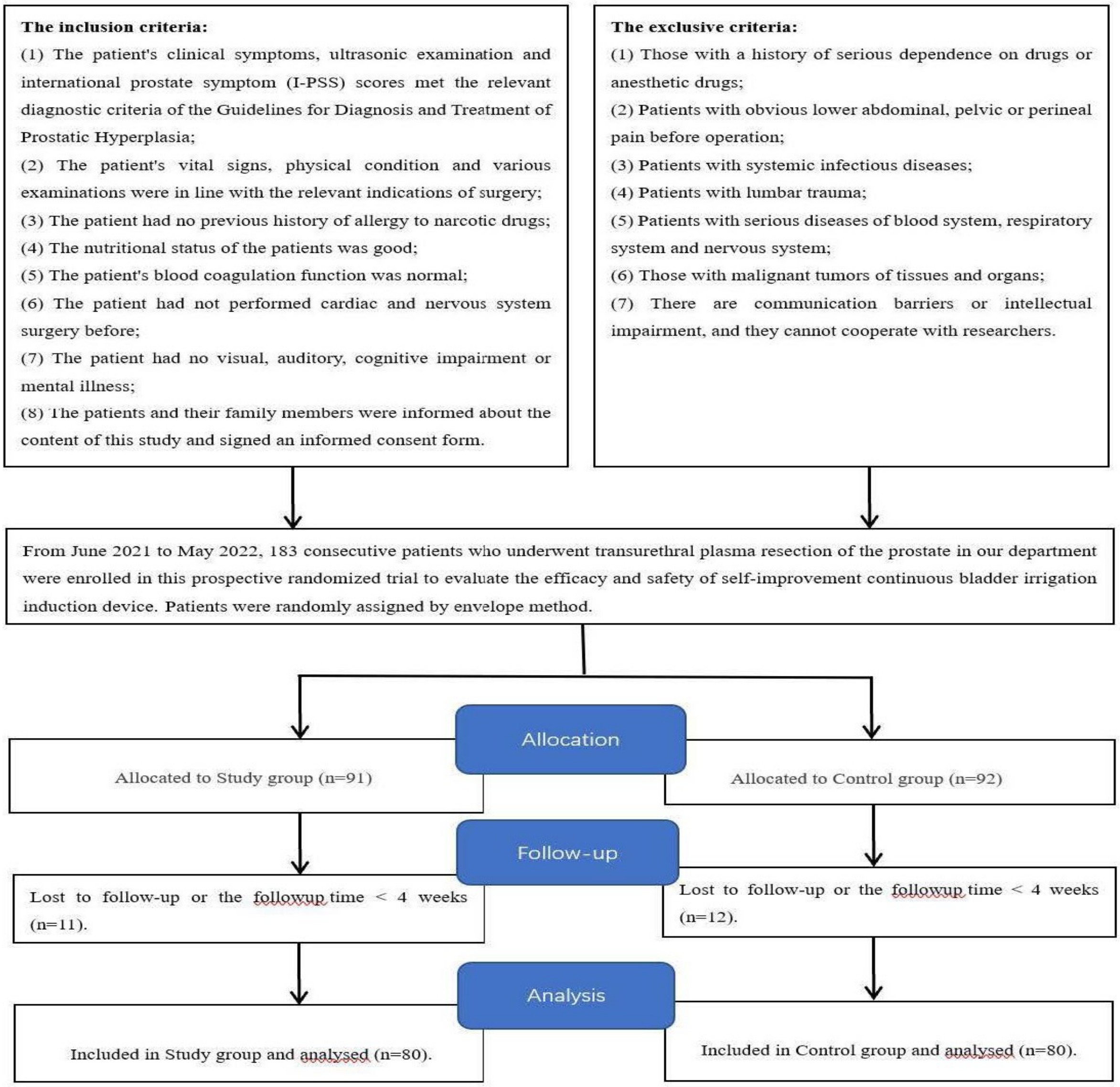


Figure 1: Flowchart for Cases selection

MATERIALS AND METHODS

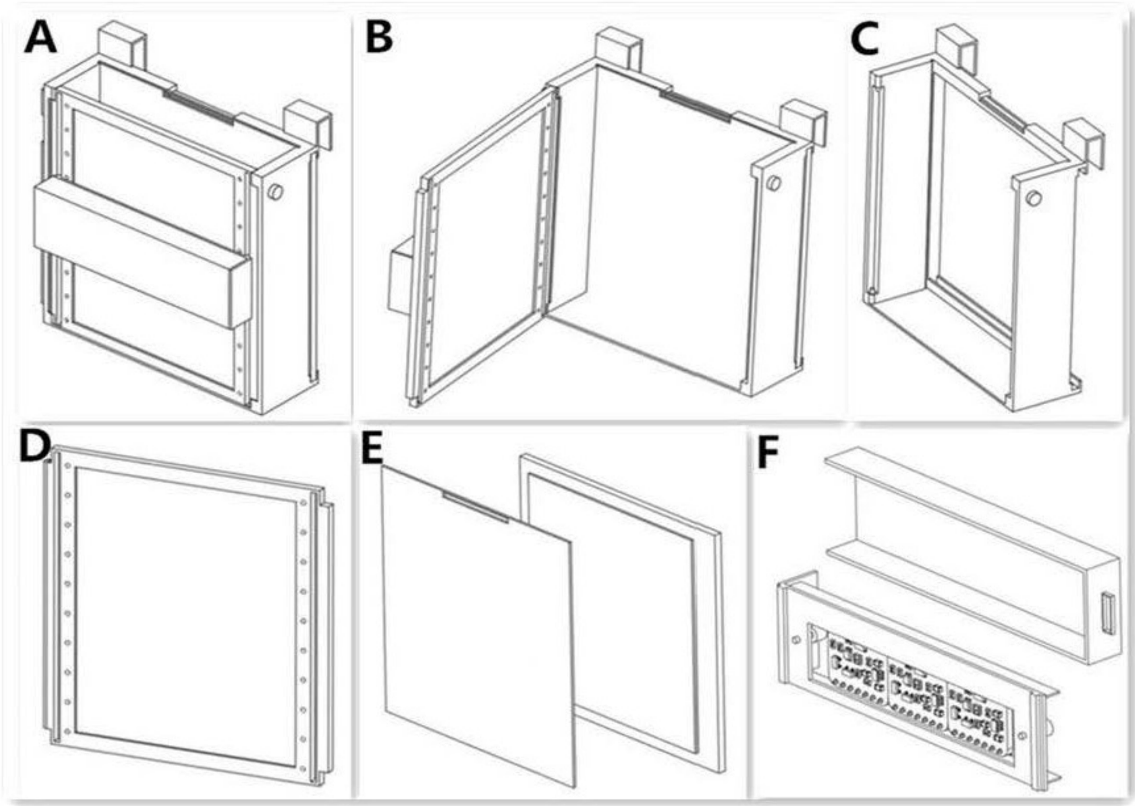
Patients

From June 2021 to May 2022, eligible patients who underwent transurethral plasmakinetic resection of the prostate in our department were selected as the subjects of this study. After applying strict inclusion criteria and randomly assigning the patients by the envelope method, 160 patients were finally included: 80 patients in the study group and 80 patients in the control group (**Figure 1**). There was no substantial difference between the two groups in terms of demographics and clinical characteristics, including mean age at diagnosis, body mass index, and history of hypertension and diabetes (All $P > 0.05$). The study was approved by the clinical research ethics committee of the Affiliated Jiangning Hospital with Nanjing Medical University (ethics approval number: 202100317). Written informed consent was obtained from all participants.

Study procedures

The control group: routine nursing methods were implemented during the perioperative period. The patient's condition and vital signs were closely monitored after the operation. Routine infusion nursing, urination nursing and medication guidance were performed, and the patient's family members were instructed to closely observe the color of the bladder flushing fluid. If the color turned red, the nursing staff members were promptly notified.

The study group: on the basis of conventional nursing methods, a new sensing device for the CBI effect (**Figure 2**) was adopted. The sensing device included an outer frame, and the upper end of the outer frame was provided with snap clips distributed in an array. One side of the outer frame was provided with a switch button, the other side of the outer frame was provided with a controller and battery, and the back side of the outer frame was provided with the first chute. The first slot was provided between the snap clips, and the front end of the first chute was provided with the second chute.



Figre 2: Diagram of CBI. A. Outer frame. B. Inside the outer frame. C. Chute. D. The snap clips. E. Clamping slot. F. Color sensor.

