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PlasmaKinetic™ versus Cold Knife Internal Urethrotomy in Terms of Recurrence Rates: A Prospective Randomized Study

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Key Words
Urethral stricture · PlasmaKinetic™ urethrotomy · Urethra

Abstract
Objective: To evaluate the efficacy and outcomes of PlasmaKinetic™ urethrotomy against cold knife direct vision internal urethrotomy in terms of recurrence rates. ***Patients and Methods:*** A total of 136 male patients with urethral strictures were enrolled into the study. The patients were allocated to cold knife or PlasmaKinetic urethrotomy groups sequentially by using computer-generated numbers. Group A (PlasmaKinetic) and group B (cold knife) included 70 and 66 patients, respectively. All patients were reevaluated at the 3rd, 9th and 18th month postoperatively with uroflowmetry. ***Results:*** Group A patients had a postoperative 3rd-month maximum flow rate value of 16.09 ml/s, whereas this same parameter was 15.15 ml/s in group B ($p < 0.05$). The urethral stricture recurrence rate up to the 9-month period was statistically significant for group A (14%) compared with group B (30%). When we compared the recurrence rates of these groups from postoperative day 1 up to the 18th month, the results were 37% for group A and 33% for group B ($p > 0.05$). ***Conclusion:*** PlasmaKinetic urethrotomy provides a better recurrence-free rate during the early period compared with conventional cold knife therapy. Nevertheless, the outcome of the stricture did not change and fibrotic tissue reformed between the 9th and the 18th month.

Introduction

Narrowing of the urethral lumen due to fibrosis, which occurs in urethral mucosa and the surrounding tissue, is defined as urethral stricture. The incidence can be up to 0.6% [1]. Most of the strictures are idiopathic; other reasons are accidental or surgical trauma [1].

Treatment alternatives of urethral stricture are direct vision internal urethrotomy (DVIU) with the cold knife method first described in 1974 by Sachse [2] (DVIU requires several energy sources like monopolar, bipolar and laser), urethroplasty by using penile skin grafts or buccal mucosa and hybrid minimally invasive urethroplasty [3, 4].

Most urologists still consider and perform minimally invasive therapies for urethral stricture as first-line management despite predictable failure. A survey about stricture management from the USA showed that 57.8% of urologists do not perform urethroplasty and 31–33% continue to manage the stricture by repeated sessions of minimal invasive therapies [5].

In this study, we evaluated the efficacy and outcomes of PlasmaKinetic™ urethrotomy (Gyrus PlasmaKinetic System, Gyrus Medical, Maple Grove, Minn., USA) against cold knife DVIU in terms of recurrence rates. To the best of our knowledge, this is the first clinical trial in the literature comparing the outcomes of PlasmaKinetic urethrotomy with cold knife DVIU.

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Patients and Methods

Our study was approved by the local ethics committee of Kafkas University Faculty of Medicine and performed in accordance with the Helsinki Declaration of the World Medical Association. All of the patients signed and understood informed consent forms concerning the applications.

A total of 136 male patients aged 44–85 years (mean age: 61.62 ± 9.954 years) with urethral strictures underwent direct vision urethrotomy between 2009 and 2012 at our institution and Kars State Hospital.

The etiology of urethral stricture was iatrogenic in 108 patients (80%) and secondary to trauma in 28 (20%). The localizations of the strictures were the penile, bulbar and membranous urethra in 19, 78 and 39 patients, respectively. All of the strictures were primary and had not been previously operated on. The stricture lengths were measured by urethrography and urethroscopy. The average length of the strictures was 13 mm.

The urethral strictures were diagnosed by clinical history, uroflowmetry, ultrasonography of the upper tract and urethrography. All of the patients were preoperatively evaluated with physical examination and laboratory tests such as complete blood count, serum biochemical analysis, urine analysis and urine culture. If there was an active urinary infection, cases were treated with the appropriate antibiotics based on the urine culture.

After clinical and preoperative evaluation, the patients were allocated to cold knife or PlasmaKinetic urethrotomy groups sequentially by using computer-generated numbers. Group A consisted of 70 patients (mean age: 61.23 ± 8.158 years) treated with PlasmaKinetic urethrotomy and group B comprised 66 men (mean age: 62.03 ± 11.610 years) treated with cold knife urethrotomy.

All patients were reevaluated at the 3rd, 9th and 18th month postoperatively. Uroflowmetry was performed for the evaluation of strictures. During the follow-up period, if the patients had complaints of voiding difficulty and the maximum flow rate (Q_{max}) was <12 ml/s, urethroscopy and urethrography were planned for excluding urethral strictures. If urethral strictures were present at urethroscopy and urethrography, these were accepted as recurrent strictures and the same technique was performed. The procedure was accepted as successful when the patient did not complain of any voiding difficulty and the Q_{max} was >12 ml/s.

Surgical Technique

All of the procedures were performed by one surgeon (K.C.). All the patients underwent urethrotomy under spinal anesthesia at the lithotomy position. Cephazolin sodium, 1 g, i.v., was administered for preoperative antibiotic prophylaxis.

