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ORIGINAL ARTICLE

To Compare the Mean Peak Flow Rate of Holmium Laser Versus Cold Knife Among Patients Undergoing Direct Visual Internal Urethrotomy

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ABSTRACT
Background: During the last two decades, laser methods have become popular among many people. The current study explores the differences in peak flows between holmium laser and cold knife during DVIU so as to maximize on the outcomes of this treatment modality in urethral strictures.
Methodology: A prospective randomized controlled trial was carried out at the Department of Urology, Liaquat National Hospital in Karachi from January 1st, 2019, to June 30th, 2019. The study enrolled 130 patients, evenly divided into two groups: The patients of Group A were opened up using a cold knife method, and Group B was done using holmium laser. After the procedure, on the 30th day, the peak flow rate comparison between the two groups was conducted by an independent t-test, with a significance level set at $p \le 0.\ 1.\ 05$. The experimental configuration and quantitative analysis approach thus formed a reliable basis for investigating the activity of the two different treatment modalities for the urethral stricture.
Results: The pre-operative mean peak flow rate was recorded as 6. 32±1. 27 ml/s in group-A and 7.3c6±1.37 ml/s in group-B. The average peak flow rate on the 3rd day was 26.66±3.69 ml/s in group-A and 28.72±4.63 ml/s in group-B. The peak flow rate on the 30th day is 24. 00±3. 44 ml/s in groups A and 20.84±2.77 ml/s in group B. The results indicated a significant mean difference for the mean peak flow rate on the 30th day according to study groups (p-value=0. 000).
Conclusion: Both knives and lasers have proved to be effective therapeutic modalities in delivering prompt relief to patients with urethral strictures. However, it was noted that those who underwent the procedure with a cold knife produced better long-term results.
Keywords: Mean Peak Flow Rate, Holmium Laser, Cold Knife, Direct Visual Internal Urethrotomy

INTRODUCTION
Urethral stricture, one of the earliest known urological conditions, remains both prevalent and challenging to manage today[1,2]. It is a common condition with a significant morbidity rate, with its estimated prevalence in developed countries being around 0.6%, potentially higher in developing countries[3]. Treatment options vary based on the length, location, and depth of scarring of the stricture, with multiple therapeutic approaches developed over time[4-5].

As treatment modalities have evolved, several minimally invasive techniques have become prominent, including electrocautery, cold-knife urethrotomy, and various types of laser treatments. These have particularly gained popularity in the last two decades[6]. Cold-knife incision avoids thermal damage to surrounding tissues but can cause mechanical injuries leading to recurrence. Electrocautery, on the other hand, may lead to significant thermal damage and subsequent recurrent strictures[6]. Among the laser treatments, the Holmium:YAG (Ho:YAG) laser has become a primary choice in recent years due to its efficacy and precision[6].

The Sachse Urethrotome, when utilized with a 0-degree telescope and a 21 Fr sheath, achieves an 80% success rate in managing strictures. This device is carefully advanced to the stricture site, and if necessary, a 5Fr guide wire assists in guiding the urethrotome. The stricture is then incised using a 12 o'clock position technique until adequately treated[4,7].

Furthermore, various lasers such as carbon dioxide, argon, potassium titanyl phosphate (KTP), neodymium (Nd), yttrium-aluminum-garnet (YAG), and holmium (Ho):YAG is involved in treating the urethral stricture disorder (6). Recent advances have highlighted the Ho:YAG laser becomes a preferred tool for endourology since it has high precision and minimal thermal effect on adjacent tissues[6].

In recent studies, participants were divided into cohorts to compare outcomes between cold knife direct vision internal urethrotomy (DVIU) and holmium laser endourethrotomy. The findings indicated variations in postoperative complications and surgical times, underscoring the differences in procedural impact[1]. Additionally, studies comparing flow rates and operative times further delineate the distinctions between these treatment modalities[6].

Both the holmium laser and cold blade urethrotomy have been proven as safe and effective methods for short bulbar urethral strictures treatment[1,8]. Each method has its own requirements and related costs. The Ho:The YAG laser, in particular, has gained recognition for its outstanding capabilities in coagulation and vaporization with minimal thermal damage compared to electrocautery and other laser modalities[6]. This study aims to assess the efficacy of optical internal urethrotomy that uses a holmium laser compared to a cold knife in the treatment of short-segment urethral strictures. .

METHODS AND MATERIALS
This research was done in the Department of Urology at Liaquat National Hospital, Karachi, during a six-month period from January 1, 2019, to June 30, 2019. The research aimed at determining variances in peak flow rates between patients undergoing two different operations for urethral stricture. Using the OpenEPI software for sample size calculation with a 95% confidence level and a power of 80%[4], it was found that 130 patients were needed for the study, with 65 patients allocated to each treatment group through non-probability consecutive sampling.

