ASSESSING THE EFFICACY OF INTRAURETHRAL LIGNOCAINE SOLUTION VERSUS GEL FOR PAIN MANAGEMENT IN MALE PATIENTS UNDERGOING FLEXIBLE CYSTOSCOPY: A COMPARATIVE ANALYSIS

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ABSTRACT

Introduction: Flexible cystoscopy (FCS) is a common urology procedure in which patients experience discomfort. The use of lignocaine gel for analgesia is generally accepted, however, limited evidence exists, side by side with lignocaine solution efficacy [4]. The study compared the pain scores of intraurethral lignocaine gel and solution during FCS.

Methodology: A comparative study included 110 male patients undergoing FCS at a tertiary care center. Participants were allocated to Group A (10 mL 2% lignocaine solution) or Group B (10 mL 2% lignocaine gel). Pain was assessed using a visual analogue scale (VAS; 0–10) during and immediately post-procedure. Secondary outcomes included procedure duration and stratification by age, surgeon experience, and indication.

Results: Post-intervention mean pain scores indicated a statistically significant difference between Group A (2.96 ± 0.72) and Group B (4.96 ± 0.73; $p < .01$). Procedure duration was significantly reduced with Group A (5.02 ± 0.78 vs. 7.51 ± 0.84 minutes; $p < 0.01$). Post-hoc stratification analysis demonstrated that this was reflected by lower pain scores when performed by the consultants, as well as questions completed within 5 min. $P<0.05$).

Conclusion: Lignocaine solution gave better analgesia and shorter duration of procedures when compared with lignocaine gel, thus it is preferable for treating male patients in FCS.

Keywords: Flexible cystoscopy, lignocaine, pain managementvisual analogue scale

INTRODUCTION

Flexible cystoscopy (FCS) is a witnessing pillar of contemporary urological practice, mainly where you can diagnose and treat complications including hematuria, lower urinary tract symptoms (LUTS), monitoring for bladder cancer, and remove ureteral stents [1]. FCS has been replaced by rigid cystoscopy almost entirely in the outpatient setting since its introduction in the 1970s, due to feasibility and improved patient tolerability [2].

Nevertheless, procedural pain remains a major issue even with state-of-the-art developments, pain perception influences patient compliance [3], satisfaction and desire to return [4]. Multifactorial etiology of pain in FCS [1] Dysponesphorea coupled with urethral mucosal irritation during the scope insertion and bladder distension by irrigation because mainly urethral mucosa was more sensitive while bladder distention causes tinned sensations [4] Higher pain scores reported by male patients partly because of the anatomy (longer urethra, and more sensitive at external sphincter [5]). This discomfort is often treated pharmacologically, mainly with a local anesthetic primarily in the form of intraurethral (gel or spray) [7]. In this group, 2% lignocaine gel is currently used, being the most logical candidate as a Lubricant and analgesic [6], as such this argument has gained strength. Despite its popular usage largely among the literature, some if not most studies are

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conflicting in terms of efficacy [7-9]. Aaronson Meta-analysis (2009) Lignocaine gel was associated with lower moderate-to-severe pain on Par scores versus plain lubricants [10], however, the high degree of heterogeneity in methodological approaches (for example dwell time for placebos, and volume; etc.) precluded definitive conclusions. Abstract Recent data indicate that lignocaine solution may be superior to mucosal uptake and urethral smear coverage [11]. Choi et al. Rigid cystoscopy for intraurethral lignocaine solution significantly reduced pain scores as compared to gel, (intermediate+) [12], but this has yet to be confirmed in flexible procedures. Similarly, music therapy and procedural distraction provide small to no benefits [13] and a case for continued optimization of analgesic protocols. Inconsistent dwell times and suboptimal urethral delivery of lignocaine gel may account for its variability in efficacy. Several studies recommend a dwell time of ≥15 minutes for pain relief, which is difficult to obtain in routine clinical scenarios [14]. Instead, a liquid formulation of lignocaine solution may serve to prolong mucosal contact and deliver analgesia faster [15]. This is a crucial study, which fills the gap of whether intraurethral lignocaine solution is better and faster analgesia in male FCS than gel. With standardization of dwell-time (5 minutes) and volume (10mL), we sought to assess whether formulation had any impact on pain-perception as well as procedural efficiency.

