

Evaluation of Combined Electro Cutter with Cold Knife in the Intractable Anterior Urethral Stricture Urethrotomy

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Abstract

Background: Sachse cold knife is conventionally used for optical internal urethrotomy to manage urethral strictures. In this procedure, the complications and recurrence rates are relatively high. We suggest combined electro cutter and cold knife as a success alternative in the management of intractable anterior urethral strictures.

Methods: In this prospective study, 87 male patients aged ≥ 18 years, with diagnosed intractable urethral stricture (≥ 2 times recurrence) who were admitted for internal optical urethrotomy during May 2010 to Jun 2013, were included. The patients were randomized into two groups: group A (electro cutter - cold knife group, $n=45$) and group B (cold knife group, $n=42$). In group A, internal urethrotomy was done with electro cutter - cold knife, and in group B, Sachse cold knife was used. Patients were followed up for 6 months after surgery in Outpatient Department on 15, 30 and 180 post-operative days.

Results: The success rates in group A and B were 46.6% (21 out of 45 patients), and 23.80% (10 out of 42 patients), respectively ($P<0.05$). The complications were seen in 11% of group A and 64% of group B. At 180 days (6-month interval), the difference between mean of PFR for electro cutter - cold knife group and cold knife group was statistically significant ($P<0.01$).

Conclusion: Combined electro cutter with cold knife urethrotomy modality is effective than conventional cold knife urethrotome in providing immediate relief in recurrent urethral strictures and has lesser complications in patients with intractable and recurrent urethral strictures.

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Introduction

Urethral stricture is a medical and the most challenging problem in urology that has been recorded for more than 2500 years throughout the history and has always been a challenge for urologists. This disease was spoken of in the ancient literature of the traditional Hindu system of medicine, the Ayurveda (660 B.C.) (1-

3), they used wooden or metal dilators for the treatment. The first internal urethrotome was designed by Civiale in 1817. Maisonneuve, in 1848, proposed the idea of the filiform wire to be introduced into the urethra and screwed to the urethrotome. In 1870, a blind procedure with 2-blade urethrotome, was introduced by Otis that was used for long time (4,5).

Direct vision urethrotomy with electric diathermy was tried by Ravasini in 1957, but it was not used until 1971 that Sachse introduced the sharp-bladed cold-knife urethrotome under direct vision, reporting 60–70% success rate with this procedure. Despite this initial success rate report, the results of previous studies indicate that 40–70% of strictures managed with endoscopic urethrotomy recur within 2 years. This was an internal urethrotomy technique under direct vision with a single cut at the 12 o'clock position.

However, although his method is known to be the primary treatment cure for many of urethral stricture cases, it yields no relatively good results in some challengeable resistant and refractory strictures which has made results insufficient with success rates of 33–60%.

This high recurrence rate in most times necessitates the need to invasive varieties of open urethroplasty with its devastating post-operative complications (6-8).

Lasers have been used for the treatment of urethral strictures since 1977. The types of lasers that have been used for urethrotomy include carbon dioxide, Nd: YAG, the KTP, the Argon, the Ho: YAG and excimer lasers. There is not superiority between laser types. Holmium: YAG is the latest laser modalities that is available for urological applications; it provides both direct contact cutting and vaporization with minimal forward scatters. However, laser modalities are not experienced in intractable urethral strictures (9).

Although internal urethrotomy continues to be the most commonly used procedure, but the optimal management is still widely debated, because recurrence rate of all types of urethrotomy ranges from 51 to 72% in the long period (10).

Despite these progresses in the treatment of urethral stricture that has been varied through the years, the success of treatment has not been totally satisfactory, especially when we encountered with intractable and recurrent strictures.

We herein suggested our experience, urethrotomy by combined cold knife with electro cutter, in 120 patients with intractable urethral strictures. The ease and relative comfortness of performing this method under spinal anesthesia has prompted us to perform this method as an ambulatory procedure.

Materials and Methods

This present prospective study was conducted in the Department of Urology in a teaching hospital, Kerman, Iran, from May 2010 to Jun 2013. The protocol was approved by the Scientific and Ethics Committee of the hospital. Informed and signed consent forms were taken from all patients after explaining the nature of the study and the consequences of the procedure. Patients had the right to withdraw from the study at any time without any problems. This study was conducted on the basis of the Null hypothesis, which indicates that there is a difference in treatment outcome between the two groups. A total of 112 male patients with diagnosed proved recurrent and

intractable anterior urethral strictures requiring optical internal urethrotomy and those who had previously undergone different unsuccessful treatments were included in this study. Follow-up was available in 87 patients (72.5%) (for 6 months). In group A, the patients underwent internal urethrotomy by cold knife and electro cutter. In group B, only Sachse cold knife was used for internal urethrotomy.

