

#### **Original Research**

# Stress urinary incontinence after holmium laser enucleation of prostate: incidence and risk factors

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#### Abstract

**Background and objective**: To evaluate the incidence and the risk factors of stress urinary incontinence (SUI) during the first year following Holmium Laser Enucleation of the Prostate (HoLEP). **Materials and methods**: Our monocentric and retrospective study includes 155 patients who underwent HoLEP for benign prostatic hyperplasia. Surgeries were performed by 2 expert surgeons. The continence was evaluated before and after surgery at 1, 3, 6 and 12 months. The predictive factors of SUI were analysed using logistic regression. **Results**: The SUI rate at 1, 3, 6 and 12 months was respectively 7.3%, 8.1%, 3.4% and 2.7%. SUI remained present in 4 patients (2.6%) at 12 months. The mean International Consultation Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-SF) score for patients with SUI was respectively 11.69  $\pm$  5.28, 8.70  $\pm$  4.24, 1.81  $\pm$  3.53 and 8  $\pm$  4.24 at 1, 3, 6 and 12 months (p < 0.05). Body Mass Index (BMI) >30 (Odds Ratio (OR), 4.69; 95% Confidence Interval (CI), 1.51–14.52; p = 0.007) and patients over 70 years old (OR, 16.23; 95% CI, 1.96–134.09; p = 0.010) were respectively identified as independent risk factors for SUI at 1 and 3 months. **Conclusions**: SUI after HoLEP is transitory in most cases. It is favoured by a high BMI and an age over 70. These criteria should be considered before choosing the operative technique and preventive measures must be taken in high-risk patients.

Keywords: Laser; Prostatic hyperplasia; Urinary incontinence; Holmium

# 1. Introduction

Transurethral resection of the prostate (TURP) and open prostatectomy (OP) still remain the "gold standard" surgical treatment for symptomatic benign prostatic hyperplasia (BPH) resistant to medical treatment [1,2].

Holmium laser enucleation of the prostate (HoLEP) has recently become an important alternative treatment modality to TURP and OP [3]. This endoscopic approach enables a complete excision of the adenoma whatever its volume. Compared to TURP and OP, HoLEP improves patients' recovery by reducing blood loss, urinary catheterisation duration and hospitalization length. Moreover, functional results are equivalent to conventional techniques [3,4].

Post-operative stress urinary incontinence (SUI) has been reported after HoLEP, with a negative influence on the patient's quality of life (QoL) [5,6]. The complication can concern up to 16% of patients 3 months after surgery, but is most often transient during the first year [7]. After 1 year, SUI recovery is rare [8].

From a technical point of view, the difference between TURP/OP and HoLEP is the direction of adenoma dissection. In a HoLEP procedure, dissection is carried out retrogradely through the urethral sphincter (trans-sphincter endoscopic enucleation). The method may induce sphincter lesion if the apical adenoma is improperly dissected [9]. Surgeons during their learning phase are especially prone to make this mistake [5]. SUI has nonetheless been reported after HoLEP performed by experienced surgeons [10,11].

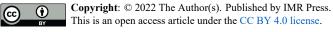
Several studies have identified peri operative urinary incontinence risk factors based on patient-reported data [11,12]. However, only a few studies have used validated urinary incontinence questionnaires to distinguish the different types of incontinence and their incidence [13,14].

The aim of this study was to evaluate the incidence of stress urinary incontinence after HoLEP and identify relevant risk factors.

## 2. Materials and methods

A retrospective monocentric study was performed using observational data from all patients undergoing HoLEP for symptomatic BPH with no satisfactory response to medication therapy between May 2018 and December 2019. The procedure was carried out in patients with moderate to severe lower urinary tract symptoms and/or severe urinary retention and/or other complications related to BPH. Patients with bladder or prostate cancer (except those on active surveillance), urethral stenosis, self catheterization, chronic renal failure or cognitive disorders were excluded from the study. HoLEP procedures were conducted by 2 expert surgeons with each one having an experience of more than 200 HoLEPs.