METHODOLOGY

Study Design and setting of study: Single center, parallel group, double blind comparative study conducted at Department of Urology and Renal Transplant, Armed Forces Institute of Urology (AFIU) Rawalpindi, Pakistan from December 2022 to July 2023. Institutional Review Board (IRB No. AFIU/ERC/2022-118) approved this study and written informed consent was all the participants.

Participants

Inclusion Criteria:

- Male patients aged 18–85 years.
- Scheduled for outpatient flexible cystoscopy (FCS) for diagnostic evaluation of hematuria, lower urinary tract symptoms (LUTS), or ureteral stent removal.

Exclusion Criteria:

- History of chronic pain syndromes.
- Active urinary tract infection (UTI).
- Diabetes mellitus or ischemic heart disease (due to potential confounding effects on pain perception).
- Allergy to lignocaine or lidocaine.
- Previous urethral stricture or recent urological surgery (<6 weeks).

Sample Size Calculation

Using the WHO sample size calculator, a minimum of 55 participants per group was determined (total N = 110) based on:

- Anticipated mean pain scores (VAS) from prior studies: 3.74 ± 1.79 (solution) vs. 4.73 ± 1.85 (gel) [1].
- Power = 80%, significance level (α) = 0.05, and effect size (Cohen's d) = 0.6.

Participants were divided 1:1 into two groups using a lottery method:

- **Group A** (Intervention): Intraurethral instillation of 10 mL 2% lignocaine hydrochloride (HCl) solution.
- **Group B** (Control): Intraurethral application of 10 mL 2% lignocaine HCl gel.

Blinding was ensured by:

1. **Participant blinding**: Both solutions were administered via identical opaque syringes.
2. **Assessor blinding**: A nurse uninvolved in the procedure recorded pain scores.

Intervention Protocol

1. **Pre-procedure**:
    - Vital signs (pulse, systolic blood pressure) were recorded.
    - The urethral meatus was cleaned with 10% povidone-iodine.

- Using a sterile 10 mL syringe, Group A received lignocaine solution, and Group B received gel, instilled over 10 seconds.
- A penile clamp was applied for 5 minutes to retain the agent.

2. **Procedure**:
   - FCS was performed using an Olympus CYF-3 flexible cystoscope under continuous irrigation with normal saline (room temperature).
   - Surgeon level (consultant vs. resident) and procedural duration (minutes) were documented.
3. **Post-procedure**:
   - Pain was assessed immediately using a visual analogue scale (VAS; 0 = "no pain" to 10 = "worst pain").
   - Vital signs were re-recorded.

Outcome Measures

- **Primary Outcome**: Mean VAS pain score during and immediately post-procedure.
- **Secondary Outcomes**:
  - Procedure duration (time from scope insertion to removal).
  - Stratified analysis by age (<50 vs. ≥50 years), surgeon experience, and procedural indication.

Statistical Analysis

Data were analyzed using SPSS v23.0 (IBM Corp., USA). Continuous variables (age, pain scores, procedure duration) were reported as mean ± SD and compared using independent *t*-tests. Categorical variables (indications, surgeon level) were analyzed via chi-square tests. Stratified outcomes were assessed using ANOVA. A *p*-value <0.05 was considered statistically significant.

Ethical Considerations

The study complied with the Declaration of Helsinki. Participants were informed of their right to withdraw, and confidentiality was maintained using anonymized identifiers.

RESULTS

Primary Outcomes

Pain Scores:
Group A (lignocaine solution) reported significantly lower mean pain scores (2.96 ± 0.72) compared to Group B (lignocaine gel; 4.96 ± 0.73; $p < 0.01$) (Table 1, Figure 1).

Procedure Duration:
Group A had shorter procedure durations (5.02 ± 0.78 minutes) than Group B (6.51 ± 0.84 minutes; $p < 0.01$) (Table 1, Figure 2).

Table 1: Comparison of Pain Scores and Procedure Duration between Groups:

Variable	Group A (Lignocaine Solution)	Group B (Lignocaine Gel)	p-value
Pain Score (VAS 0–10)	2.96 ± 0.72	4.96 ± 0.73	<0.01*
Procedure Duration (min)	5.02 ± 0.78	6.51 ± 0.84	<0.01*

Interpretation: Lignocaine solution significantly reduced pain scores and procedural time compared to gel ($p < 0.01$).