The front end of the outer frame was provided with a second slot and a clamping slot. The second slot was also provided with a front cover that could rotate and fit. The outside of the front cover was provided with an adjustment frame that could slide and fit. The adjustment frame was provided with a color sensor that was fixedly connected. The new sensing device could be hung beside the patient's bed, and the urine drainage bag was placed in the sensing device for fixation. A color sensor was set outside the sensing device, and the controller was connected to the irrigation device. The irrigation operation could be automatically adjusted or stopped according to different colors of urine. After the operation, a signal was sent to inform the nurse to con-

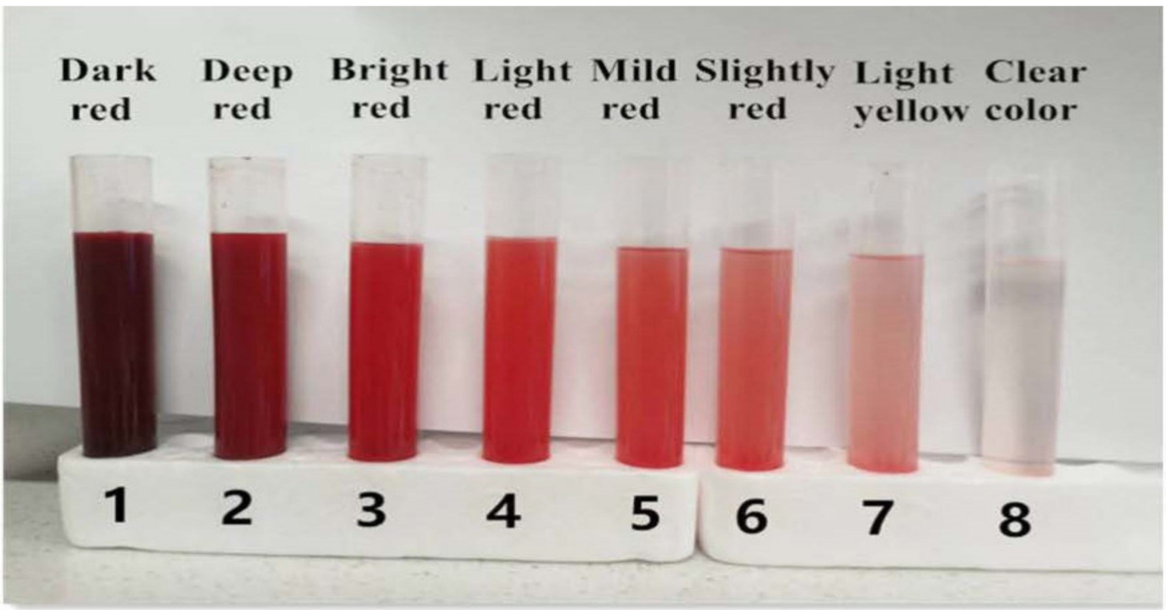


Figure 3. Colorimetric card

Table 1. Comparisons of patients' demographics and clinical characteristics between two groups

Variables, mean ± SD or n (%)	Study Group (n=80)	Control Group (n=80)	*P* value
Age, year	71.3 ± 6.1	69.8 ± 7.4	.16
BMI, kg/m^2	23.5 ± 3.1	23.9 ± 2.5	.37
IPSS	26.8 ± 2.7	26.3 ± 3.3	.30
Prostate volume, mL	67.2 ± 5.5	66.8 ± 6.1	.66
Operation time, min	59.3 ± 6.7	60.7 ± 6.1	.17
Preoperative indwelling catheter			
No	56 (70.0)	59 (73.7)	-
Yes	24 (30.0)	21 (26.3)	.60

BMI = body mass index; SD = standard deviation; IPSS = international prostate symptom score;
*$P <$ 0.05.

duct an on-site observation.

Eight different color numbers were set in the system of the new bladder irrigation sensor, and the bladder irrigation dripping speed was automatically adjusted according to the color number memorized in the system. The matching method of different color numbers was as follows: Briefly, 1.28 ml of patient's venous blood and 8.72 ml of 0.9% sodium chloride injection was taken for mixing; then they were diluted to a solution with a concentration of 12.8%. This method was used to prepare 6.4%, 3.2%, 1.6%, 0.8%, 0.4%, 0.2%, 0.1%, and other liquids of different concentrations, and the liquids were placed in a transparent container (**Figure 3**). The colors of the eight solutions matched the corresponding flushing speed, and then they were inputted into the bladder irrigation sensor device. When the color of the flushing solution was close to dark red or the drainage was not smooth, the device would automatically adjust the dripping speed and send out an alarm. After observation, the nurse would immediately notify the doctor to flush the catheter with positive pressure, and if necessary, perform surgery to stop bleeding. During the process of using the new bladder irrigation device, the nurse supervised, guided, and collected various data for each patient.

