# Pain and anxiety assessment during cystourethroscopy in males using voiding instruction: A prospective, randomized controlled study

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**Abstract** Introduction: Office cystourethroscopy is one of the common and most frequent urological procedures. Pain and anxiety during the procedure might lead to noncompliance and incomplete cystoscopic examination. Negotiating cystoscope through external sphincter is the most painful and uncomfortable distressing part of cystoscopy. To overcome this, manual compression of irrigation bag during cystoscopy has been used and found to be helpful. Numerous other methods were also studied. Despite these, cystoscopy is still painful and causes anxiety in patients. External sphincter gets relaxed naturally during the act of micturition. Based on this principle, pain and anxiety were studied with voiding instruction during cystourethroscopy.

**Objective:** To study the effect of voiding instruction on anxiety and pain during cystourethroscopy using the Hamilton Anxiety Rating Scale (HAM-A) and visual analogue scale (VAS), in a well-matched Eastern Indian male patient population in a prospective, randomized pattern.

**Methods:** A total of 100 male patients were recruited from those who underwent cystourethroscopy examination in SSKM Hospital and were prospectively randomized into two groups: cystoscopy with or without voiding instruction. Pre- and postprocedure HAM-A score and postprocedure VAS score were recorded.

**Results:** The mean postprocedural pain (VAS) score between voiding instructed and noninstructed groups reached statistical significance:  $3.06 \pm 1.98$  (Range, 2–5) and  $5.16 \pm 2.86$  (Range, 4–8), respectively (P < 0.001). Preprocedure HAM-A score was similar between both groups. Postprocedure median HAM-A score was statistically significantly lower (mean 17.86  $\pm$  2.8 vs. 19.76  $\pm$  3.12; P < 0.001) in voiding instructed group.

**Conclusion:** Pain and anxiety level during cystourethroscopy examination in males can be significantly reduced when the patient is instructed to void during cystourethroscopy examination.

Keywords: Anxiety, cystoscopy, cystourethroscopy, pain, voiding

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# **INTRODUCTION**

Office cystourethroscopy is one of the common and most frequent urological procedures done for different urological conditions, but this is a painful and distressing procedure for patients. This might cause noncompliance leading to incomplete cystoscopy examination.<sup>[1,2]</sup> Numerous methods to reduce pain and discomfort such as prior lidocaine gel insertion, listening to music, and watching video monitor have been studied and applied in clinical practice.<sup>[3-6]</sup> Despite these methods, cystourethroscopy is still somewhat painful and leads to anxiety in patients.

Negotiating cystoscope through the external sphincter is the most painful, uncomfortable, and distressing part during cystourethroscopy.<sup>[7]</sup> Easy and comfortable negotiation of cystoscope through the external sphincter with manual compression of irrigation bag (which opens up the sphincter) during passage through external sphincter has been found to be a useful method.<sup>[8]</sup>

Similarly, external sphincter gets relaxed during micturition process which might be helpful in reducing pain during instrumentation. Recent publication supports this hypothesis. They had done a randomized study and found that pain level during urethral catheterization in males can be significantly reduced when the patient is instructed to void during the insertion of the catheter into the urethra.<sup>[9]</sup>

Therefore, our hypothesis was that pain and anxiety can be reduced if the patient is instructed to void during the cystourethroscopy. Hence, we evaluated the effect of voiding instruction on anxiety and pain during cystourethroscopy using the Hamilton Anxiety Rating Scale (HAM-A) and visual analog scale (VAS).

# MATERIAL AND METHODS

# Study type

After ethics committee approval, we did a prospective, randomized study for anxiety and pain assessment in male patients, who underwent cystourethroscopy under local anesthesia in the Department of Urology, SSKM Hospital, Kolkata, India. Randomization was done with computer-generated randomized number.

# Selection criteria

Male patients of age 18 years or more, who underwent cystourethroscopy for hematuria evaluation, Double J stent removal, or follow-up evaluation of endoscopically managed bladder tumor, were included in the study. Patients were excluded from the study based on the following exclusion criteria:

- Known urethral stricture or history of recent urethral manipulation (within 7 days)
- Lower urinary tract infection (urine culture positive)
- Known urethral painful diseases such as chronic pelvic pain syndrome or interstitial cystitis
- Known mental, psychiatric, or neurological disease that affects pain and anxiety assessment
- Recent use (within previous 24 h) of analgesics
- Detection of stricture or gross urethral anomaly during cystourethroscopy.

# Pain and anxiety scale

Postcystourethroscopy, pain was assessed with VAS. VAS is a self-administered, well-validated, and reliable tool for assessing pain. In scale, 0 score shows no pain and 10 shows the worst possible pain.