Enucleation was performed according to the threelobe technique described by Gilling [15] with early apical dissection using the white line technique to differentiate be-



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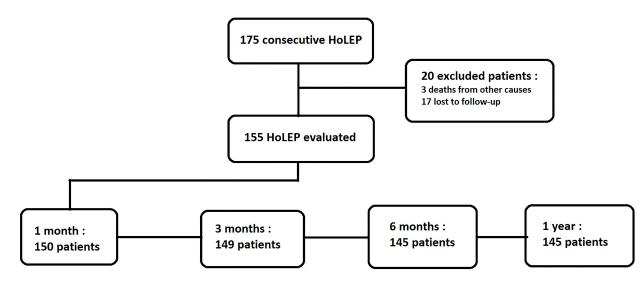


Fig. 1. Flow chart.

tween apical adenoma and urethral sphincter. For enucleation, a reusable 1000  $\mu$  laser fiber was inserted through a 24.5 Fr endoscope and the holmium generator was set to 100 W (2 J, 50 Hz). The Morscope Wolf Piranha<sup>TM</sup> (Richard Wolf GmbH, Knittlingen, Germany) was used for morcellation of the adenoma.

Enucleation of the lobes was carried out using the retrograde approach. The first step was to prepare the bladder neck by making a T incision at 5 and 7 o'clock to avoid ureteral meatus injury during midlobe enucleation. The second step involved detaching each lateral lobe at the apex of the adenoma, starting with a superficial incision of the mucosa at low power (20 W) (white line technique). The posterior incision opposite the veru (hockey stick-shaped) joined a second anterior incision to form an inverted Y. Once released at the apex, the lateral lobe was gradually pushed back into the plane of the capsule by the ballistic action of the laser beam at 100 W. In order to limit potential effects of leverage on the sphincter, no mechanical push was applied to the endoscope [16]

Pelvic floor muscle training (PFMT) was systematically prescribed if SUI was reported by patients at the first follow-up.

Patients' pre-operative evaluation included Internationnal Prostatic Symptom Score (IPSS), Qol-IPSS and ICIQ-SF questionnaires as well as a clinical and rectal examination, an uroflowmetry including peak flow and postvoid residual volume (PVR), an assessment of prostatic volume by trans-rectal ultrasound and a PSA test.

The post-operative evaluation was systematically carried out at 1, 3, 6 and 12 months. At each point of follow-up, a flow measurement with PVR as well as IPSS, Qol-IPSS and ICIQ-SF questionnaires were collected. The number of daily urinary pads was also recorded at each visit. The PSA test was performed at 3 and 12 months.

Demographic and perioperative data were collected in

a standardized and retrospective manner from the computerized medical record of each patient.

Statistical analyses were implemented with SPSS Statistics Version 20 (IBM Corp., Chicago, IL, USA). To compare pre- and post-operative continence status, a nonparametric *t*-test was used. The predictive factors for the occurrence of post-operative SUI were chosen according to the literature [17] and were analysed with logistic regression. A *p*-value below 0.05 was considered as statistically significant. The cut-off value for age and BMI were chosen according to the literature [17]. The cut-off value for prostate volume, operative and enucleation time, enucleated weight, energy delivered and efficiency coefficient were that our average results.

This study was approved by the ethics committee of the Hospices Civils de Lyon and registered with the CNIL (Commission Nationale de l'Informatique et des Libertés) under number 18-127.

# 3. Results

175 HoLEPs were consecutively carried out in our institution, of which 155 were assessed (Fig. 1). The demographic and perioperative data are set out in Table 1. Complete functional results at 1, 3, 6 and 12 months are reported in Table 1. The nature and severity of urinary leakage is detailed in Table 2. The rate of SUI de novo at 1, 3 and 6 months post-surgery was respectively 7.3%, 8.1% and 3.4%. Despite beginning bladder and sphincter rehabilitation in the first postoperative month in all patients with urinary leakage, SUI persisted in 4 patients (2.7%) at 12 months. However, only 2 patients (1.3%) wore one pad per day at 12 months. The mean ICIQ-SF score for patients with SUI was respectively 11.69  $\pm$  5.28, 8.70  $\pm$  $4.24, 1.81 \pm 3.53$  and  $8 \pm 4.24$  at 1, 3, 6 and 12 months (Table 2). In univariate and multivariate analysis, Body Mass Index (BMI) >30 (OR, 4.69; 95% CI, 1.51–14.52;