A randomized control trial design was employed. The study included males aged 18 to 70 years with short segment urethral strictures (length <2 cm), while excluding those younger than 18 or older than 70, patients with multiple or recurrent strictures, those with active urinary tract infections, complete urethral obliteration on urethroscopy, and patients with pan-anterior strictures, posterior stenosis, failed prior interventions, or lichen sclerosis changes. Short segment urethral stricture was defined based on radiological findings (retrograde urethrography and micturating cystourethrography) and clinical symptoms such as a peak-flow rate less than 15ml/sec or the presence of obstructive symptoms.

Research was conducted using approval of CPSP and through getting the consent of participants or their guardians. The patients were diagnosed with urethral stricture based on their clinical history, uroflowmetry, and imaging studies. They were then randomly assigned into two groups, one undergoing cold knife direct vision internal urethrotomy (DVIU) and the other having holmium laser internal urethrotomy (HLIU).

This technique involved setting up the patient in the lithotomy position, navigating the guide wire over the stricture, and employing a Sachse urethrotome with 0-degree telescope and 21 Fr sheath in incising the stricture at 12 o'clock position. This was repeated until the urethra was sufficiently opened to accommodate the scope. This was followed by the insertion of a 20 Fr Foley catheter.

The holmium laser technique used a side channel with a 21 Fr sheath and a 0-degree scope to introduce a 365 µm holmium laser fiber. The Versa power laser was adjusted to 0.6 to 1.2 Joules and 6 to 12 Watts. After the stricture at 12 o'clock position was cut and the scope was carefully withdrawn, a 20 Fr Foley catheter was placed.

Uroflowmetry was used to assess patients postoperatively at Day 3 and 30 days later, with the operating time also recorded. The outcome was primarily measured by the mean peak flow rate at day 30 post-treatment. Data were analyzed using SPSS Version 21, comparing mean values and standard deviations of various quantitative variables. An independent t-test determined the significance of differences in peak flow rates, with further stratification by age, stricture length, and other factors to assess their impact on outcomes, maintaining a significance level at p ≤ 0.05.

RESULTS

We recruited a cohort of 130 men aged 18 to 70 years. The mean age of Group A was 29. 89±4.98 years, while group B also had a mean age of 29.89±4.98 years. The average stricture length was 1.34±0.23 cm in group A and 1.41±0.21 cm in group B. Operative durations were similar between the groups, with a mean of 12.53±1.65 minutes for Group A and 12.47±1.46 minutes for Group B.

The mean peak flow rate in preoperative state was 6.1.32±1.27 ml/s in the Group A; 2.36±1.37 ml/s in Group B. On the third day post-operation, the mean peak flow rate increased to 26.66. 3±3.69 in Group one and 28 in Group two. 72±4.63 ml/s for Group A whereas 24 ml/s for Group B on day 30. But, the continuous decline of the peak flow rate was observed. 24.00±3.44 ml/sml/s in Group A and 20.84±2.77 ml/s as Group B and shown in Table 1.

Frequency and percentage of operative time groups are presented in Figure 1.

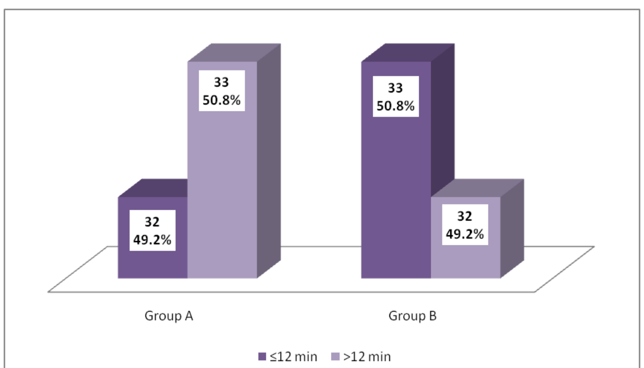

Figure 1: Frequency of Patients According to Operating Time Group (N=130)

Stratification was done for age, length of stricture, and operating time to compare groups for mean peak flow rate at 30th day. We found significant mean peak flow rate at 30th day difference for patient with age ≤30 years (p=0.009), with age >30 years (p=0.000), with stricture length ≤1.3 cm (p=0.000), with stricture length >1.3cm (p=0.001), with operative time ≤12 minutes (p=0.000) and with operative time >12 minutes (p=0.000) as presented from Tables 2-4.

Table 1: Descriptive Statistics of Sociodemographic and Clincial Variables

Variables	Group A (n=65)	Group B (n=65)
Age In Years	29.89 ± 4.98	31.13 ± 5.34
Stricture Length	1.34 ± 0.23	1.41 ± 0.21
Operating Time In Mins	12.53 ± 1.65	12.47 ± 1.46
Preoperative Peak Flow Rate (Ml/S)	6.32 ± 1.27	7.36 ± 1.37
Peak Flow Rate At 3rd Day (Ml/S)	26.66 ± 3.69	28.72 ± 4.63
Peak Flow Rate At 30th Day (Ml/S)	24 ± 3.44	20.84 ± 2.77

Table 2: Mean Peak Flow at 30th Day According to Study Group for Patient With Age≤30 Years (N=59)

