



# Uroflow stop test with electromyography: a novel index of urinary continence recovery after RARP

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## Abstract

**Purpose** Urinary incontinence (UI) is one of the most bothersome surgical side effects after robot-assisted radical prostatectomy (RARP). Alteration of both smooth and striate urethral sphincter occurs after RARP. Since the contraction of perineal muscles is involved in the complex mechanism of urinary continence, the uroflow stop test (UST) seems to predict early continence recovery after RARP. The UST was added of perineal surface electromyography (EMG) evaluation to evaluate the latency time (LT) between muscular contraction and the complete stop of urine flow. Our aim was to present UST–EMG as a new tool in the investigation of UI, implying pelvic floor integrity, and to evaluate whether an early return ( $\leq 3$  months) to preoperative LT could be associated with early recovery of UC ( $\leq 3$  months).

**Methods** After prospectively enrolling 137 patients who underwent RARP with a minimum follow-up of 6 months, we identified two groups: Group 1 (93 patients) with early ( $\leq 3$  months) pre-surgical LT recovery and Group 2 (44 patients) with late  $> 3$  months or not able to reach pre-surgical LT recovery.

**Results** Between the two groups, there were significant differences in terms of different surgical technique (nerve-sparing versus non-nerve-sparing) and pads use at 3 and 6 months after RARP ( $p < 0.05$ ). No differences were recorded neither in postoperative maximum flow-rate, nor in postoperative symptoms score.

**Conclusions** UST with EMG can be considered as a noninvasive, reproducible and easily performable tool. LT is applicable in the clinical evaluation to predict urinary continence recovery after RARP.

**Keywords** Urinary incontinence · Prostate cancer · Radical Prostatectomy · Pelvic floor

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## Introduction and objectives

The fast recovery of urinary continence is one of the most important goals in men who undergo radical prostatectomy [1, 2]. Regardless of the surgical approach, urinary incontinence (UI) is one of the most bothersome surgical side effects, severely impairing patients' quality of life (QoL). Despite several preoperative characteristics being related to UI, its main influencing factor is represented by the surgical alteration produced by the bladder-urethral section, which leaves the external striated sphincter as the main urethral mechanism of urinary continence [3].

The UI is often seen during the early phase after Robot-assisted radical prostatectomy (RARP) impacting the cost of care and surgeon-patient relationship [4, 5]. UI occurs for 20–30% of all patient who have undergone RARP at 90 days after surgery and 4–31% at 12-months [6–8]. A clinical

early identification of UI after RARP could be of paramount importance to determine the best follow-up program [9, 10].

Even if the introduction of robotic surgery has lessened the incidence of UI, patients can present with different subtypes of mixed or pure stress urinary incontinence (SUI) [11]. The surgical-induced deficiency or inability of the striated external urethral sphincter is determined as the main cause of SUI, together with the failure of pelvic floor muscles (PFMs) to adequately resist to intra-abdominal pressure increase. In fact, their common striatal innervation and simultaneous contraction are at the basis of the pelvic floor muscle training (PFMT). Since the SUI was historically assessed by a subjective self-reported criterion by the patient, it can be said that there is no objective, noninvasive instrument for clinical evaluation [7]. However, the uroflow stop test (UST) was recently proposed to ascertain early recovery of urinary continence after RARP [3]. UST was afterward regarded as a surrogate for the pelvic floor integrity, considering the neuro-physiological implications of its positivity (capacity to stop the urine flow for almost three seconds) [4, 12]. In order to improve the clinical accuracy of this examination, we added pelvic floor's electromyography to UST (UST–EMG) [13]. This tool allows us to calculate the latency time (LT) between the start of PFMs muscular contraction and the stop of the urinary stream.

The aim of our study was to assess the accuracy of UST–EMG to evaluate the postoperative SUI. The secondary aim was to assess whether an early return to preoperative LT ( $\leq 3$  months) during UST–EMG of the pelvic floor could be associated with early recovery of urinary continence after RARP.

## Materials and methods

### Subjects

This prospective study was conducted in a single High Volume tertiary Institute. After institutional and ethical review board approval (Protocol No. 12129/17), from January 2017 to April 2018, we enrolled 180 patients with clinically localized prostate cancer (PCa), who underwent RARP, with a minimum follow-up time of 6 months. According to our protocol, a written informed consent was obtained from every participant prior to enrollment and before surgery. Forty-three patients were excluded from our analysis because they did not meet the inclusion criteria as reported below.