	Mean $\pm$ Standard deviation or N
Preoperative data	
Age (year)	$69.53 \pm 7.58$
BMI (kg/m <sup>2</sup> )	$26.25\pm4.13$
Diabetes	34
Prostate cancer under active surveillance	11
Prostate volume (mL)	$88.81 \pm 43.55$
PSA (ng/mL)	$6.84 \pm 5.98$
ASA score (American Society of Anaesthesiology) (mean)	$2.04\pm0.71$
ASA Score	
1	36
2	77
3	42
Antiplatelet agent	31
Direct oral anticoagulant	11
Antivitamin K	5
Urinary catheterisation	58
Operative data	
General anaesthesia	67
Spinal anaesthesia	88
Length of surgery (min)	$105.68 \pm 48.93$
Volume of irrigation fluid (L)	$34.55 \pm 16.17$
Energy delivered (kJ)	$201\pm99.59$
Enucleated weight (g)	$51.87 \pm 32.11$
Efficiency coefficient (weight enucleated/operating time) (g/min)	$0.49\pm0.20$
Postoperative data	
Duration of irrigation (day)	$1.08\pm2.22$
Duration of urinary catheterisation (day)	$1.63\pm2.62$
Length of stay (day)	$1.86 \pm 2.43$
Hemoglobin loss (g/dL)	$1.29 \pm 1.24$

Table 1. Patients' characteristics and urinary function.	Table 1.	Patients'	characteristics and	l urinary	function.
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Table 2. Urinary function follow-up and incidence of SUI.

	Baseline	1 month	3 months	6 months	12 months		
	Mean $\pm$ Standard deviation or N (%)						
Patients	155	150	149	146	150		
IPSS	$20.16\pm5.93$	$7.49 \pm 4.73 *$	$5.70\pm5.25*$	$3.84 \pm 4.31 *$	$3.30\pm3.75^{\ast}$		
QoL	$4.59 \pm 1.34$	$1.75\pm1.69^*$	$1.28 \pm 1.48 *$	$0.82\pm0.97*$	$0.69\pm0.84*$		
Mean ICIQ-SF score (global)	$4.11 \pm 4.56$	$3.69\pm5.20$	$2.58\pm4.62$	$1.81\pm3.53$	$1.02\pm2.58$		
Mean ICIQ-SF (SUI)	0	$11.69\pm5.28*$	$8.70 \pm 4.24 *$	$7.45\pm2.84^{*}$	$8 \pm 4.24*$		
Qmax (mL/s)	$8.56\pm3.85$	$18.90\pm9.29^*$	$22.90 \pm 11.06*$	$22.81\pm9.89^*$	$23.43\pm11.66*$		
PVR (mL)	$165.07 \pm 147.23$	$62.26 \pm 83.97 *$	$60.31 \pm 60.63 *$	$58.57 \pm 72.04*$	$47.33\pm65.57*$		
PSA (ng/mL)	$6.84 \pm 5.98$		$1.65\pm1.62^{\ast}$		$1.95\pm2.05*$		
SUI	0	11 (7.3%)	12 (8.1%)	5 (3.4%)	4 (2.7%)		
Other UI	37 (23.9%)	50 (33.3%)	30 (20.1%)	21 (14.4%)	14 (9.3%)		
Patients with daily pads for SUI	0	8 (5.3%)	4 (2.7%)	2 (1.4%)	2 (1.3%)		

\* p < 0.05 compared to baseline.

p = 0.007) was an independent risk factor for the occurrence of post-operative SUI at 1 month, whereas age >70 years (OR, 16.23; 95% CI, 1.96–134.09; p = 0.010) was an independent risk factor for occurrence at 3 months (Table 3). Diabetes, ASA score, use of antiplatelet or anticoagulant, urinary catheterism, prostate volume, operative and enucleation time, enucleated weight, energy delivered and efficiency coefficient were not found to be risk factors (Table 3). At the time of the study, none of the patients presenting SUI required an implantable device.

# 4. Discussion

Transient stress urinary incontinence is a complication commonly reported after HoLEP. Its occurrence varies in