Follow-up

All patients were followed up within four weeks after discharge. The comfort and complication rate in the two groups were compared. (1) Comfort: comfortable, optimistic and positive psychological state, no pain and adverse reaction in the body; Normally, the psychological state was good, and occasionally there may be physical adverse reactions or pain; uncomfortable, anxiety and depression, obvious body pain, and adverse reactions; (2) Complications: They included bleeding, urinary tract infection, urinary incontinence, and cystospasm. During the process of bladder irrigation, the amount of irrigation fluid and duration were recorded.

All procedures performed in studies involving human participants were in accordance with the ethical standards of Affiliated Jiangning Hospital with Nanjing Medical University and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Statistical analysis

SPSS v.22.0 for Windows (IBM Corp., Armonk, NY, USA) was used to perform statistical analysis. Continuous variables were presented as mean ± standard deviation. Patient demographics, follow-up time, and clinical outcomes were compared between the two groups using an independent samples t test; Chi-squared test was used to compare other clinical characteristics between the two groups. The main assumption underlying chi-square test, no expected cell count less than 1 and at most 20% of expected cell counts less than 5. A $P <$ 0.05 was considered statistically significant.

RESULTS

In this study, 160 patients were randomly assigned to two groups: 80 patients were included in the study group and the other 80 patients were included in the control group. The patients' demographics and clinical characteristics are shown in **Table 1**. The mean age was 71.3 ± 6.1 years in the study group and 69.8 ± 7.4 years in the control group, respectively. There was no significant difference between the two groups in terms of body mass index (P = .37), international prostate symptom score (IPSS) (P = .30), prostate volume (P = .66), operation time (P = .17), or preoperative indwelling catheter (P = .60).

Comfort is the first feeling expressed by inpatients and one of the important indicators for evaluating nurs-

Table 2. Comparisons of clinical outcomes between two groups

Variables, n (%)	Study Group (n=80)	Control Group (n=80)	*P* value
Comfort			
Very comfortable	47 (58.8)	39 (48.8)	-
Normally comfortable	31 (38.8)	32 (40.0)	-
Uncomfortable	2 (2.4)	9 (11.2)	-
Overall comfort	78 (97.5)	71 (88.7)	.023*
Amount of irrigation fluid, L	26.4 ± 3.7	27.8 ± 3.2	.011*
Hospital stays, d	3.3 ± 0.8	3.6 ± 0.5	.005**
Complications	1 (1.3)	7 (8.8)	.021*
Bleeding	0 (0.0)	2 (2.5)	-
Urinary tract infection	0 (0.0)	2 (2.5)	-
Incontinence	0 (0.0)	2 (2.5)	-
Cystospasm	1 (1.3)	1 (1.3)	-

SD = standard deviation;
*$P < 0.05$, **$P < 0.01$.

ing satisfaction. The levels of comfort included very comfortable, normally comfortable, and uncomfortable (**Table 2**). In this study, patients' overall comfort in the study group was significantly higher than that in the control group (97.50% vs. 88.75%, *P* = .023). Meanwhile, the average amount of irrigation fluid in the study group was obviously lower than that in the control group (26.4 L vs. 27.8 L, *P* = .011). In addition, patients in the study group had a significantly shorter hospital stay than the controls (3.3 days vs. 3.6 days, *P* = .005). With respect to the secondary important variables, complications could not be ignored. They mainly included bleeding, urinary tract infection, incontinence, and cystospasm. The overall incidence of complications in the study group was significantly lower than that in the control group (1.25% vs. 8.75%, *P* = .021). No other serious complications occurred in both groups.

DISCUSSION

The incidence rate of BPH is higher in middle-aged and elderly men. Mild BPH patients are usually treated with drugs, but they can only maintain the state of illness and cannot alleviate the disease. With extension of the course of the disease and aggravation of the disease, most patients need to undergo surgery to remove the focus to alleviate the clinical symptoms and signs(11,12). Transurethral resection of the prostate offers advantages, such as less trauma and quick recovery, but it is still an invasive operation, which causes certain damage to tissues around the focus(13). In addition to the influence of the patient's psychological factors, physical factors, cognitive factors, and other factors, postoperative complications, such as bleeding, urinary tract infection, and cystospasm, can easily develop, which not only affects recovery from the disease, but also reduces the quality of life of the patient(14). Therefore, it is very important to take comprehensive nursing measures while implementing prostate surgery to prevent complications, improve patient comfort, and promote recovery.