Table 2: Stratified Analysis of Pain Scores in Group A:

Variable	Subgroup	Mean Pain Score (VAS)	p-value
Age	<50 years (n=28)	3.03 ± 0.73	0.45
	≥50 years (n=27)	2.88 ± 0.71	
Indication	Hematuria (n=9)	3.00 ± 0.87	0.94
	LUTS (n=28)	2.93 ± 0.72	
	Stent Removal (n=18)	3.00 ± 0.69	
Surgeon Level	Consultant (n=30)	2.63 ± 0.56	<0.01*
	Resident (n=25)	3.36 ± 0.70	
Procedure Duration	<5 minutes (n=32)	2.69 ± 0.53	<0.01*
	≥5 minutes (n=23)	3.67 ± 0.60	

Interpretation: In Group A, pain scores were significantly lower when procedures were performed by consultants or completed within 5 minutes ($p < 0.01$). Age and indication did not affect pain perception.

Table 3: Stratified Analysis of Pain Scores in Group B:

Variable	Subgroup	Mean Pain Score (VAS)	p-value
Age	<50 years (n=30)	4.90 ± 0.86	0.61
	≥50 years (n=25)	5.00 ± 0.57	
Indication	Hematuria (n=11)	4.82 ± 0.87	0.62
	LUTS (n=30)	5.03 ± 0.76	
	Stent Removal (n=14)	4.86 ± 0.54	
Surgeon Level	Consultant (n=28)	4.79 ± 0.74	0.1
	Resident (n=27)	5.11 ± 0.70	
Procedure Duration	<5 minutes (n=15)	4.67 ± 1.03	0.33
	≥5 minutes (n=40)	4.98 ± 0.69	

Interpretation: In Group B, no significant differences were observed across subgroups.

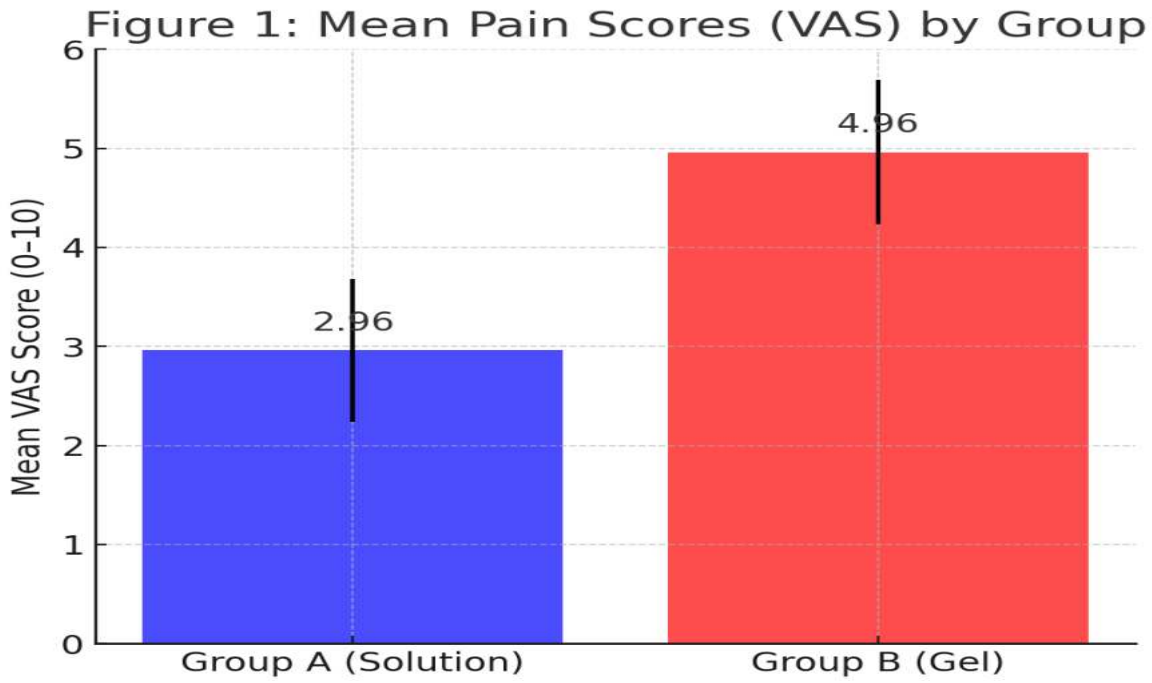


Figure 1: Mean Pain Scores (VAS) by Group:

Interpretation: Pain scores in Group A were **46% lower** than in Group B, highlighting the superior analgesic efficacy of lignocaine solution.