To minimize selection bias and ensure that the type of injury was homogeneous, Inclusion criteria were - (1) presence of obstructive symptoms, (2) PFR < 15 ml/s, (3) anterior urethra strictures length \leq 2 cm, and (4) recurrent stricture history. Exclusion criteria that used in this study were (1) Complete urethra lumen obstruction, (2) Balanitis Xerotica Obliterans, (3) Age <18 years, (4) Multiple strictures, and (5) Active UTI. Preoperative evaluation included a comprehensive history and a detailed physical examination, complete blood count (CBC), urine analysis, urine culture and sensitivity test, renal function tests,

uroflowmetry, micturating cystourethrography (MCU), retrograde urethrography (RGU), sonourethrography (for evaluation of periurethral fibrosis and spongiofibrosis) and urethroscopy using 0° telescope (the location and extent of the stricture along with the urethroscope ability to pass through the stricture was noted).

Uroflowmetry was done in all patients. The procedure was performed under spinal anesthesia in lithotomy position. Antibiotic (Ciprofloxacin, 500 mg) was given just before

and 12 h after procedure and continued for next 5 days. Glycine solution 1.5% was used for irrigation during the procedure.

All procedures were performed by a single surgeon (A. A. K.).

In group A, under direct urethoscopic vision using a 19F rigid cystoscope, after which first cold knife urethrotomy was performed through mucosal thickness and then fibrose layer was electrically incised at a low wattage (90 - 120 W) with a mono-polar cutter resector until healthy tissue (spongiosal tissue).

In group B, the stricture was incised through mucosal thickness and fibrose layer until healthy tissue using the knife at 12 o'clock position. The procedure was repeated till the stricture was adequately opened up and reach healthy tissue.

In both groups, if necessary, a 5F ureteric catheter or a 0.038 inch guidewire was passed through the side channel to guide the urethrotome, then the urethrotomy was performed in the 12 o'clock position using a 21F urethrotome. Procedure was completed with cystoscopy. Easy negotiation of the telescope into the urinary bladder after the operation was taken as the success of the procedure. At the end of the procedure, a 16-18 F Foley catheter was inserted per urethra which was removed after 24 h followed by uroflowmetry test. Visual analog pain score (VAS) was used for the determination of post-operative pain. Analgesic (indomethacin suppository) was used if necessary. The patients were discharged from hospital on the next day.

Operative time was recorded as the time interval beginning with the passing of optical urethrotome from external urethral meatus, continuing with procedure either by combined procedure or cold knife and ending with the removal of urethrotome from external urethral meatus. Spontaneous voiding with peak flow rate more than 15 ml/s without any requirement of post-operative urethral dilatation was taken as a successful procedure.

Patients were followed up in Out Patient Department on 15, 13, and 180 post-operative days. At every follow-up visit, if voided volume was <200 ml, the uroflowmetry test was performed and if it dropped to less than 15 ml/s, urethral dilatation was performed.

The Kaplan-Meier method was used to estimate survivor function for the 2 treatment methods (survival time was regarded as the time to first stricture recurrence) and the log-rank test was used to compare the efficacy of treatments.

Results

A total of 112 male patients with diagnosed urethral strictures requiring optical internal urethrotomy were included in this study. In this study, the two groups were compared with respect to age distribution, etiology of stricture, site of the stricture and pathologic characteristics of urethral strictures (severity of periurethral fibrosis and spongiofibrosis (Table 1-2)).

Follow-up was available in 87 patients (77.5%). In group A (n=45), the patients underwent internal urethrotomy with combined

electro cutter with cold knife. In group B (n=42), Sachse cold knife was used for internal urethrotomy. The estimated stricture-free rate as success rate at 12 months was 46.6% after combined internal urethrotomy and 23.80% after optical internal (Sachse) urethrotomy, and the difference was statistically significant ($P=0.04$) (Figure 3).