All patients underwent previously reported cognitive fusion biopsy before surgery, based on a 3-T prostatic MRI [14]. ASA (American Society of Anesthesiology) and Charlson Comorbidity Index were used to classify performance status and comorbidity, respectively. Every patient underwent Uroflowmetry (UF), UST–EMG, International

Prostatic Symptoms Score (IPSS), International Index of Erectile Function-5 (IIEF-5) score, pre- and postoperatively. We recorded UST–LT recovery, nerve sparing (NS) execution, Positive Surgical Margins (PSM) status, and postoperative complications (according to Clavien-Dindo classification). Pad-test and direct interview (response to question number 5 of EPIC questionnaire) were performed at 3 and 6 months in order to evaluate patients' continence status. Patients were considered fully continent when they used no pad.

All patients were postoperatively instructed to perform PFMT toward the first 3 months. Study population was divided into two groups: Group 1 including patients with an early ( $\leq 3$  months) preoperative LT recovery and Group 2 including patients with a late  $> 3$  months or not able to reach preoperative LT recovery according to UST–EMG results. Then, we compared preoperative as well postoperative clinical and surgical characteristics between the two groups.

### Surgical procedure

All interventions were performed by one skilled surgeon (EM) to reduce the impact of the treatment on the results. In case of low-risk disease, a full nerve sparing extraperitoneal RARP was performed in each case according to PERUSIA technique (posterior, extraperitoneal, robotic, under santorini, intrafascial anterograde) that was previously described [15]. In case of high-risk disease, an extrafascial technique with monolateral demolition of neuro-vascular bundle (monolateral nerve sparing) or bilateral non-nerve-sparing technique was performed on the basis of fusion biopsy results. Urethro-vescical anastomosis was always performed by running suture using double needles Quill®, without peri-sphincteric reconstruction.

### Exclusion criteria

Non-organ confined PCa. Preoperative radiotherapy or previous prostatic surgery. Neurological or diabetic disease. Prostate volume  $> 70$  ml. Positive bioptic cores in the anterior zone (preservation of DVC not applicable). Preoperative incontinence. Pre- and postoperative maximum flow rate  $< 15$  ml/s at uroflowmetry and evidence of anastomotic leakage at postoperative cystography.

### Uroflow stop test (UST) with EMG record of PFMs

All patients had UST–EMG preformed before surgery, at the time of urethral catheter removal, and at 1, 3, and 6 months after surgery. The EMG evaluation (Mediwatch®, Northpoint Parkway, West Palm Beach, FL, USA) was always performed after preparation of the skin with depilation and attentive brush with 70% alcoholic

solution to remove the dirt and skin dead cells. Disposable pre-gelled adhesive Ag/AgCl surface electrodes of 20 mm with 10 mm of conductive area were applied at 3 and 9 o'clock of peri-anal surface and one reference electrode over the right anterior iliac spine. Measured intra-electrodes impedance was of 10.7 K $\Omega$ . The acquired electromyographic signal was filtered (25–500 Hz), amplified (gain 1000 units, bandwidth 0–1 kHz) using a differential amplifier with common mode rejection ratio of >95 dB and input impedance > 1000 M $\Omega$ , digitized (24 bit resolution, 4000 Hz A/D sampling frequency), rectified and digitally filtered (50 Hz–10 kHz). The signal was averaged over 20 ms, RMS 1.2  $\mu$ V at bandwidth 2 Hz to 10 kHz.

The stop command was given with an audio signal after 5 s from the beginning of urination. At least a maximum flow rate of 15 ml/s was chosen to mimic a non-obstructed normal flow [3]. UST was considered positive when a voluntary interruption of urine flow for at least 3 s is achieved. Figure 1 graphically shows how we proceed to calculate the LT after giving the stop command. The LT was calculated from the beginning of pelvic floor contraction to the effective stop of urine flow (Fig. 1).

