Clinical Trial/Experimental Study

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A novel automatic regulatory device for continuous bladder irrigation based on wireless sensor in patients after transurethral resection of the prostate

A prospective investigation

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Abstract

Background: Benign prostatic hyperplasia is a common progressive disease in aging men, which leads to a significant impact on daily lives of patients. Continuous bladder irrigation (CBI) is a supplementary option for preventing the adverse events following transurethral resection of the prostate (TURP). Regulation of the flow rate based on the color of drainage bag is significant to prevent the clot formation and retention, which is controlled manually at present. To achieve a better control of flow rate and reduce inappropriate flow rate–related adverse effects, we designed an automatic flow rate controller for CBI applied with wireless sensor and evaluated its clinical efficacy.

Methods: The therapeutic efficacy was evaluated in patients receiving the novel automatic bladder irrigation post-TURP in the experimental group compared with controls receiving traditional bladder irrigation in the control group.

Results: A total of 146 patients were randomly divided into 2 groups—the experimental group (n=76) and the control group (n=70). The mean irrigation volume of the experimental group (24.2±3.8 L) was significantly lower than that of the controls (54.6±5.4 L) ($P<0.05$). Patients treated with automatic irrigation device had significantly decreased incidence of clot retention (8/76) and cystospasm (12/76) compared to controls (21/70; 39/70, $P<0.05$). There was no significant difference between the 2 groups with regard to irrigation time (28.6±2.7 vs 29.5±3.4 hours, $P=0.077$).

Conclusion: The study suggests that the automatic regulating device applied with wireless sensor for CBI is safe and effective for patients after TURP. However, studies with a large population of patients and a long-term follow-up should be conducted to validate our findings.

Abbreviations: BPH = benign prostatic hyperplasia, CBI = continuous bladder irrigation, TURP = transurethral resection of the prostate.

Keywords: automatic regulating device, continuous bladder irrigation, transurethral resection of the prostate, wireless sensor

1. Introduction

Benign prostatic hyperplasia (BPH) is a common disease in older men with age of more than 50 years.[1] BPH is characterized by the enlargement of the prostate and clinically associated with lower urinary tract symptoms. Although BPH is not a life-threatening disease, it has been a health concern and significantly affected the life quality of patients.[2] The current therapies for BPH mainly include transurethral resection of the prostate (TURP) and open prostatectomy.[3] However, the TURP is commonly associated with adverse events in patients following surgery, thus the adjuvant therapy options for preventing the complications are urgently needed.

Continuous bladder irrigation (CBI) is a supplementary approach for BPH management after surgery with a view to preventing clot retention, cystospasm, and hemorrhage postoperatively.[4] Besides, CBI has been proposed to inhibit the hemorrhagic cystitis[5] and increase the survival rate following stem cell transplantation.[6] Although CBI is widely used for preventing the complications following TURP, it is not easy for nurses to take CBI for patients.[7] Nurses are responsible for ensuring a continuous flow of prescribed solution during the whole procedure. Thus, it is imperative to assess the blocked catheter by checking the color of drainage bag and controlling the flow rate.[7] Currently, the flow rate of irrigation fluid is controlled manually by nurse according to the color of drainage fluid. Inappropriate flow rate may result in adverse effects such as clot retention, cystospasm, and hemorrhage. However, research

Editor: Miao Liu.

Funding/support: The work was supported by Social Development fund of Nantong (BK2013020).

The authors have no conflicts of interest to disclose.

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Medicine (2016) 95:52(e5721)

Received: 16 June 2016 / Received in final form: 28 November 2016 / Accepted: 28 November 2016

http://dx.doi.org/10.1097/MD.0000000000005721

references of the manual to control the flow rate are rare. In order to achieve a better control of flow rate of irrigation fluid and reduce inappropriate flow rate–related adverse effects, we designed the automatic flow rate controller for bladder irrigation applied with wireless sensor and evaluated its clinical efficacy for patients after TURP. We expect that our study would provide therapeutic implication for patients undergoing CBI.

2. Methods

2.1. Patients and groups

Between July 2013 and July 2014, a total of 146 patients with BPH who were admitted in the urology department of our hospital were included in our study. All the patients underwent TURP and then were subjected to CBI. The age of the included patients ranged from 58 to 80 years, and the prostate volume was less than 80 mL based on transrectal ultrasonography. Patients with coagulation disorders, infectious, cardiovascular, and cerebrovascular diseases were excluded from this study. Magnetic resonance and needle puncture were conducted to exclude patients with prostatic cancer.

The included patients were randomly divided into experimental and control groups based on the odevity of admission number. Patients in the control group received conventional bladder irrigation with 0.9% saline solution. Those patients in the experimental group were irrigated with automatic regulating device applied with wireless sensor. All the patients or their parents provided informed consent before the study. Approval was obtained from the ethics committee of the Second Affiliated Hospital of Nantong University.