Anxiety was assessed with HAM-A. It is widely used and easily applicable psychometric scale for anxiety assessment. The scale includes 14 items and each item contains 5 points (0–4). The sum of all scores of 14 items shows the anxiety level. A higher score indicates higher anxiety level. The scale was implied pre- and postprocedure.

## Study methods

After inclusion and exclusion measures, we provided patients a serial number on first-come, first-served basis. Randomization was done between two groups (n = 50 in each group): (1) voiding instructed group (VIG; voiding instruction given during passage of scope through membranous urethra) and (2) nonvoiding instructed group (NIG; no specific instruction given during passage of scope).

Age, indication of cystoscopic examination, pulse, blood pressure, and anxiety score were documented ahead of procedure. Disinfection of the penis was done with povidone-iodine solution. Ten milliliters of 2% lignocaine jelly was instilled intraurethrally and kept for 15 min using an occlusive penile clamp at the tip of the penis. All procedures were done in a specialized closed cystoscopy room by a single urology resident. The patient was placed in a standard lithotomy position. A 17 Fr rigid sheath cystoscope was used in all procedures. On the basis of randomization, the patients were instructed or not instructed to void during the passage of cystoscope through the external sphincter. After completion of the procedure, their vital signs were monitored and VAS and HAM-A scores were recorded.

Data were analyzed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY: USA). Parametric and nonparametric tests were applied for analysis. P < 0.05 was considered statistically significant.

# RESULTS

A total of 198 patients underwent cystourethroscopy during the study (mid-August 2017 to mid-December 2017). Among them, ninety patients were excluded based on the selection criteria. Eight patients were excluded at the time of scopy due to the detection of stricture urethra. Finally, fifty patients were included in each group.

Mostly patients were aged  $\geq$ 40 years and evenly distributed in both groups. Hematuria evaluation or posttransurethral resection of bladder tumor cystoscopic surveillance were the indication for cystourethroscopy in 45 (90%) and 46 (92%) patients in VIG or NIG, respectively [Table 1]. Both groups were well balanced in terms of precystoscopy variables such as pulse rate, systolic, diastolic blood pressure, and anxiety score [Table 2].

Postcystourethroscopy systolic and diastolic blood pressures were homogenous in both groups while pulse rate, anxiety score, and pain score were lower in VIG (P < 0.05). Pain and anxiety scores (HAM-A) of VIG were  $3.06 \pm 1.98$  and  $17.86 \pm 2.8$ , respectively. The lower level of VAS and HAM-A score in comparison to NIG ( $5.16 \pm 2.86$  and  $19.76 \pm 3.12$ , respectively) was not by chance (P < 0.05) [Table 3].

Further, paired *t*-test revealed that the anxiety score was decreased after scopy in VIG (19.26  $\pm$  3.8–17.86  $\pm$  2.8; P < 0.001), while the anxiety score of NIG was increased after scopy (19.42  $\pm$  4.01–19.76  $\pm$  3.12; P = 0.008) [Table 4].

### DISCUSSION

Cystourethroscopy is one of the most frequent urological procedures for different urological conditions, but this is a painful and distressing procedure for patients. Incomplete examination and noncompliance may result owing to pain during scopy.<sup>[1,2]</sup>

To reduce pain and discomfort, numerous studies have been done and employed in routine clinical practice. Lidocaine gel insertion is one of them. Aaronson *et al.* had done a meta-analysis of four randomized trials and concluded prior intraurethral lidocaine gel insertion curtail 1.7 times moderate-to-severe pain. Among the four included randomized trials in meta-analysis, only one trial had documented favorable result.<sup>[3]</sup> The similar nonbeneficial result of other three trials, the meta-analysis done by Patel *et al.* of nine different studies also concluded

#### Table 1: Nonmodifiable variables

Variables	VIG (n)	Noninstructed group (n)	Р
Age (years)			
18-25	2	1	0.287
25-30	2	2	
30-40	9	8	
40-50	19	18	
>50	18	21	
Indication of cystoscopy			
Hematuria evaluation	24	26	0.368
Follow-up (postTURBT)	21	20	
Double J stent removal	5	4	

TURBT: Transurethral resection of bladder tumor; VIG: Voiding instructed group

#### Table 2: Precystourethroscopy variables

Variables	Mea	Р	
	VIG (n)	Noninstructed group (n)	
Pulse Rate (per min)	89.64±18.2	89.36±18.8	0.858
Systolic BP (mmHg)	131.24±18.08	133.08±19.8	0.337
Diastolic BP (mmHg)	80.96±10.8	80.16±11.2	0.857
Anxiety score (HAM-A score)	19.26±3.8	19.42±4.06	0.685