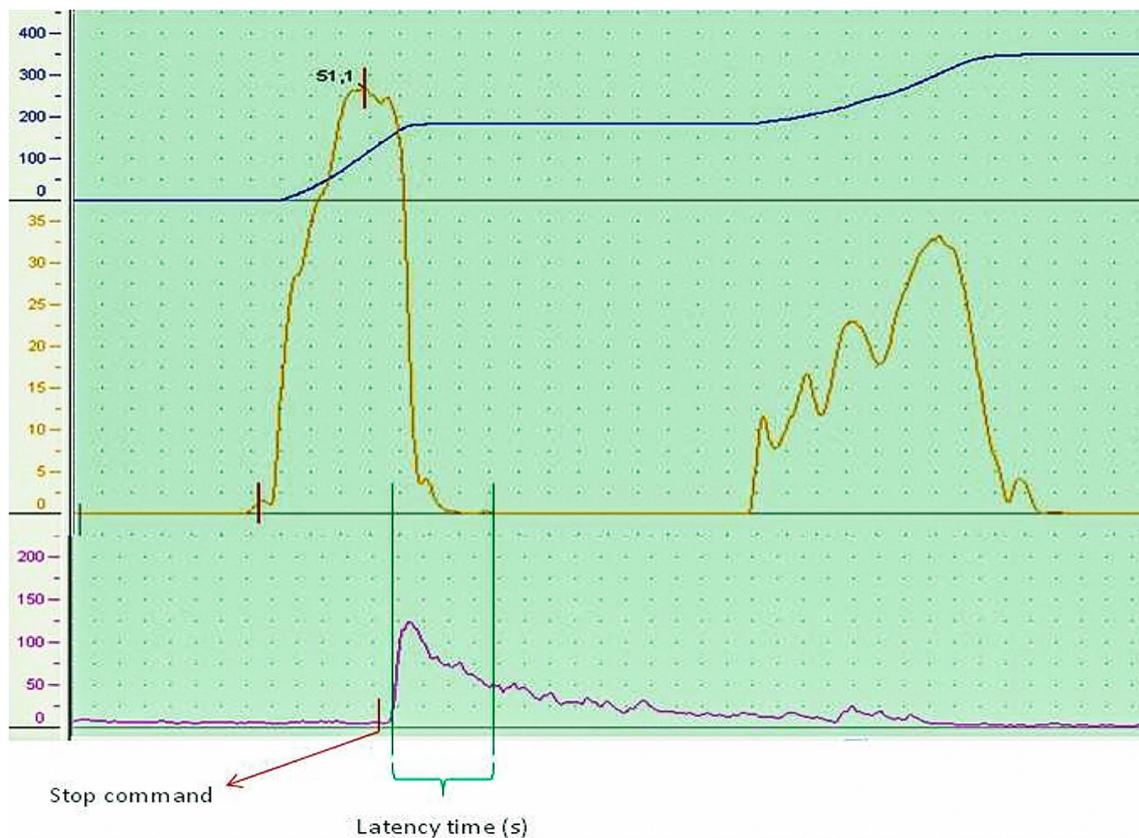
## Statistical analysis

Statistical analysis was performed using the SPSS© software. Student *t* test and Chi-square test were used for the analysis of quantitative variables and categorical variables, respectively. A *p* value of 0.05 was chosen to determine statistical significance between the studied parameters in the two groups.

## Results

Finally, 137 patients who underwent RARP by using PERUSIA technique were finally enrolled in our analysis. According to UST–EMG results, we identified 93 patients with an early preoperative LT recovery that were included in Group 1 and 44 patients with a late or not able to reach pre-surgical LT recovery (Group 2).

Table 1 shows the preoperative characteristics in the two groups. The two groups were homogeneous for clinical characteristics. In particular, they did not differ in mean preoperative prostate volume, thus reducing the potential influence of this parameter in our analysis. At the same time, the mean maximum flow rate at preoperative UF was also comparable