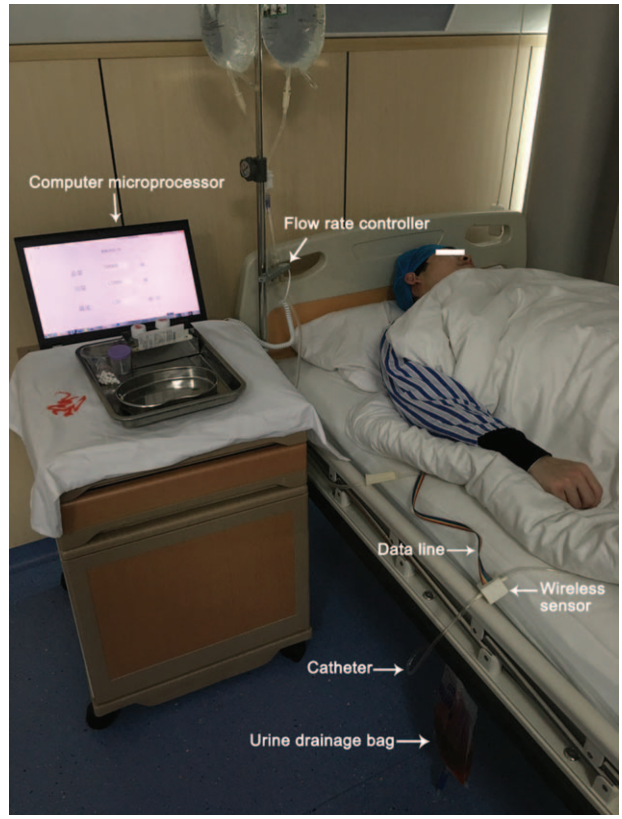

Figure 1. The clinical construction of the automatic regulating device for continuous bladder irrigation.

2.2. Conventional bladder irrigation

The bladder irrigation was performed for patients in the control group at conventional irrigation rate. The irrigation rate was initially managed at 150 dpm within 2 hours postoperatively. At 2 to 8 hours after operation, the elution drop rate was maintained at 120 dpm. The irrigation rate was then adjusted within 30 dpm based on the color of drainage solution. When the flushing fluid was clear or showed reddish color, the bladder irrigation was stopped.

2.3. CBI with automatic regulating device

In the experimental group, the flow rate of bladder irrigation was controlled using the automatic regulating device. The apparatus of automatic bladder irrigation applied with wireless sensor system was composed of 3 modules, including color monitor for drainage solution, flushing fluid rate adjusting controller, and computer microprocessor (Fig. 1). After TURP, patients were placed in regular hospital beds. The color monitor was mounted on evacuating catheter, and the irrigation adjusting controller was installed in Murphy dropper of flushing line. The light signals for the color change were captured by light/frequency sensor and analyzed by computer microprocessor to automatically adjust irrigation rate (Fig. 1). The system parameters were set by experts according to the individual patient's condition.

2.4. Evaluation

All the patients were followed up until hospital discharge. During the process of bladder irrigation, the irrigation fluid amount and the time of duration were recorded. Clot retention and cystospasm in patients were observed. Besides, the hospital stays of patients were calculated after leaving hospital.

2.5. Statistical analysis

The statistical analysis was performed by SPSS 16.0 software (SPSS Inc., Chicago, IL). All the data were displayed by mean ± SD (standard deviation). Measurement data were analyzed by Student *t* test, and the enumeration data were analyzed by chi-square test. $P < 0.05$ was considered to be significantly different.

3. Results

A total of 146 patients with the mean age of 70.1 years were randomly assigned to experimental (n = 76) and control groups (n = 70). In the control group, there were 68 Han Chinese people and 2 other ethnic people. The patients in the experimental group included 73 Han and 3 other ethnic people. The number of patients with ages ranging from 50 to 70 years was 32 in the control group and 29 in the experimental group. The groups were not significantly different with regard to age, ethnic history, family income, length of illness, BMI, international prostate symptom score, prostate volume, surgery time, and preoperative indwelling catheter ($P > 0.05$, Table 1).

As shown in Table 2, the mean amount of irrigation fluid usage in the experimental group (24.2 ± 3.8 L) was significantly lower than that in the control group (54.6 ± 5.4 L) ($P < 0.05$). The irrigation duration of patients was not significantly different between the experimental and the control groups (28.6 ± 2.7 hours; 29.5 ± 3.4 hours, $P > 0.05$). The bladder irrigation with

Table 1

Comparison of basic characteristics of patients between 2 groups.