However, although this method has been shown to improve early stage patients and had relatively good results, it has not been satisfactorily effective in difficult and resistant patients, and success rates have been reported to be between 33% -60%. In group A, the procedure was successfully completed, the mean operative time was 20.5 min (range 17-24 min), total complications in this group were five (11.11%), (Figure 1), which was managed conservatively. During 6-month follow-up of this group, peak flow rate of less than 10 ml/s was recorded on uroflowmetry in 24 patients (19.23%) and regarded as recurrence rate. On the other hand, in Group B, internal urethrotomy was also completed successfully in all patients allotted under it, the mean operative time was 6.45 min (range 5-10 min.), 27 patients (64%) had some complications (Figure 1), and recurrence rate was 76.2% in this group.

In this study, the successful procedure was the complete and easy passage of the telescope into the bladder at the end of each operation. The pain score had not more than three in both groups so two groups were comparable for pain score.

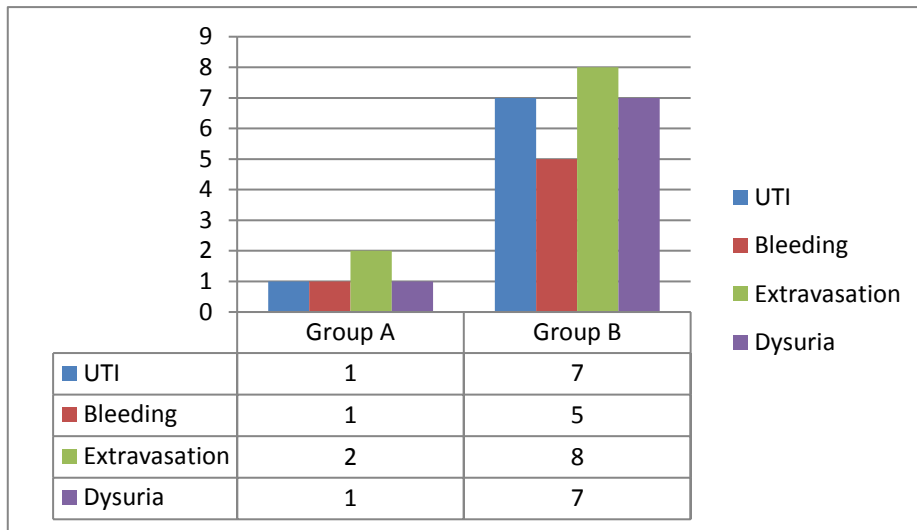


Figure 1. Comparison of complications between two groups.

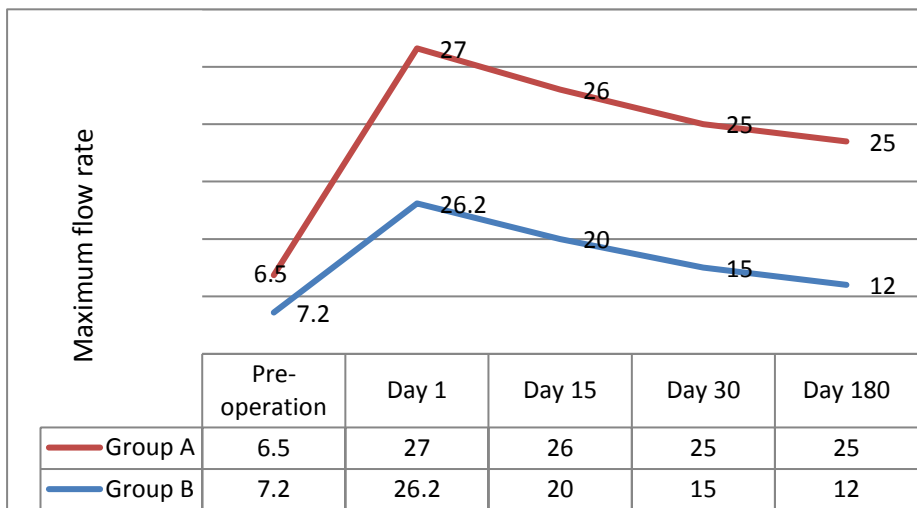


Figure 2. Changes in PFR (peak flow rate).

