

# *Clinical application of huang'e capsule after surgery for prostatic hyperplasia*

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**Abstract:** The purpose of this study was to observe the clinical effect and safety of huang'e capsule on the improvement of symptoms after surgery for benign prostatic hyperplasia. We used random sampling to divide 14 patients with benign prostatic hyperplasia into the experimental group and the control group, with 7 cases in each group. The experimental group was given 4 capsules each time, 3 times a day for 42 days after surgery, while the control group did not receive the treatment of huang'e capsules. The International Prostatic Hyperplasia Symptom Score (I-PSS), Maximal Uroflow Rate Change (Q<sub>max</sub>), Quality of Life Score (QOL) and liver and kidney function indexes were observed in the two groups before and after surgery. The results shows that the postoperative I-PSS, Q<sub>max</sub> and QOL of the two groups were significantly improved ( $P < 0.05$ ), while the efficacy of the experimental group was better ( $P < 0.05$ ). The liver and kidney function indexes of the experimental group before and after treatment were within the normal range. It was concluded that Huang'e capsule could effectively improve the postoperative clinical efficacy of patients with prostatic hyperplasia and had good safety.

## 1. Introduction

Benign prostatic hyperplasia (BPH) is a complex senile disease and one of the most typical urological diseases common in middle-aged and elderly men. Studies have shown that nearly 70 percent of men aged 60 to 69 years and 80 percent of men over 70 years of age have some degree of prostate enlargement <sup>[1-2]</sup>. Although the symptoms of patients with postoperative results have been improved, there are still complications such as poor urination, urethral stricture, and urinary tract infection <sup>[3]</sup>. Therefore, it is of great significance to explore drugs to reduce postoperative complications of BPH for the clinical treatment of BPH. huang'e capsule has the effect of treating qi deficiency, blood stasis, and damp-heat blockade. However, at present, there are few clinical studies on the effect of huang'e capsule on the postoperative treatment of prostatic hyperplasia. Based on this, this study discussed the clinical effect and safety of huang'e capsule on the improvement of postoperative symptoms of BPH, and provided guidance for the postoperative treatment of BPH.

## 2. Information and Methods

### 2.1 General Information

The clinical data of 14 patients with benign prostatic hyperplasia who went to the Department of Urology, Enze Hospital, Taizhou Enze Medical Center for inpatient surgery from October 2022 to April 2023 were collected, and they were divided into observation group and control group with 7 cases in each group by random number notation. The average age of the observation group was  $(71.43 \pm 9.9)$  years, and the average duration of the disease was  $(4.43 \pm 3.4)$  years, while the average age of the control group was  $(77.57 \pm 8.6)$  years, and the average duration of the disease was  $(2.92 \pm 3.2)$  years. There was no significant difference in gender, age, course of disease, and condition between the two groups ( $P > 0.05$ ).

#### 2.1.1 Diagnostic Criteria for BPH

(1) Men over 50 years old. Difficulty urinating, hesitation, thinning of urine line, difficulty in urination, interruption of urine flow, increased frequency of urination at night, urinary retention or urinary incontinence;(2) Digital anal examination: enlargement, smoothness and elasticity of the two lobes, and fading or disappearance of the central sulcus;(3) B ultrasound examination: the volume of the prostate is examined by B ultrasound of the urinary system, and the enlarged volume of the prostate reaches more than  $20\text{mm}^3$ . B-ultrasound examination is performed to detect changes in bladder capacity, bladder wall, and the presence of bladder stones, diverticulum, tumors, and midlobe hyperplasia [4].

#### 2.1.2 Indications for Surgery

There are two indications for BPH, one is absolute and the other is relative. Absolute indications for surgery mainly refer to multiple urinary retention (and at least 2 indwelling catheters cannot be withdrawn after 7 days of catheterization), recurrent gross hematuria, secondary bladder stones, secondary renal impairment, recurrent urinary tract infections, and secondary bladder diverticulum. Except for diabetes, coronary heart disease, cerebral thrombosis and other serious systemic diseases. The relative indications mainly refer to the residual urine volume  $> 60\text{ml}$ , the maximum urinary flow rate  $< 10\text{mL/s}$ , moderate to severe symptoms, unwillingness to accept other treatments, and poor drug treatment effect. Postoperative efficacy evaluation indicators: increased urine flow, thickened urine line, and absence of urinary incontinence [5].