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	1 month				3 months			
Characteristics	Univariate analysis		Multivariate analysis		Univariate analysis		Multivariate analysis	
			C	Odds Ratio (	(95% CI) <i>p</i> value			
Age ( $<70 \text{ vs} \ge 70$ ), years	2.25 (0.79-6.42)	0.13	1.68 (0.51–5.48)	0.39	14.37 (1.81–114.3)	0.012	16.23 (1.96–134.09)	0.01
BMI ( $<30 \text{ vs} \ge 30$ )	5.19 (1.79–15.07)	0.002	(1.51–14.52)	0.007	2.49 (0.76-8.16)	0.13	2.98 (0.83-10.72)	0.09
Diabetes	1.21 (0.36-4.00)	0.757			1.70 (0.55–5.31)	0.358		
ASA ( $<3$ vs $\geq$ 3)	3.15 (0.76–13.1)	0.11			1.38 (0.39–4.85)	0.61		
Anti-aggregation or anticoagulant treatment	1.75 (0.62-4.93)	0.29			1.39 (0.47-4.10)	0.545		
Prostate volume ( $<$ 90 vs $\geq$ 90), g	0.86 (0.31-2.39)	0.77			0.60 (0.17-2.08)	0.42		
Urinary catheterism	1.19 (0.43–3.33)	0.73			0.82 (0.24–2.87)	0.76		
Enucleation time ( $\geq 60$ vs <60), min	2.78 (0.86-8.98)	0.09			0.97 (0.20-4.7)	0.97		
Operating time ( $\geq$ 90 vs <90), min	0.67 (0.24–1.85)	0.44			0.78 (0.24–2.52)	0.67		
Energy delivered (<200 vs $\geq$ 200), kJ	1.31 (0.48–3.60)	0.60			1.02 (0.31–3.38)	0.97		
Enucleated weight $<50 \text{ vs} \ge 50$ ), g	1.38 (0.50–3.79)	0.53			1.20 (0.37–3.9)	0.76		
Efficiency coefficient (<0.5 vs $\geq$ 0.50), g/min	1.38 (0.50–3.80)	0.529			1.20 (0.37–3.91)	0.759		
	6 months				12 months			
Characteristics	Univariate analysis		Multivariate analysis Univariate		Univariate anal	analysis Multivariate analysis		ysis
			(	Odds ratio (	(95% CI) <i>p</i> value			
Age ( $<70 \text{ vs} \ge 70$ ), years	5.96 (0.68-52.22)	0.11	6.27 (0.67–59.03)	0.11	4.70 (0.51-43.01)	0.17	5.04 (0.47-53.84)	0.18
BMI ( $<30 \text{ vs} \ge 30$ )	2.39 (0.46–12.28)	0.30	2.45 (0.42–14.23)	0.32	3.16 (0.32-30.75)	0.322	1.17 (0.09–15.64)	0.906
Diabetes	0.70 (0.08-6.24)	0.752			0.88 (0.10-8.18)	0.913		
ASA ( $<3$ vs $\geq$ 3)	1.36 (0.24–7.73)	0.73			1.83 (0.3–11.38)	0.52		
Anti-aggregation or anticoagulant treatment	0.45 (0.05-3.98)	0.474			0.54 (0.06-4.95)	0.584		
Prostate volume ( $<90 \text{ vs} \ge 90$ ), g	1.26 (0.25-6.44)	0.78			0.83 (0.13-5.09)	0.84		
Urinary catheterism	0.32 (0.04–2.83)	0.31			0.43 (0.05-3.98)	0.461		
Enucleation time ( $\geq 60$ vs < 60), min	0.97 (0.11-8.65)	0.98			1.22 (0.13–11.39)	0.86		
Operating time ( $\geq$ 90 vs <90), min	0.78 (0.15-4.01)	0.77			0.52 (0.08-3.18)	0.48		
Energy delivered (<200 vs $\geq$ 200), kJ	0.70 (0.13-3.97)	0.69			0.95 (0.15-5.86)	0.96		
Enucleated weight ( $<$ 50 vs $\geq$ 50), g	6.29 (0.72–55.14)	0.10			1.81 (0.29–11.14)	0.52		
Efficiency coefficient ( $<0.50 \text{ vs} \ge 0.50$ ), g/min	6.31 (0.72–55.33)	0.096			4.97 (0.54-45.54)	0.156		

Table 3. Univariate and multivariate logistic regression analysis for predicting postoperative stress urinary incontinence.

