Effectiveness of Portable Ultrasonic Scalpel for Urology Surgery: A multi-center prospective controlled clinical trial in China

ISPOR 2025
#ISPORAnnual

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BACKGROUND & OBJECTIVES

- In recent years, urology has been rapidly developed, gradually transforming into precise medicine.
- Ultrasonic scalpels are widely used in urology surgery at present. Although portable ultrasonic scalpels have appeared, which are easy and convenient to use and install, the existing clinical evidence on their safety and effectiveness is scarce.
- This study aimed to evaluate the clinical effectiveness of portable ultrasonic scalpels applied in urology surgery and compare their safety and effectiveness with traditional ultrasonic scalpels, providing evidence for clinical decision-making

portable ultrasonic scalpel

traditional ultrasonic scalpel

METHODS

- From February to August 2023, a multi-center, non-randomized, prospective, controlled clinical trial was conducted in three tertiary hospitals in China.
- Intervention group: 45 urological patients treated by portable ultrasonic scalpels
- Control group: 45 urological patients treated by traditional scalpels with the same period of hospitalization
- The basic information and clinical data of patients were collected. The quality-of-life data were obtained by the EQ-5D-5L scale at preoperative, discharge, one month, and three months after surgery, respectively.
- The descriptive analysis and generalized linear model were used in the data analysis.

RESULTS

- A total of 82 patients were included in the study: 39 in the intervention group and 43 in the control group
- The average hospital stays, intraoperative blood loss, and postoperative blood loss in the intervention group were lower than those in the control group (P > 0.05).
- From baseline to discharge, the decrease in QALYs in the intervention group was smaller (-0.134 vs. -0.287, P<0.05).
- During the follow-up period, there were no significant differences in the changes in QALYs between the two groups.
- The decline in QALYs was significantly influenced by variables such as intraoperative blood loss and surgical site.

Baseline Characteristics

Basic situation	Portable group (n=39) number (%)	Control group (n=43) number (%)	χ2	P
Sex			0.125	0.723
Male	23(58.97)	27(62.79)		
Female	16(41.03)	16(37.21)		
Age			1.893	0.595
<50 yr	8(20.51)	13(30.22)		
50-60 yr	12(30.77)	10(23.26)		
60-70 yr	12(30.77)	10(23.26)		
≥70 yr	7(17.95)	10(23.26)		
BMI			3.099	0.377
<18.5	1(2.56)	2(4.65)		
18.5-24.0	14(35.90)	19(44.19)		
24.0-28.0	15(38.46	18(41.86)		
≥28.0	9(23.08)	4(9.30)		
Health Insurance			1.301	0.729
Basic medical insurance for urban and rural residents	15(38.47)	19(44.19)		
Basic medical insurance for employees	22(56.41)	23(53.49)		
Socialized medicine	1(2.56)	0(0.00)		
Out-of-pocket	1(2.56)	1(2.32)		
Tumor nature			0.186	0.666
Benign	20(51.28)	20(46.51)		
Malignancy	19(48.72)	23(53.49)		
Surgical site			4.966	0.291
Renal	20(51.28)	16(37.21)		
Adrenal gland	14(35.90)	16(37.21)		
Prostate	4(10.26)	10(23.25)		
Ureter	1(2.56)	0(0.00)		
Bladder	0(0.00)	1(2.33)		

Surgical effectiveness indicators

- The average hospitalization days（8.08±2.83days vs 9.12±4.11days）, intraoperative blood loss（88.54±170.01ml vs 117.91±304.58ml）, postoperative blood loss（112.31±185.73ml vs 142.60±275.17ml） and consumables costs（13524.93±4828.74 CNY vs 13832.54±6040.40 CNY） in the portable ultrasound knife group were lower than those in the control, with no significant difference.

Changes in quality-of-life

- The EQ-VAS score at discharge of the intervention group was higher than that of the control group (73.67±16.29 vs 67.51±11.54, P=0.05).
- The reduction in QALYs from baseline to discharge was smaller in the intervention group (-0.134 vs -0.287, P<0.05)

QALYs and EQ-VAS scores of urology patients in different groups at different time points

Group	Time point	QALY means (SD)	EQ-VAS score means (SD)
Portable ultrasonic scalpels group	Baseline	0.880(0.161)	74.74(18.85)
	At discharge	0.746(0.272)	73.67(16.29)
	One month after surgery	0.962(0.056)	77.92(12.42)
	Three months after surgery	0.963(0.098)	83.41(10.32)
Control group	Baseline	0.921(0.077)	73.79(15.15)
	At discharge	0.634(0.335)	67.51(11.54)
	One month after surgery	0.950(0.080)	77.44(12.46)
	Three months after surgery	0.968(0.053)	81.23(10.50)

CONCLUSIONS

- There were no significant differences in baseline characteristics or changes in QALY between the intervention and control groups.
- Portable ultrasonic scalpels in urology surgery may be equally effective as traditional ones in clinical outcomes, with additional benefits in reducing QALY decline at discharge.
- Further research with large samples and long-term follow-up should be conducted.