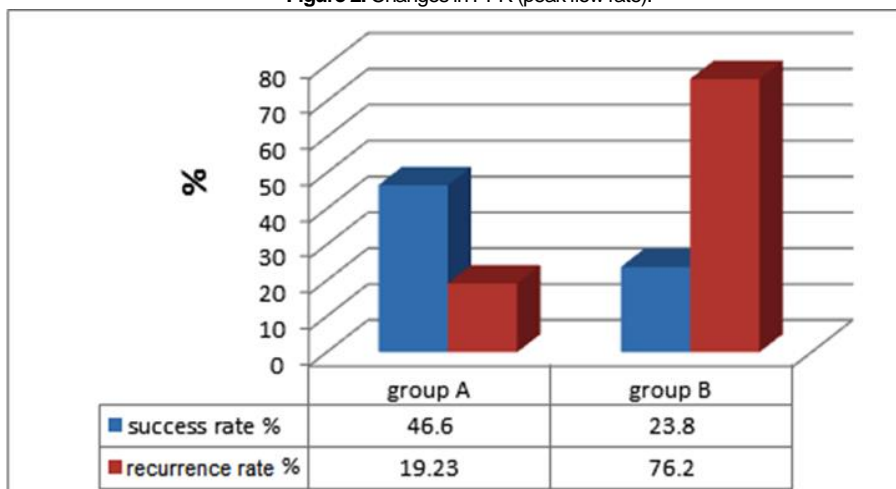


Figure 3. Comparison of the final success and recurrence rates between two groups

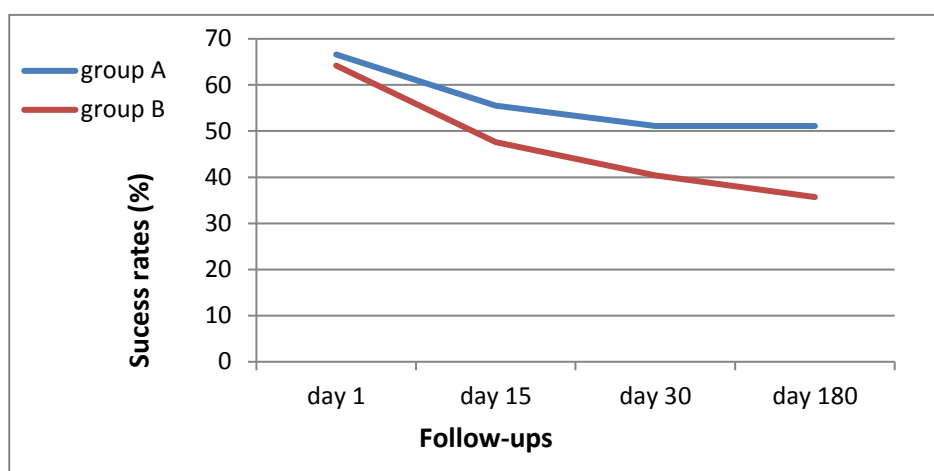


Figure 4. Comparison of success rate follows in both groups.

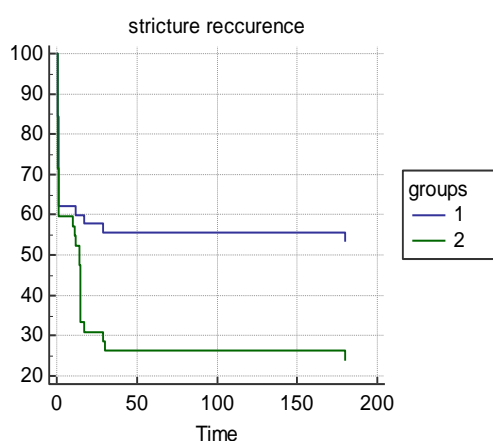


Figure 5. Kaplan-Meier: Stricture recurrence analysis by number of follow-up days (Group 1= combined group, Group 2 = cold knife only group)

Table 1. The etiology and anatomical site of Urethral stricture

Etiology	
Iatrogenic	32(36.76)
Trauma	25(28.73)
Idiopathic	15(17.24)
Infection	12(28.79)
Congenital	3(3.44)
Anatomical site of Strictures	
Penile	35(40.22)
Bulbar	38(43.67)
Bulbo- membranous	14(16.09)

Table 2. Patient characteristics.