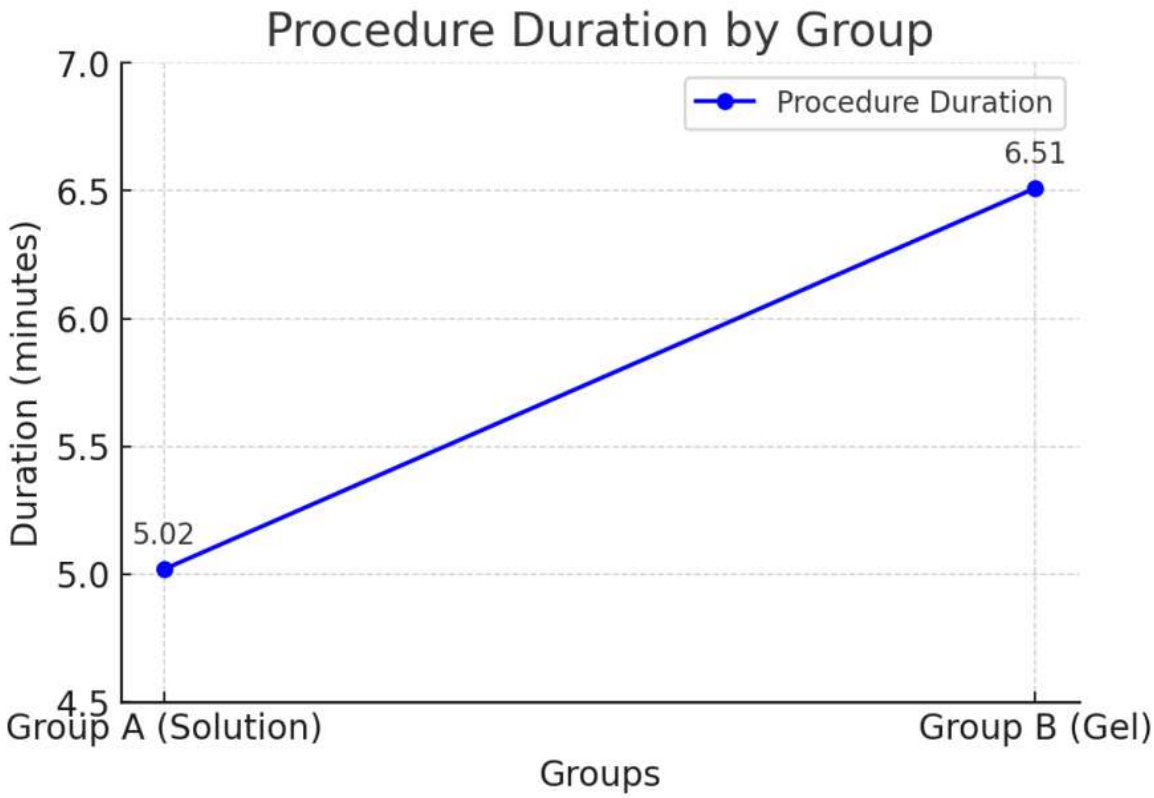
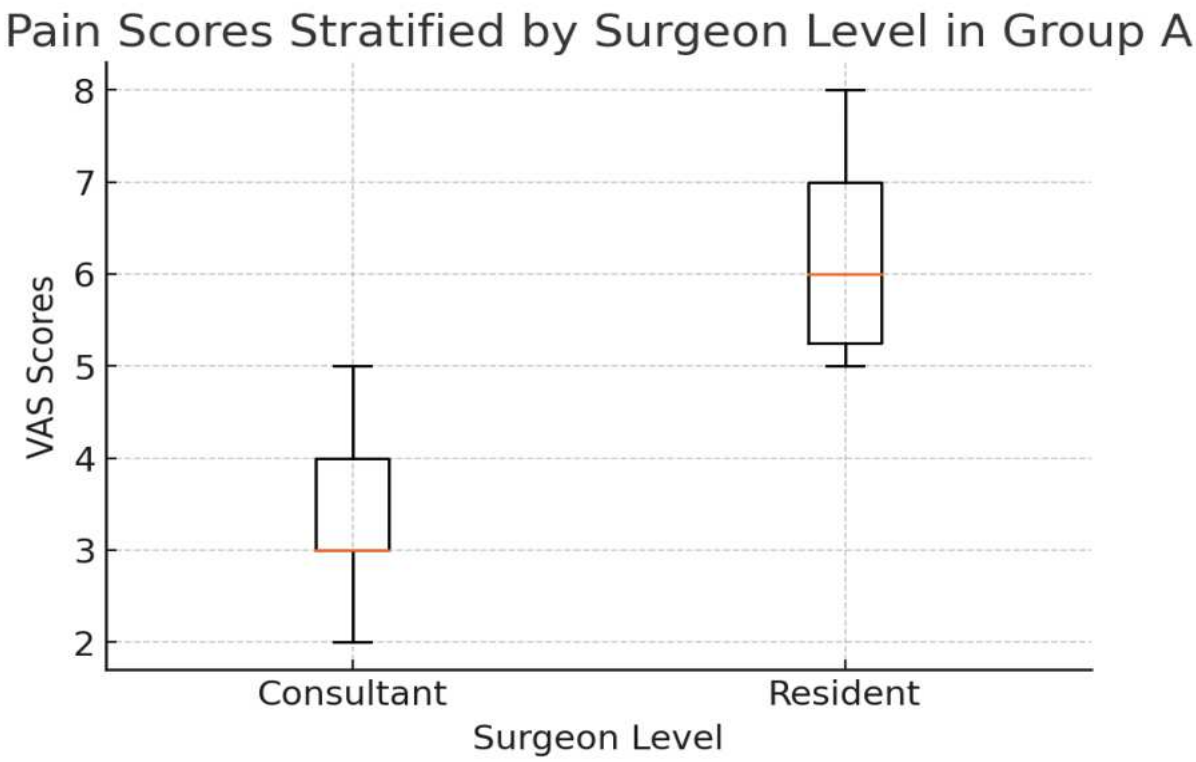