Items classification		Experimental group (n=76)	Control group (n=70)	$t/Z/\chi^2$	P
Age, y		69.83±6.11	69.90±5.73	0.072*	0.942
Family income, RMB/mo		5700 (4200–6700)	5750 (4275–6800)	0.035†	0.972
Length of illness, mo		16.00 (13.00–18.75)	15.00 (13.00–18.25)	0.063†	0.950
BMI		23.05±1.80	23.50 (21.78–24.42)	0.006†	0.995
IPSS		27.00 (23.00–29.00)	26.11±3.52	0.466†	0.641
Prostate volume, mL		61.00±10.37	59.96±10.40	0.606*	0.545
Surgery time, min		59.00 (50.00–72.75)	60.00 (50.00–70.00)	0.411†	0.681
Resection volume		44.89±10.16	44.51±10.38	0.224*	0.823
Nation	Ethnic Han	73	68	0.155‡	0.526
	Others	3	2		
Preoperative indwelling catheter	No	53	45	0.491‡	0.484
	Yes	23	25		

BMI = body mass index, IPSS = international prostate symptom score.
* *t* test.
† Mann–Whitney test.
‡ chi-square analysis.

automatic regulating device significantly decreased the incidence of clot retention (8/76) and cystospasm (12/76) in patients of the experimental group compared with the controls (21/70; 39/70, $P<0.05$). In addition, the patients in the experimental group had significantly shorter hospital stays (5.4±1.2 days) than the controls (5.9±1.9 days) ($P<0.05$).

4. Discussion

Currently, the automatic regulatory device for regulating the irrigation fluid of CBI has been less reported. In this paper, as far as we know, we reported a novel automatic CBI apparatus for the first time and tested its clinical efficacy in patients after TURP. The study found that the novel device was safer and more effective than the traditional irrigation method. The application of this device might improve the clinical outcome of patients and promote the recovery of patients. We anticipate that the application of this device will provide valuable insights into the improvements of outcome in patients after TURP.

Our data showed that the incidence rate of clot retention and cystospasm in patients irrigated with automatic regulation device was lower than that in patients with traditional method. It suggests that the automatic regulatory device leads to less-adverse effects and is safer than the traditional method. With regard to the reasons for the difference, in the control group, the flow rate of irrigation fluid is regulated by medical care personnel according to subjective judgment. It is reported that the color recognition for drainage fluid varies for individuals, which leads to incorrect flow rate regulation.[8] Even the color of drainage fluid is observed frequently, the transient changes of color cannot be captured by nurses, which may increase the risk for blood clots formation, cystospasm, and clot retention. In contrast, in the experiment group, the patients were treated with the automatic regulatory device, and the automatic bladder irrigation system was capable to detect the color change timely. In order to realize the quantitative relation between color and flow rate, different stages of color were labeled with flow rate in the computer microprocessor. Therefore, the flow rate was regulated objectively and accurately.

In addition, our results showed that mean irrigation volume in the experimental group (24.2±3.8 L) was significantly lower than that in the control group (54.6±5.4 L) ($P<0.05$). This observation might be due to the fact that with the traditional bladder irrigation, the flow rate was regulated at liberty based on subjective experience. Based on the clinical experience, the medical care personnel or patients' family members are inclined to regulate the flow rate faster than theory value, which may increase the irrigation volume. However, fast flow rate cannot prevent the complications of bladder irrigation. The automatic bladder irrigation system was characterized by accurate control, real-time monitor, and automatic adjustment. Therefore, in the experimental group, the flow rate was regulated accurately. Moreover, there were no significant differences with regard to irrigation time and hospital stay between the 2 groups, which suggests that the novel irrigation system does not lengthen the time of irrigation and hospital stays of patients.

In recent years, although color chart has been designed for controlling the flow rate of bladder irrigation, the flow rate is adjusted manually,[7] which may lead to blood clots formation and retention following irrigation. In this paper, novel automatic

Table 2

Clinical results of bladder irrigation in patients of 2 groups.

Items		Experimental group (n=76)	Control group (n=70)	P
Amount of irrigation fluid, L		24.2±3.8	54.6±5.4	0.000
Irrigation duration, h		28.6±2.7	29.5±3.4	0.077
Hospital stays, d		5.4±1.2	5.9±1.9	0.002
Catheter obstruction (n)	Yes	8	21	0.003
	No	68	49	
Cystospasm (n)	Yes	12	39	0.000
	No	64	31	

regulatory device for CBI based on wireless sensor was designed. The red–green–blue color/frequency sensor module was applied, which consisted of white light source, transparency window, transparency window, and wireless communication part. The output frequency of color/frequency sensor showed linear relation with light intensity. The color data of the drainage solution in the catheter were processed by 32-bit ADuC7026 microprocessor, and the flow regulation was conducted by stepping motor driving by general-purpose input/output. The whole process involved digital data process and digitization, which enhanced the accuracy. Besides, compared with traditional CBI, the color changes of the drainage solution were monitored in the pipe in real time, which also contributed to the accuracy.

The study also has some limitations. First, it has a limited sample size. Second, the follow-up is not long enough. A larger number of patients with a longer follow-up are necessary to test the maintenance of clinical efficacy of this automatic bladder irrigation device before its wide application in clinical practice.

In conclusion, the automatic bladder irrigation device promotes digitization of drainage color and controls the flow rate in a standardized manner. Compared with the traditional bladder irrigation, the novel automatic bladder irrigation decreased the incidence of complications following irrigation. The study suggests that it is a safe and effective method for patients after TURP. Our work provides novel insights into flow rate regulation of bladder irrigation.

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