Continuous bladder irrigation is required after TURP, and the color of the flushing fluid is particularly important(15). Some hospitals have innovatively put forward the concept of a colorimetric card, i.e., they routinely use urine drainage bags to collect patients' urine, and then the nurses compare the colorimetric card through bladder flushing and carry out corresponding follow-up operations according to the color of urine released (9,10). The self-made bladder flushing colorimetric card has good practicability and scientificity. It uses the patient's blood to dilute the ratio, and applies the color of the colorimetric card corresponding to the flushing speed to bladder flushing after TURP, which provides an objective basis for the nursing staff to adjust the bladder flushing speed. At the same time, it is helpful for the nursing staff to master the key points of bladder flushing and ensure smooth implementation of bladder flushing. However, the bladder flushing colorimetric card also has its own disadvantages. Its overall efficiency is low. When the light changes, it may affect the contrast effect, and the error is large. Therefore, we propose a sensor device for the bladder flushing effect to solve the above-described problems of the colorimetric card. Through application of the CBI sensor device, the observation points of bladder irrigation were better, faster, and more stably mastered, and the level of specialized nursing was improved. Our study showed that the average amount of irrigation fluid in the study group was obviously lower than that in the control group (26.4 L vs. 27.8 L, *P* = .011). In addition, patients in the study group had a significantly shorter hospital stay than the controls (3.3 days vs. 3.6 days, *P* = .005). To a certain extent, the workload of nursing staff is reduced, and the work efficiency of nursing staff and accuracy of disease observation records are improved(16). In clinical practice, due to lack of a unified color standard for the bladder irrigation fluid, subjective and vague colors of the irrigation fluid, such as blood and light blood, are often used in nursing records, which lack the accuracy, dynamicity, and objectivity required by nursing documents(17). For application of this specific CBI device, there are eight different color numbers in the system. When dark red and bright red colors appear, the system will send an alarm, and the nursing staff will be on the scene in time to deal with them, instead of observing the patient's urine color every hour, which not only unifies the judgment standard of the color of the CBI, and accurately observes and records the dynamic changes in the patient's condition, but also ensures the objectivity and authenticity of the nursing documents.

The purpose of our study is to explore the efficacy and safety of the CBI device in patients after TURP. Comfort and complication rate are important evaluation indicators(18). Before the operation, the responsible nurse should do a good job of spreading awareness about the relevant knowledge among the patients and their families, so that they can understand the method of using the device and the basic situation after the operation. At the same time, it can better cooperate with the postoperative nursing work, reduce the blindness of seeking medical staff due to anxiety of patients' families about the color of drainage fluid. In this study, patients' overall comfort in the study group was significantly higher than that in the control group (97.50% vs. 88.75%, *P* = .023). However, the most common complication after TURP is bladder spasm, which increases the pain of patients, prolongs the hospitalization time, and increases the economic burden on patients(19,20). Repeated bladder spasm can easily lead to secondary bleeding and urinary tract infection, and it can seriously affect postoperative rehabilitation of patients(21). The incidence of complications in the study group was significantly lower than that in the control group (1.25% vs. 8.75%, *P* = .021). Therefore, application of this CBI sensor device offers many advantages, such as standardizing the bladder irrigation speed, reducing the incidence of bladder spasm, improving the timely treatment rate of bleeding, decreasing the amount of bladder irrigation fluid, lessening the economic burden on patients, promoting the rehabilitation of patients, improving the comfort of patients, and reducing postoperative complications.

However, this study has some limitations. The time for follow-up was short and it may have affected the outcome. Furthermore, we only counted the relevant symptoms through the patient's main complaint, which may have caused subjective deviation. Finally, the study was based on a single center with a small sample size, and there may have been a certain amount of sampling error. Therefore, large-scale, multicenter, prospective studies are required to further prove the above conclusions. It is likely that the ideal procedure will be formulated through a long period of clinical application and observation.

CONCLUSIONS

Implementation of a new self-improved CBI sensor device for patients after TURP can improve the patients' awareness regarding disease-related knowledge, alleviate their fear and anxiety, improve their compliance and comfort with treatment and nursing, and reduce the incidence of complications. In our opinion, this method is safe and reproducible in clinical practice; however, large-scale, multicenter, prospective studies are required to further prove the above conclusions.

CONFLICT OF INTEREST

The authors declare that they have no competing financial interests.

Availability of Data and Materials

The datasets used and analysed during the current study available from the corresponding author on reasonable request.

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