VIG: Voiding instructed group, SD: Standard deviation, HAM-A: Hamilton Anxiety Rating Scale; VAS: Visual analog scale; BP: Blood pressure

#### Table 3: Postcystourethroscopy variables

Variables	Mea	Р	
	VIG	Noninstructed group	
Pulse rate	84.28±15.6	90.12±17.5	0.001
Systolic BP (mmHg)	130.52±16.01	133.56±14.4	0.979
Diastolic BP (mmHg)	80.24±10.8	80.52±11.5	0.803
Anxiety score (HAM-A score)	17.86±2.8	19.76±3.12	< 0.001
Pain score (VAS score)	3.06±1.98	5.16±2.86	< 0.001
Mild pain (1-3)	36	2	
Moderate pain (4-6)	14	39	
Severe pain (7-10)	0	9	

VIG: Voiding instructed group, SD: Standard deviation, HAM-A: Hamilton Anxiety Rating Scale; VAS: Visual analog scale; BP: Blood pressure

Table 4: Anxiety score (Hamilton Anxiety Rating Scale score)

Group	mean±2 SD		
	Precystourethroscopy	Postcystourethroscopy	
VIG	19.26±3.8	17.86±2.8	< 0.001
NIG	19.42±4.01	19.76±3.12	0.008

VIG: Voiding instructed group, NIG: Nonvoiding instructed group, SD: Standard deviation

that lidocaine jelly has no favorable effect over plain lubricating gel.<sup>[4]</sup>

The soothing effect of listening music has been examined by Raheem *et al.* Over a 2-year period, a prospective, randomized controlled study of 137 veteran patients in North American Veterans Affairs healthcare system had been done. Two groups, flexible cystoscopy with or without music, were formulated on the basis of biased coin flipped randomization. Both anxiety and pain had been shown to be significantly less in the music listener group.<sup>[5]</sup> Observing scopy procedure and detailed explanation of the procedure to patients were studied by Soomro *et al.*, and they found significantly less pain in the observing group.<sup>[6]</sup> However, Patel *et al.* had challenged this beneficial effect and stated that there is no significant improvement of pain by watching the procedure.<sup>[10]</sup>

Negotiating scope through external sphincter was found to be the most distressing and painful part by Taghizadeh et al. <sup>[7]</sup> To easily negotiate external sphincter, manual compression of irrigation bag during the passage of scope was studied over gravity irrigation. Gunendran et al. had concluded that there was notable amelioration of pain in manual compression of irrigation fluid group.<sup>[8]</sup> This study suggests that opening of external sphincter improves the comfort of patients undergoing cystoscopy. Another natural method to relax external sphincter is voluntary urination. Recently, this principle is applied during catheterization for multichannel urodynamic study by Stav et al. Two groups, patients instructed to void or not instructed to void during catheter insertion, were formed. Pain score was evaluated in view of catheter insertion technique. They concluded that there was substantial improvement of pain by simple voiding instruction.<sup>[9]</sup>

As per our best knowledge, no previous study was done to investigate the effect of natural voiding process during cystourethroscopy on pain and anxiety. The pain was substantially and statistically less in VIG over NIG  $(3.06 \pm 1.98 \text{ vs. } 5.16 \pm 2.86, \text{ respectively})$ . It suggests that voiding instruction is helpful to negotiate cystoscope through external sphincter with ease and comfort. In view of less pain, anxiety and pulse level were also low in VIG. The anxiety level in VIG (19.26  $\pm$  3.8–17.86  $\pm$  2.8) was reduced significantly, while the anxiety level in NIG (19.42  $\pm$  4.01–  $19.76 \pm 3.12$ ) was significantly increased after scopy. This analysis further supports our hypothesis. However, the pain score was higher with respect to the study done by Stav et al. The reason for higher pain score is self-explanatory as they had done a study with 12F Tiemann urethral catheter in comparison to 17 Fr sheath rigid cystoscope.

Both groups were similar in terms of prescopy variables due to randomization, but blinding was not done during the study. This is our limitation, which may result in bias. Rigid cystoscope was used for the present study that can be replaced by a flexible cystoscope. Therefore, we argue to further blind randomized multicentric study to generalize this concept in clinical use.

# CONCLUSION

This prospective, well-matched, randomized study indicates that simple voiding instruction during the passage of scope through external sphincter might be one of the easy but imperative methods to ameliorate pain and anxiety. Hence, we recommend to implement this method during cystourethroscopy as additional adjunct to relieve pain and anxiety.

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# **Conflicts of interest**

There are no conflicts of interest.

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