**Fig. 1** Graphic shows a UST–EMG postoperative examination with calculation of latency time

**Table 1** Preoperative characteristics

	Group 1	Group 2	<i>p</i> value
Age (years, mean)	61.7 (51–68)	63.8 (49–70)	0.096
BMI (kg/m <sup>2</sup> )	27.1 (23.5–33.2)	26.8 (22.8–32.7)	0.295
Charlson Comorbidity Index	4.2 (3–8)	4.3 (2–8)	0.349
Gleason Score $\geq$ 7 (no. of pts)	53 (57%)	23 (52.3%)	0.738
Prostate volume (ml, mean)	46.6 (25–68)	51.9 (27–62)	0.549
IPSS (mean, range)	12.2 (3–18)	11.5 (4–20)	0.213
QoL (mean, range)	3.2 (1–5)	3.1 (1–6)	0.317
IIEF-5 (mean, range)	17.4 (14–25)	15.9 (12–23)	0.052
Maximum flow rate (mean, range)	18.4 (15–22)	19 (15–27)	0.087
Latency time (mean, range)	1.27 (1.19–1.63)	1.29 (1.20–1.58)	0.053

**Table 2** Intra-operative and postoperative characteristics

	Group 1	Group 2	<i>p</i> value
Nerve sparing (NS)	87 (93.5%)	35 (79.5%)	<b>0.014</b>
Full-NS	58 (66.7%)	20 (57.1%)	
Partial-NS	29 (33.3%)	15 (42.9%)	
No nerve-sparing	6 (6.5%)	9 (20.5%)	
Positive surgical margin (PSM)	17.2%	15.9%	0.956
IIEF-5 Score (mean, range) 3 mos	13.1 (7–20)	12.3 (4–19)	0.138
IPSS Score (mean, range) 3 mos	6.1 (2–9)	6.3 (3–11)	0.322
QoL (mean, range) 3 mos	2.2 (0–4)	2.4 (0–4)	0.182
Postoperative complications	11.8%	13.6%	0.982
Clavien-Dindo I–II	81.8%	83.3%	
Clavien-Dindo III–V	18.2%	16.7%	
Pad-test (3 mos.)			<b>0.023</b>
Continent pts	67 (72%)	23 (52.3%)	
Incontinent pts	26 (28%)	21 (47.7%)	
Pad-test (6 mos.)			<b>0.001</b>
Continent pts	85 (91.4%)	31 (70.5%)	
Incontinent pts	8 (8.6%)	13 (29.5%)	

Bold values indicate statistical significance

in the two groups. The preoperative value of LT was homogeneous for all the patient, and no difference was highlighted between the two groups in terms of preoperative LT.

Median catheterization time and hospital stay were 7.1 days (range 6–12) and 6.9 days (range 1–11) with no significant difference ( $p > 0.05$ ). In Group 1, both full nerve-sparing and partial nerve-sparing were performed in significantly different percentage of patients ( $p < 0.05$ ). No significance was found in terms of PSMs rate and postoperative complications. No major complications occurred. No enrolled patient underwent adjuvant radiotherapy.