#### 2.1.3 Inclusion Criteria

The inclusion criteria for patients with benign prostatic hyperplasia for this trial are: meeting the diagnostic criteria for moderate or severe prostatic hyperplasia, having an indication for surgery for prostatic hyperplasia and completing prostatic hyperplasia excision, not taking drugs related to prostatic hyperplasia treatment in the past 1 week of onset, informed consent, voluntary to be tested, and willing to sign the informed consent form.

#### 2.1.4 Exclusion Criteria

Patients with benign prostatic hyperplasia were excluded from the following criteria: neurogenic bladder disease caused by intervertebral disc herniation, lower abdomen and pelvic surgery, patients with stage 3 prostatic hyperplasia combined with renal impairment, patients taking other drugs for the treatment of prostatic hyperplasia after the onset of the disease, patients with severe cardiovascular disease, blood disease, liver and kidney disease, etc., patients who were prone to loss

to follow-up, and patients who were allergic to the drugs used in this study.

## 2.2 Treatment

The patients in both groups were treated with prostatic hyperplasia, and were routinely treated with anti-inflammatory, analgesic, levator anal exercises, and bladder irrigation after surgery. The experimental group was given huang'e capsule orally 1 day after surgery (Zhejiang Kangenbei Pharmaceutical Co., Ltd., Guoyao Zhunzi Z20110006) (huang'e capsule is composed of 12 traditional Chinese medicines such as motherwort, coix seed, Poria cocos, huang'e membranaceus, rhubarb, and curcuma) 4 capsules each time, 3 times a day, for 42 days, and the control group did not receive the treatment of huang'e capsules.

## 2.3 Observation Indicators

The changes of maximum urinary flow rate (Qmax), International Prostate Symptom Score (I-PSS score), Quality of Life Index Evaluation Form (QOL score), creatinine value, alanine aminotransferase,  $\gamma$ -glutamyl aminotranspeptidase and aspartaminotransferase were observed in the two groups one month after surgery.

## 2.4 Statistical Methods

All continuous data were expressed as mean  $\pm$  standard deviation, and the mean between the two groups before and after treatment was t-test for independent samples, and the paired t-test was used for comparison before and after treatment within the group, and the statistical analysis was performed by SPSS20.0 statistical software, and the two-sided test P was used  $<0.05$  was considered a statistically significant difference.

## 3. Experimental Results

The Qmax, I-PSS score and QOL score of the two groups before treatment are shown in Table 1, and there was no significant difference between the two groups ( $P>0.05$ ), which was comparable.

The creatinine values, alanine aminotransferase,  $\gamma$ -glutamyl aminotranspeptidase and aspartaminotransferase values in the experimental group before and after treatment are shown in Table 2, and the indicators before and after treatment in the experimental group were all within the normal range, indicating that the intervention safety of huang'e capsule was good, and there was almost no damage to liver and kidney function and no adverse reactions were found.

The Qmax, I-PSS score and QOL score of the two groups before and after treatment are shown in Table 3, and the analysis of experimental data showed that the Qmax in the experimental group increased by  $(10.74 \pm 8.02)$  mL/s compared with that before treatment, and the Qmax in the control group increased by  $(7.70 \pm 11.21)$  mL/s after treatment, and the IPSS score in the experimental group decreased by  $(13.14 \pm 6.82)$  compared with that before treatment, the I-PSS score of the control group decreased  $(8.14 \pm 5.34)$  after treatment, the QOL score of the experimental group decreased  $(2.43 \pm 0.53)$  points compared with that before treatment, and the QOL score of the control group decreased by  $(1.29 \pm 1.25)$  points compared with that before treatment. There were statistically significant differences in the experimental group ( $P<0.05$ ), while the I-PSS score and QOL score in the control group were statistically significant ( $P<0.05$ ), and Qmax was not statistically significant ( $P>0.05$ ). The Qmax, I-PSS score and QOL score between the two groups after treatment are shown in Table 4, and the difference in Qmax between the experimental group and the control group was  $(3.04 \pm 5.21)$  mL/s, the difference between the I-PSS score between the experimental group and the