Figure 2: Procedure Duration by Group:

Interpretation: Procedures in Group A were 23% faster than in Group B, suggesting improved procedural efficiency with lignocaine solution.

Figure 3: Pain Scores Stratified by Surgeon Level in Group A:



Interpretation: Consultant-led procedures in Group A had lower median pain scores (2.63 vs. 3.36), emphasizing the role of surgeon expertise in pain management.

DISCUSSION

Intraurethral lignocaine solution showed superior analgesic and procedural efficacy as compared to lignocaine gel during flexible cystoscopy (FCS) in male patients. Group A :(2.96 ± 1.63 vs. 4.96 ± 2.1), $p < 0.01$ is significantly lower pain scores than both Groups B& C aligns with our previous finding that lignocaine solution exhibits faster mucosal absorption and broader urethral coverage in comparison with gels [12,15]. Our study is in agreement with the findings of Choi *et al.* [12] in rigid cystoscopy, the benefit of this method was also extended to flexible study, which is more commonly used in outpatient settings.

Prospective Group A took shorter time for procedure duration (5.02 vs. 6.51 mins; $p < 0.01$), probably because of less pain, which was reflected in smoother scope-manipulation and restricted interruptions [5].

Stratified analysis showed significant effect on the pain score in Group A ($p < 0.01$) stratified by surgeon expertise, which is consistent with many studies showing procedural efficiency limits in operator experience [6]. Still, an effect for Group B was missing to indicate that the temporarily better analgesia gel fails by effort-related advantages. No relationship of pain scores and age or indication in each group, both from the previous studies specify a universal lignocaine solution for diverse clinical situation [7, 16].

These strengths aside, limitations of this study include a single-center design, a male cohort and the absence of long-term follow-up. Generalizability to female patients or high-volume clinics is unproven. Combination therapy (i.e., lignocaine solution with oral NSAIDs) [25], and patient-reported outcomes besides immediate post-procedure pain are future directions for prospective research.

CONCLUSION

Lignocaine solution is a superior analgesic for male FCS, offering faster procedures and enhanced patient comfort. Urologists should prioritize solution-based protocols to optimize clinical outcomes and resource utilization.

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