	Group A	Group B	P-value
Age (years) Meant± SD	45 35±3.6	42 32±2.6	0.212
With other injury N (%)	11(24.44)	13(30.95)	0.085
Complication N (%)	5(11.11)	27(64.28)	*0.032
Recurrence history Meant±SD	2.8±2.1	2.1±1.8	0.122
Stricture length (cm.) Meant± SD	1.6±0.4	1.8±0.5	0.125
fibrosis and spongiobrosis (Sever type %)	39.08%	43.67%	0.132

Significant*

Discussion

Sachse cold knife is conventionally known as the last gold standard endoscopic urethrotomy, but with Sachse cold knife alone, the efficacy of internal urethrotomy is 35–60% and stricture reoccurs in 89% of patients according to EAU Guidelines (2008) (11).

Urethral stricture recurrence is unexpected and unpredictable, such that even after long symptom-free periods, about Two-thirds of urethral strictures recurred after the first urethrotomy with a 4-month interval. More than fifty percent of recurrences present within one year after IU and only 6% present after 5 years. By these methods, only 5.8% of the second internal urethrotomy procedures for stricture recurrence are successful (12). Waleed Altaweel also has claimed that there is no significant difference in the stricture-free rate between single and multiple procedures by cold knife urethrotomy (13).

The low success rate and the recurrence of stricture despite treatment have prompted the search for new treatment methods. Different treatment modalities such as Ho: YAG laser, dilatation, stent placement, and submucosal injection of fibrolitic agents as initial treatment or after conventional cold knife urethrotomy have been used for urethral stricture disease.

Since 1984, lasers have been used in urethrotomies. The Holmium (Ho: YAG) laser, demonstrates the shallowest absorption (<0.5 mm) with smallest effect on surrounding tissues and is presumed to reduce scar tissue formation. Data published until now have not demonstrated a significantly better outcome with Ho: YAG treatment over other types of laser or cold-knife urethrotomy. Perhaps, the

postoperative development of re-stricture not only depends on laser type, but also on many other factors as stricture condition (14,15).

There have been a few prospective randomized clinical trials in the recent years on comparative study of Holmium laser over conventional cold knife for internal urethrotomy. In these studies, although operative time was shorter in laser group when compared with cold-knife group but the Recurrence-free rate at 3 months was similar between two groups (9).

The use of electrocautery in urethrotomy first time was tried by Ravisini in 1957 and caused more damage to urethral layers, particularly to mucosal layer, and also rapid recurrence rates and extensive fibros formations (16). It was replaced by cold knife urethrotomy by Sachse in 1974. Rodrigues compared the electrocautery urethrotomy with cold knife in 1978 and for the poor results of electrocautery method in comparison with Sachse urethrotomy, the use of this method has been significantly reduced (17).

In the present study, 87 male patients with history of recurrent urethral strictures (aged 18-60 years) were randomly divided into combined electro cutter -cold knife (n=45) and cold knife alone (n=42) groups. By uroflowmetry, the treatment effectiveness and complications were assessed at 6- months follow-up. Post-operative fall in the peak flow rate was noted during the follow-up period in both groups, but the rate of fall was different. Initially, on the first post-operative day, peak flow rate in both groups was at parallel level, but thereafter, persistent fall in peak flow rate in uroflowmetry was observed in the cold knife

group compared to the combined group and at the end of sixth month, the difference was statistically significant indicating persistent effect of urethrotomy in the combined group.

The main reasons to perform this review about the efficacy of this electrocautery urethrotomy method, were first to study the patients with frequent recurrences who had not responded to other ways, and secondly to reduce the risk of recurrence in this group. In this study, the depth and extent of urethral fibrosis were pre-operatively measured by ultrasound for adjusting the rate and duration of urethrotomy cutting charges to avoid further damage to urethra tissues and to reduce the extent of re-fibrosis. Finally, by combined urethrotomy, the mucosal layer damage, which may possibly decrease delayed healing and effect on formation of more fibrous, has been reduced.

In this study, the effect of modern and controllable electro-cautery combined with cold knife technique in patients with recurrent stenosis was compared, while recent studies have only compared the effectiveness of cold knife with new methods such as laser or monitored the effect of adjuvants methods as dilation, fibrolitic agents injection by cold knife urethrotomy in the first time urethrotomies (10, 18-21). Dutkiewicz et al. in a randomized comparative study in Poland, objectively analyzed the results of urethrotomy using the Ho: YAG laser with classical urethrotomy (each group contained 25, without statistically significant differences in etiology of stricture, their number, localization, length, or relevant symptoms) (22). Similar to the present study, assessment of treatment effectiveness and

complications were made on the basis of uroflowmetry after treatment. The results did not confirm a higher treatment effectiveness of the Ho: YAG urethrotomy over the classical internal urethrotomy at a 1-year follow-up.