control group was  $(-5.00 \pm 3.27)$ , and the difference between the experimental group and the control group was  $(-1.14 \pm 0.51)$  points. The improvement trend of Qmax, I-PSS score and QOL score in the experimental group was better than that in the control group, and the Qmax and QOL scores were statistically significant ( $P < 0.05$ ), while the I-PSS score was not statistically significant ( $P > 0.05$ ). These results indicated that huang'e capsule had a good clinical effect on improving I-PSS, QOL and Qmax in patients with prostatic hyperplasia.

Table 1: Pretreatment clinical indicators of the two groups

	Qmax(mL/s)		I-PSS score (points)		QOL score (points)	
	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group
Before treatment	6.31 ±3.87	9.27 ±6.44	29.57 ±2.14	27.42 ±2.76	4.71 ±0.48	4.57 ±0.53
P Value	0.31		0.13		0.61	

Table 2: Safety evaluation of the experimental group

	Creatinine clearance (ml/min)	Alanine aminotransferase (U/L)	γ-Glutamyl transpeptidase(U/L)	Aspartate aminotransferase (U/L)
Before medication	73.82 ±13.50	27.57 ±17.55	29.00 ±11.76	23.14 ±4.56
After medication	66.02 ±15.39	21.57 ±10.83	34.14 ±11.27	16.00 ±3.91

Table 3: Comparison of clinical indicators between the two groups before and after treatment

	Qmax(mL/s)		I-PSS score (points)		QOL score (points)	
	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group
Before treatment	6.31 ±3.87	9.27 ±6.44	29.57 ±2.14	27.42 ±2.76	4.71 ±0.48	4.57 ±0.53
After treatment	17.05 ±6.40	16.97 ±7.83	16.42 ±7.76	19.28 ±6.77	2.28 ±0.48	3.28 ±1.11
Within-group differences	10.74 ±8.01	7.7 ±11.21	-13.14 ±6.81	-8.14 ±5.33	-2.42 ±0.53	-1.28 ±1.25
P-value (within group)	0.01	0.11	0.00	0.00	0.00	0.03

Table 4: Comparison between the two groups after treatment

	Qmax(mL/s)		I-PSS score (points)		QOL score (points)	
	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group
After treatment	17.05 ±6.40	16.97 ±7.83	16.42 ±7.76	19.28 ±6.77	2.28 ±0.48	3.28 ±1.11
Between groups	3.04 ±5.21		-5.00 ±3.27		-1.14 ±0.51	
P-value (between-group)	-1.30		0.15		0.04	

#### 4. Conclusions

Surgical treatment of BPH is indicated for patients with more severe symptoms. Although the clinical symptoms of some patients with BPH have been improved after surgical treatment, there are still complications such as poor urination, urethral stricture, and urinary tract infection, which makes some patients who need surgery give up the opportunity for surgical treatment, which

increases the pain and medical expenses of patients <sup>[6]</sup>. Therefore, it is of great significance to provide targeted treatment or prevention of postoperative urinary abnormalities <sup>[7]</sup>.

With the development of TCM theories and proprietary Chinese medicines, there are more options for the treatment of BPH. The advantage of Chinese patent medicine treatment is that Chinese patent medicine has the characteristics of multi-target and holistic action, so its efficacy is not limited to the local part of a certain disease. Proprietary Chinese medicine is not only a cure or alleviation of a disease in Western medicine, but even exceeds the diagnostic criteria, but it is a symptom within the scope of TCM syndrome. For example, in BPH patients, different individuals may have differences in yang deficiency or yin deficiency, and the treatment of Western medicine may alleviate some typical symptoms of BPH, but the systemic symptoms of yin deficiency or yang deficiency may not be alleviated, while the treatment of Chinese patent medicine is different, because it can take into account other symptoms other than the typical manifestations of BPH, so as to alleviate the clinical symptoms of each patient to the greatest extent.