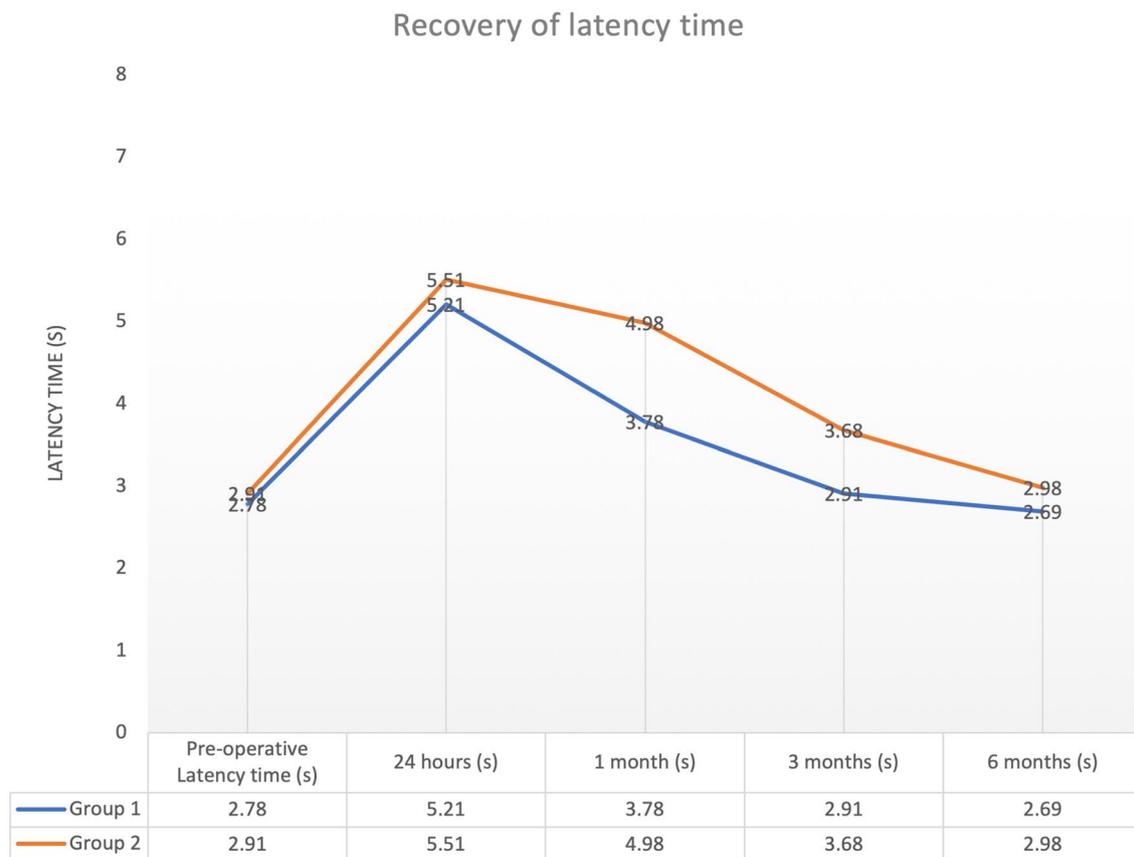
The key result was a statistically significant difference between the two groups in terms of incontinence rate at 3 and 6 months after RARP ( $p < 0.05$ ) as shown in the Table 2. In the group 1, 26 patients (28%) were incontinent at 3

months although these had an early recovery of preoperative LT. Out of these, 8 patients (8.6%) became continent at 6 months after surgery. In Group 2, the incontinence rate at 3 and 6 months was, respectively, 47.7% and 29.5%. Figure 2 shows LT recovery within the two groups.

Moreover, regarding the different technique (nerve-sparing versus non-nerve-sparing) there was a significant difference in UST–EMG results between the two groups. Patients with positive UST had a faster recovery of UC, regardless of pad-free rate. No differences were recorded in the postoperative mean flow-rate proving that all patients were unobstructed after RARP without potential influence of detrusor underactivity. No differences were also recorded between IPSS and ICS postoperative score between the two groups, thus excluding the presence of important storage symptoms as a confounding factor in our analysis.

## Discussion

Two peri-urethral sphincter are considered as major grantors to urethral closure pressure: the proximal smooth muscular mechanism and the distal striated one called urethral sphincter. However, their relative participation to guarantee the continence status remains uncertain [16–18]. The smooth muscle is accounted to provide baseline urethral pressure via a resting tone with limited dynamic activity, while the striated sphincter is thought to have a key role in preventing urine loss because its primary potential to react to sudden pressure increases [13, 19]. Anatomically, the striated sphincter is described as a  $\Omega$ -shaped loop of fibers inserting dorsally into the perineal body and encircling the anterior and lateral aspects of the urethra [17, 18]. Pelvic common somatic innervation is at least dual, via the pudendal nerves and the pelvic nerves, respectively, both arising from sacral levels S2–S4 [20–23]. We can speculate the contraction of perineal muscles to be contemporary to the contraction of the external urethral sphincter, in consideration of the common striatal innervation. Beyond the sphincters' activity,



**Fig. 2** Graphic shows the mean latency time at the reported intervals

other factors such as elastic tension in the urethra, ligaments, fascia, and the watertight seal of soft tissues are also involved in urinary continence [24, 25].

The UST was suggested as a valid test to predict early urinary continence and as a good surrogate for pelvic floor integrity, after RARP [4, 12]. During this examination, the patient performs a voluntary contraction of the urethral striated muscle during micturition [3]. In this sense, the UST turns out to be a good tool in identifying the patient's ability to stop urine flow and therefore define the continence ability.