Variable Group		Study Group		P-Value
		Group A	Group B	
Age≤30 Years (N=59)	Mean	23.34	21.01	0.009*
	SD	3.86	2.61	
Age>30 Years (N=71)	Mean	24.60	20.71	0.000*
	SD	2.93	2.92	

Independent t- test were applied
P-value ≤0.05 considered as Significant.
*Significant at 0.05 levels

Table 3: Mean Peak Flow at 30th Day According to Study Group for Patient With Stricture Length ≤1.3 cm (N=62)

Variable Group		Study Group		P-Value
		Group A	Group B	
Stricture Length ≤1.3 cm (N = 62)	Mean	24.39	20.96	0.000*
	SD	3.35	2.89	
STRICTURE LENGTH>1.3 CM (n=68)	Mean	23.44	20.77	0.001*
	SD	3.55	2.73	

Independent t- test were applied
P-value ≤0.05 considered as Significant.
*Significant at 0.05 levels

Table 4: Mean Peak Flow at 30th Day According to Study Group for Patient With Operating Time

Variable Group		Study Group		P-Value
		Group A	Group B	
Operating Time≤12 Min (N=65)	Mean	23.86	20.81	0.000*
	SD	3.39	2.68	
Operating Time>12 Min (N=130)	Mean	24.13	20.86	0.000*
	SD	3.53	2.91	

Independent t- test were applied
P-value ≤0.05 considered as Significant.
*Significant at 0.05 levels

DISCUSSION

The treatment of urethral stricture (US) has been a significant clinical challenge documented throughout history, with references found in ancient Hindu, Egyptian, Greek, and Islamic literature. Historical figures such as Abu Baker Al-Razi and Ibn Sena have made notable contributions to its management, emphasizing the importance of catheter use and urethral irrigation techniques[4, 9]. Today, urethral stricture management encompasses a range of approaches including dilation, urethrotomy, stent implantation, and urethroplasty, reflecting its complex nature[4].

Male urethral stricture disease not only affects the quality of life but also imposes substantial healthcare costs[10]. It is commonly caused by trauma or iatrogenic interventions, although infectious and less common etiologies such as congenital or malignant conditions are also recognized contributors[11]. The clinical manifestation of US typically includes symptoms of urinary obstruction similar to those of benign prostatic hyperplasia, which can complicate the diagnosis[10,12].

Despite advancements in surgical techniques, achieving long-term success in US treatment remains elusive due to high recurrence rates and varied surgical outcomes[13]. Since the introduction of Sachse's optical internal urethrotomy (OIU) in 1974 in the United States, the search for more effective treatments has led to the adoption of the Holmium laser, which has shown promise particularly from the early 1990s[13].

Recent research by Atak et al. demonstrated a significant innovation in the field, comparing the efficacy of the Holmium laser and the conventional cold knife method in treating urethral stricture. Their findings indicated not only shorter operative times with the laser but also superior long-term outcomes in terms of recurrence rates[4]. This aligns with other studies that emphasize the Holmium laser's effectiveness in restoring urethral patency with minimal impact on urogenital function[14].

Furthermore, studies have also explored the primary causes of the US, revealing varying contributions of trauma, medical procedures, and infections, which underscore the heterogeneity of this condition[97,6]. For instance, a study conducted by AL-Mosawi HY and another by AL-Farzai AS found different distributions of causative factors, indicating the influence of geographic and demographic variables on the incidence of US[15,6].

The recent comparative study in this research between the Holmium and Cold Knife groups over a 6-month period provides additional insights into the post-operative outcomes, showing a marked decline in the peak flow rate over time for the Cold Knife group compared to a more stable outcome for the Holmium group[4]. These findings are supported by other research, such as the work by Hussain M et al. and Jain SK et al., which further documents the complications associated with these procedures, highlighting the superior safety profile of laser treatments[4,16-18]. Furthermore, a study by Ali MM et al[19] confirms the high success rates of Holium laser treatment and concludes that it is a safe and effective treatment option for urethral strictures.

Despite the strengths of this study, it is essential to consider the limitations of these studies, such as small sample sizes and the potential lack of generalizability due to the studies being conducted in specific urban environments. In conclusion, the evolution of urethral stricture treatment from ancient techniques to modern laser therapies illustrates significant progress. However, the complex nature of this condition requires ongoing research to refine these approaches and ensure that they are adaptable to various patient populations, thereby enhancing overall treatment efficacy and patient outcomes.

CONCLUSION

This study establishes the fact that both CK and HoLU are effective procedures for managing short segment urethral strictures. Even though both methods give instant relief in cases of single and short urethral strictures (<2 cm), the cold knife technique has a more lasting effect over time. Inversely, the holmium laser which needs more technical knowledge and longer operating hours is also another viable option after internal urethrotomy procedure. These results reiterate the significance of selection of an appropriate technique of surgery which is based on the individual patient attributes and characteristics as well as the attributes of stricture to ensure the desired results.

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