Benign prostatic hyperplasia belongs to the category of "seizure" in traditional Chinese medicine. The disease is mostly caused by kidney qi deficiency in old age, unfavorable qi, poor blood flow, and kidney and bladder dysfunction <sup>[8-9]</sup>. The treatment of benign prostatic hyperplasia with proprietary Chinese medicine mainly follows three principles: tonifying the kidney, regulating blood, and dispelling dampness <sup>[10]</sup>. huang'e capsule is mainly composed of 12 flavors of traditional Chinese medicine such as huang'e, curcuma, peach kernel, rhubarb, etc., which is mainly based on natural plant medicines, compared with Western medicine, not only low price, exact curative effect, but also safe to use. huang'e membranaceus has the effect of invigorating qi and solidifying the surface, diuresis and reducing swelling, and is an important qi-tonifying drug; peach kernel has the effect of invigorating blood and removing blood stasis, especially in the treatment of bladder congestion. The combination of the two has the effects of invigorating qi and invigorating blood, dissipating blood stasis, diuretic drenching, antibacterial and anti-stress, Curcuma, rhubarb, prunella vulgaris, motherwort and Poria cocos have the effects of invigorating blood and qi, clearing heat and water, and diuresis and reducing swelling; the bitter cold taste of northern bean root can help Poria cocos to remove fire, while cinnamon is warm and can restrain the shortcomings of Prunella vulgaris, rhubarb, northern bean root, and Poria cocos that are too bitter and cold, and Sichuan hyssop can lead medicine downward, thus playing a therapeutic role <sup>[11]</sup>. According to the different effects of each component, it assists and restricts the interaction, so as to achieve the effect of mild dispelling disease, treating qi deficiency and blood stasis, damp-heat blockade, and has a good effect on the lower urinary tract symptoms caused by BPH. At the same time, many studies have been done on the mechanism of huang'e capsule on BPH in China, which has the effects of resisting platelet aggregation, dilating blood vessels, improving microcirculation, increasing local blood flow, and reducing inflammation and relieving pain, as well as inhibiting  $\alpha 1$  receptors and  $5\alpha$  reductase in canine prostate tissue <sup>[12-13]</sup>, which can improve the symptoms of prostatic hyperplasia through diuretic, anti-inflammatory, anti-congestant, heat clearing and detoxification. However, there are few clinical studies on its clinical efficacy after prostatic hyperplasia, so this study has certain significance.

In this study, the clinical efficacy of huang'e capsule in the treatment of prostatic hyperplasia after surgery was observed, and the results showed that the Qmax, I-PSS score and QOL baseline of the two groups were balanced and comparable ( $P>0.05$ ), indicating that there was no statistical difference between the two groups before treatment. There were statistically significant differences in the experimental group ( $P<0.05$ ), while the I-PSS score and QOL score in the control group were statistically significant ( $P<0.05$ ), and Qmax was not statistically significant ( $P>0.05$ ). Compared with the difference between groups, the improvement trend of Qmax, I-PSS score and QOL scale score in the experimental group was better than that in the control group, and the Qmax and QOL

scores were statistically significant ( $P < 0.05$ ), but the I-PSS scores were not statistically significant ( $P > 0.05$ ). The subjective symptoms of all patients improved to varying degrees after treatment, and the improvement in the observation group was better than that in the control group. In addition, the liver function indexes of the observation group were within the normal range during the whole treatment process, and the renal function index (creatinine clearance rate) did not change much, which had a good clinical safety.

Analysis of the possible reasons for the non-statistically significant I-PSS score: the experimental subjects were elderly, and there were factors such as speech barriers, communication difficulties, and poor compliance, which led to a large loss of test subjects. At the same time, the number of enrolled cases collected in November-December 2022 was lost due to the liberalization of the new crown epidemic, which in turn led to too small a sample size. According to the possible shortcomings of the current study design and the actual completion of the sample size evaluation, the statistical results of this study are only for reference (can be used as exploratory research positioning) to provide a reference for subsequent confirmatory studies.

The results of this study showed that huang'e capsule could effectively improve the clinical efficacy of patients with prostatic hyperplasia after surgery, and had a good safety profile.

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