In short and thin segment strictures, the cold knife possibly divides fibrous tissue completely and separates the scarred epithelium so then the healing occurs by the secondary intention. But in long, sever and thick fibrous tissues, the cold knife usually cannot divide it completely, and persistence to divide it by this method causes poor cutting or over cutting, leading to complications in the form of massive bleeding or extravasations of irrigating fluid, as an early complication. In this study, extravasations were observed in 8 controls (19.04%), which may explain the later recurrences due to the extensive fibrosis formation. On the other hand, according to the recent reports, the Holmium laser urethrotomy also may cause deep tissue penetration and coagulation on urethra in thick urethral fibrosis and lead to some grave complications.

In this study, antibiotic (Ciprofloxacin) was given before and after the procedure and continued for 5 days; the untreated pre-operative urinary infection increases the recurrence rate significantly.

Our mean operation time for combined group [20.5 min (range 17-24 min)] is comparable to the other studies such as the study by Atak et al., (16.4-8.04 min). Kamal reported mean (range) operative time as 22.3 (15 ± 35) min, working with diode laser. With cold knife, mean operative time of 7.44 min (range 5-10 min) is much shorter than the study of Atak et al., (23.8-5.47 min), and finally

Kursat Cecen reported mean operative time of 16 min (range 10–32) in PlasmaKinetic™ urethrotomy (23-24).

The complications associated with all kinds of internal urethrotomy include bleeding, UTI, urosepsis, extravasation, incontinence, impotence, and recurrence of stricture (23). The overall post-operative complications in our study were seen in 36.78% of cases. All were minor in nature; five patients in cold knife group and only one patient in combined group had bleeding during the procedure which was managed well, and eight patients developed extravasations of irrigating fluid in perineum in cold knife group (vs. two patients in combined group). None of the patients had pain score more than three on Visual Analog Pain Score. The high rates of the complications is due to pathologic condition of the patients in this study and it may be related to the control group (cold knife only), because in such patients, the use of cold knife is not the appropriate choice, although other recent modalities such as laser and PlasmaKinetic™ urethrotomy have not been experienced in this field. Ozcan L et al. in a new experience, described a PlasmaKinetic urethrotomy method. and claimed their method is safer and a short-duration procedure with better results in comparison with cold knife urethrotomy, so it seems comparable with our technique (25).

Variety of different techniques such as urethral calibration with a catheter, uroflowmetry, flexible cystourethroscopy, AUA symptom index and urethrographic studies, and the need to repeat a procedure have been used to follow up the patients after all kinds of urethrotomies, however, there is no uniformly

accepted method of follow up. Hussain et al., stated that the catheter free status with Q max more than 15 ml/s is an excellent result and there is no requirement for any other intervention (26-27). In our study, reduction of peak flow rate to less than 10 ml/s in uroflowmetry during follow up was considered as failure of the procedure. Our success rate in recurrent urethral strictures by combined urethrotomy was 46.6% (vs.23.8% in cold knife urethrotomy), and although it is not comparable with first time urethrotomies but according to recent reports, the success rates of first time urethrotomies are not very promising, it varies in different reports with different methods and long-term results are generally low. In the short-term follow-up (less than 6 months), success rates were 70 to 80 percent. After one year, however, recurrence rates approach 50 to 60 percent and by five years, recurrence falls in the range of 74 to 86 % (28). Santucci also reported success rate of 8% in the first urethrotomy, repeat urethrotomy, and up to about five procedures, also had poor success rates (0 to 9%) and it was suggested that any optical urethrotomy should be reserved as a temporary resolution for poor surgical candidates or until final decision, it can be planned and executed (29). However, different studies have proposed different etiologies as poor responders to optical internal urethrotomies, technical and anatomical factors such as reduced visibility during the operation and stricture quality (length and fibrous thickness), and also patients' comorbidities may have effect as predictors of recurrence. The early results about recurrence-free rate by combined

urethrotomy showed relatively favorable results in comparison with cold knife conventional therapy. We think until further studies in this field, the combined urethrotomy is an effective method for the management of recurrent and intractable urethral stricture disease.

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Conclusion

Combined electro cutter with cold knife urethrotomy modality is more effective than conventional cold knife urethrotome in providing immediate relief to patients with recurrent urethral strictures and had less complications in patients with intractable and recurrent urethral strictures.

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