Table 4. SUI rates after HoLEP reported in the literature.							
Authors, years	Patients	Surgical technique and setting	Centres operators	Continence questionnaires	SUI before 1 year	SUI at 1 year	
Placer, 2009 [14]	125	3 lobes 2 J, 50 Hz	Monocentric 1 surgeon	Yes, ICIQ-SF	6 (4.8% ) At 6 months	6 (4.8%)	
Shuichiro Kobayashi, 2016 [20]	127	3 lobes 100 W	Monocentric 2 surgeons	No	17 (13.3%) At 3 months	2 (1.5%) (mixed UI)	
Jong Kil Nam, 2015 [7]	391	3 lobes 2 J, 40 Hz	Monocentric 1 surgeon	No	13 (3.3%) At 3 months	1 (0.3%)	
Jeongyun Jeong, 2015 [21]	110	3 lobes 80–100 W	Monocentric 1 surgeon	Yes, ICIQ-SF	-	-	
Elzayat, 2005 [3]	552	3 lobes 80–100 W	Monocentric 1 surgeon	No	24 (4.2%) Between 1 and 6 months	3 (0.5%)	
Shah, 2007 [10]	280	2–3 lobes 2 J, 50 Hz	Monocentric 1 surgeon	No	-	2 (0.7%)	
Vavassori, 2008 [22]	330	3 lobes 60–80–100 W	Monocentric 1 surgeon	No	24 (7.3%) At 3 months	2 (0.6%)	
Elmansy, 2011 [23]	949	-	Monocentric 1 surgeon	No	47 (4.9%) At 3 months	8 (1.04%)	
Krambeck, 2013 [24]	1065	3 lobes	Moncentric Several surgeons	No	60 (12.5%) At 3 months	5 (1.8%)	
Lerner, 2010 [12]	77	3 lobes	Monocentric 1 surgeon	No	17 (26%) At 3 months	2 (3%)	
Cho, 2011 [5]	204	3 lobes 2.6 J, 30 Hz	Bicentric Several surgeons	No	9 (5%) At 3 months	2 (1.1%)	
Minagawa, 2017 [13]	74	En-Bloc 1.5 J, 20 Hz	Monocentric 3 surgeons	Yes, ICIQ-SF	3 (5.5%) At 3 months	-	
Elmansy, 2019 [25]	60	Top-down	Monocentric 1 surgeon	No	2 (3.3)	-	
Our Study	155	3 lobes + white line 2 J, 50 Hz	Monocentric 2 surgeons	Yes, ICIQ-SF	12 (10.7%) At 3 months	4 (2.6%)	

## Table 4. SUI rates after HoLEP reported in the literature

the literature from 3.3% to 26% at 3 months (Table 4). Fortunately, most patients recover within the first year [7]. However, its assessment in several studies is only based on patient reported data (Table 4, Ref. [3,5,7,10,12-14,20-25]), and one possible explanation for the variation of reported SUI rates is the lack of a standardized evaluation. Without the use of a validated questionnaire, incidence and prevalence of postoperative urinary incontinence could be underestimated, and precise determination of the type of incontinence is difficult [18]. The ICIQ-SF is a validated questionnaire in male urinary incontinence that distinguishes different types of urinary incontinence and estimates their severity [19]. The present study showed respectively 11.4% and 10.5% de novo SUI at 1 month and 3 months. The use of the same questionnaire at each follow up point confirmed the transient nature of SUI. Indeed, only 4 patients (2.6%) reported a persistent mild urinary leakage at one year despite PFMT.

Two main independent demographic risk factors for the occurrence of SUI during the first 3 postoperative months were identified: age greater than 70 years (p < 0.02) and a BMI greater than 30 (p < 0.007). These results confirm those of Nam et al. [7] who reported, in a retrospective series of 391 patients, a significantly higher rate of transient SUI in patients over 65 years old. In another retrospective and multicentric series of 2346 patients, increasing age and elevated BMI were also significantly associated with urinary incontinence [17]. Other demographic risk factors such as a history of diabetes mellitus and a pre-operative prostate volume greater than 81 g have also been reported [17] but were not found in our study. Intrinsic sphincter insufficiency in elderly, overweight and diabetic patients could favour the occurrence of transient SUI after endoscopic enucleation [26].

SUI after prostatic surgery is due to sphincter injury during procedure and/or functional underactivity especially in patients with diabetes or with large prostate. In this study, we did not identify any intraoperative factor that could induce transient SUI. However, during HoLEP, some factors could cause an occlusion defect of the urethra-sphincter complex which lead to transient SUI: widening of the bladder neck, tearing of muscle fibres due to excessive use of mechanical thrust, heat damage to muscle fibres due to excessive use of laser energy at the apex of the adenoma, incomplete occlusion due to circumferential tearing of the proximal sphincter's mucosa (seal effect). An early apex dissection can reduce these damages to the sphincter. Elmansy et al. [23] showed that a decrease in PSA level greater than 84%, reflecting the amount of removed prostate tissue, was associated with a higher risk of stress urinary incontinence. Similarly, enucleation weight have been considered as an independent intraoperative predictive factor of urinary incontinence at 3 and 6 months [17]. In the same way, technical difficulty like poor visibility of the operating field due to excessive bleeding was linked to a higher risk of