The reported definition of positive UST is 3s full stop and has been arbitrarily chosen by the proposing authors in order to ascertain that the patient could unequivocally stop urinary flow on printed flow chart [3]. Nonetheless, during UST examination the flow could be arrested at different times by the patient after received the stop-command. For this reason, the cited definition of positivity could not be entirely considered as a parameter of the continence capacity without a time-based evaluation. We added perineal EMG evaluation about to objectivate the time between muscular contraction to the complete stop of urine flow, calling it latency time (LT). In this sense, the integration of perineal surface's EMG is suggested as a solution to evaluate the beginning of PFM

contraction. In our opinion, the return to preoperative LT at UST-EMG evaluation could better suggest the restoration of continence capacity after RARP.

Literature indicates that the addition of pelvic floor EMG increases the adequacy of measurements and interpretation [25–27]. Surface electrodes account for cross talk from adjacent muscles, in particular, the levator ani and pubo-perinealis components which appear all to have an important role in continence mechanism [28]. Surface electrodes permit a noninvasive recording of the activity of one or more muscle rather than only some muscular fibers that could be done with needle electrodes [27, 29, 30]. Moreover, Tomita et al. in a study on surface EMG conclude that until 10 mm of subcutaneous tissue there is no effect the EMG record with interelectrode distance up to 20 mm [31]. However, no study on UST including EMG testing of the pelvic floor is currently found in the literature. Theorizing a synergistic contraction of the PFM and the sphincter, the LT was calculated starting from the EMG peak until the flow was interrupted (Fig. 1). Stafford et al. in a study conducted on the activation of pelvic floor contraction used a 6 Fr transurethral self-developed surface electrode to evaluate the EMG volume of the

external urethral sphincter (EUS). Even if a minimal urethral trauma was declared, they reported mild discomfort upon urination for 1 to 2 days after the procedure [32, 33]. In our study, a tubeless procedure was preferable to avoid any possible cause of obstruction during the urine stream and to reduce the risk of any possible EUS contraction secondary to annoying stimuli. Obtaining a maximum urine flow of at least 15 ml/min is of paramount importance to exclude that possible detrusor underactivity or anastomotic and urethral obstruction could fake the UST result.

Bianchi et al. analyzed EUS EMG with needle electrode in men before RARP and after surgery to investigate possible predictive factors for post-surgical continence outcome but did not find a difference between the continent and incontinent group [25]. Liu et al. in a case-control study on men undergone nerve-sparing radical prostatectomy, non-nerve-sparing radical cystectomy, and the control group, found a significantly prolonged motor unit potential between surgery group and control group but did not find significant differences between nerve-sparing and non-nerve-sparing surgery in EUS EMG. In our experience in the non-NS group, the recovery of the preoperative LT is significantly slower with respect to the nerve-sparing group. This could be attributable to the better preservation of neuro-vascular autonomic integrity related to PERUSIA technique. This procedure consents the complete preservation of the endo-pelvic fascia and of the Santorini Complex avoiding the urethral retraction [15]. If we think urinary continence to be the result of a co-partnership of several pelvic muscles, the anatomic integrity of vascular and nervous supply help their contractile activity.

In order to raise muscular strength, patients performed PFMT between the first and the third postoperative months. Additionally, we can consider the time of 3 months to be sufficient to a normal scar healing process and to recover the nervous activity from neurapraxia after a NS procedure [34].

For all these reasons, a faster control of the urinary flow, as should happen in the daily activity of men who have undergone to RARP, is the main parameter of our study. Surface EMG recording permits the measuring of the time between the beginning of the muscular contraction up to the interruption of the urinary stream. In this way, the UST–EMG allows us to remove from the LT calculation the “neurological” response time that goes from the stop command to the striated contraction, thus allowing the standardization of the conditions.

The EMG positioning is simple and easily reproducible. UST–EMG would seem to lend itself very strongly to assessing the return to the preoperative continence ability of each patient and could be of additional interest to determine the integrity of the neuro-sphincter system. Limitations of our study are represented by the single surgeon experience and the short follow-up of patients. External validation of the UST–EMG tool is needed to validate our results.

## Conclusion

The UST–EMG could be considered as a noninvasive, reproducible and easily performable tool. Its application would seem to be useful also to assess SUI after RARP, in order to early address patient to specific therapies. Future application of this examination at subsequent times in the patients’ follow-up may allow to study the efficacy of pre-operative as well as postoperative supporting rehabilitation’s protocols for SUI.

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