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inappropriate endoscopic manipulations and thus urethral sphincter injury [7,20,23]. Another explanation concerns the percentage of prostatic tissue removal: the higher it is, the larger prostatic fossa is, causing urine trapping which leaks during stress maneuvers. Several authors have also suggested that reducing the energy delivered during enucleation, in particular when near the urethral sphincter, could minimize the risk of thermal damage without increasing operating time [13]. Unfortunately, no consensus for the optimal setting has yet been reached.

Several HoLEP techniques have been reported since the first procedure described by Gilling [5]: 2-lobes technique [24], En-Bloc technique [27], white line technique [28], anteroposterior dissection HoLEP [29], Top-Down HoLEP [25]. In a non-randomized retrospective monocentric study, Endo et al. [29] reported a decrease of incontinence rate (2.7% vs 25.2%) in favour of anteroposterior dissection HoLEP versus Gilling's method. However, these results have not been confirmed. More recently, Colchetti et al. [30] described a modified HoLEP technique Cap HoLEP [30] which allows significant improvement in the postoperative urinary incontinence rate. This technique preserves the anterior prostate portion proximal to the external sphincter, that acts as a protective barrier, reducing mechanical stress and laser energy widespread on the sphincter. As described earlier, our technique is a mix of the white line and the 3-lobe techniques. Our modifications based on early apex dissection avoid stretching the urethral sphincter by first separating the adenoma from the sphincter area. Lateral lobe enucleation was carried out through the adenoma apex until reaching the capsule. Small apical adenomatous remnants were left in place as sphincter protective flaps. With this method, only 2 patients (1.3%) reported a persistent mild stress urinary incontinence requiring one pad per day at one year. However, in the absence of comparative studies, it is impossible to identify one technique that would preserve continence more safely.

In our study, HoLEP was carried out by 2 operators which had conducted at least 200 HoLEP procedures. It is well known that the learning curve affects the incidence of SUI after HoLEP [7,12]. Fifty procedures at least are necessary to master the technique [31]. In this phase, the unassisted beginner surgeon is exposed to an increased risk of SUI by sphincter injury due to an inappropriate apex dissection [10,12,14] as well as an excessive operating time [32]. For these reasons, increasing the initial number of cases [12] and structuring mentorship programs (video viewing, simulator training and active proctoring) are needed to improve the safety of HoLEP procedures [33]. Moreover, avoiding potentially complicated cases (prostate volumes greater than 80 g, anticoagulated patients, patients with prostate cancer, prior prostatic radiotherapy) during the learning phase has been recommended [31].

The current study has several limitations. It is a noncontrolled study based on a retrospective design with a small number of patients. In addition, there were no objective measurements, such as a pad test or a voiding diary. Finally, urodynamic tests other than uroflowmetry were not routinely performed. However, the use of the same surgical technique by two experienced operators in the same hospital and the systematic evaluation of postoperative urinary incontinence by a standardized and validated questionnaire help reduce biases due to patients' interview, learning curve and different practices.

### 5. Conclusions

In this study, we found a low SUI rate one year after HoLEP. Transient SUI was more frequent in elderly and overweight patients. These results should be considered when informing patients about postoperative complications. Careful patient selection and appropriate preventive and therapeutic care (weight loss, PFMT) could help decrease transitory SUI rate. Additional prospective and comparative studies on larger cohorts are needed to support these results.

### Abbreviations

TURP, Transurethral resection of the prostate; OP, open prostatectomy; BPH, benign prostatic hyperplasia; HoLEP, Holmium laser enucleation of the prostate; PFMT, Pelvic floor muscle training; BMI, Body Mass Index.

#### **Author contributions**

HF and RC designed the study and supervised the project. HY collected and analysed the data. HF and RC performed the operations. LB, TD and MC aided in interpreting the results and worked on the manuscript. HY, HF and RC wrote the paper. All authors discussed the results and commented on the manuscript.

#### Ethics approval and consent to participate

All subjects have given their written informed consent. This study was approved by the ethics committee of the Hospices Civils de Lyon and registered with the CNIL (Commission Nationale de l'Informatique et des Libertés) under number 18-127.

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### **Conflict of interest**

The authors declare no conflict of interest.

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