We used a 19-F cystoscope and Plasma-Cut™ instrument for the PlasmaKinetic group. The Plasma-Cut instrument was easily passed through the working channel of the cystoscope (fig. 1). First, a safety guide wire was applied through the stricture and cutting of the stricture was performed at 12 o'clock under 60 W with 0.9% sodium chloride as irrigation.

A 20.5-F urethrotome was used for the cold knife urethrotomy group. As in the other group, a safety guide wire was first passed through the stricture and the urethrotomy was performed at 12 o'clock.

For both groups, an 18-F Foley catheter was inserted and left in the bladder for 72 h at the end of the procedure.

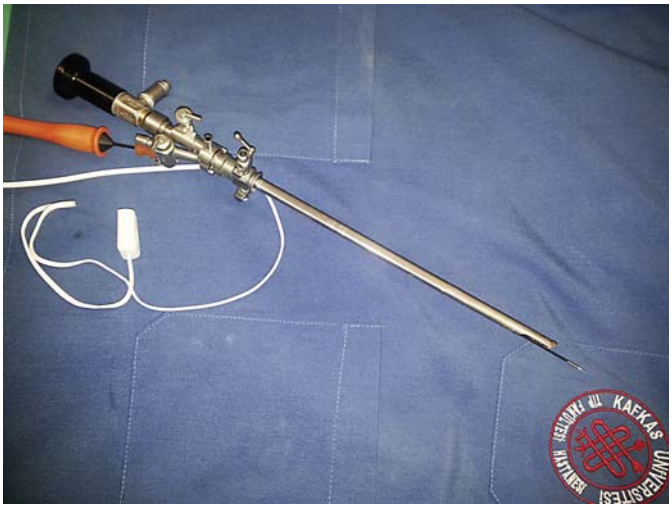

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Fig. 1. A 19-F cystoscope and Plasma-Cut instrument was used for the PlasmaKinetic group. The Plasma-Cut instrument was easily passed through the working channel of the cystoscope.

Statistical Analysis

The data were analyzed using SPSS for Windows, version 16.00. Means, medians and standard deviations were used for descriptive statistics. The characteristics of the 2 operative groups were compared with each other. The characteristics with normal and non-normal distributions were compared by using the Student t test and the Mann-Whitney test, respectively. A p value of <0.05 was considered significant.

Results

Group A (n = 70, 51.4%, mean age: 61.23 ± 8.158 years) were treated with PlasmaKinetic urethrotomy. Group B (n = 66, 48.6%, mean age: 62.03 ± 11.610 years) were treated with cold knife urethrotomy.

There were no statistically significant differences between the 2 groups in terms of age ($p > 0.05$) and preoperative Q_{max} values ($p > 0.05$). The mean preoperative Q_{max} values for groups A and B were 6.31 ± 1.732 and 6.27 ± 2.019 ml/s, respectively. The average operation time was 16 min (range 10–32).

A statistical difference between the 2 groups was observed when we compared the 3rd-month uroflowmetry results. Group A patients had a mean postoperative Q_{max} value of 16.09 ± 1.726 ml/s, whereas group B had a mean postoperative Q_{max} value of 15.15 ± 1.591 ml/s ($p = 0.001$).

The urethral stricture recurrence rate up to the 9-month period was statistically significant for group A (n = 10, 14%) compared with group B (n = 20, 30%; p =

Table 1. Pre- and postoperative mean Q_{max} values and recurrence rates of the 2 groups

	n	Q_{max}, ml/s		Recurrence, %	
		preoperative	3rd month	9th month	18th month
Group A: PlasmaKinetic	70	6.31	16.09	14	37
Group B: cold knife	66	6.27	15.15	30	33

0.025). When we compared the recurrence rates of these groups from postoperative day 1 up to the 18th month, the results were 37% (n = 24) for group A and 33% (n = 22) for group B. This result was not statistically significant (p = 0.643). All of the strictures recurred at the same sites and none of our patients were considered for open urethroplasty due to the short length of the strictures (table 1).

We obtained excellent visualization throughout the procedure with negligible blood loss. During the follow-up period, no intra- or postoperative complications such as bacteremia, urinary retention, hemorrhage or false route were observed. All patients were continent after removal of the urethral catheter and satisfactorily voided.

Discussion

Ischemic spongiofibrosis of the urethral wall causes true urethral strictures. These strictures narrow the urethral lumen and cause voiding problems. If untreated, they cause irreversible changes in the upper and lower urinary tract.

The most common cause of urethral strictures in current clinical practice is idiopathic; other reasons include accidental or surgical trauma [1].

Treatment alternatives of urethral strictures involve many surgical techniques. Although urethroplasty has the highest success rate, endoscopic treatment is still preferred by most urologists due to its simplicity and safety [5].

Since Sachse [2] first described endoscopic urethrotomy in 1974, this technique has been the most commonly used surgical technique in urology for strictures. Although this technique is very popular in current clinical practice, the efficacy rate is 35–60% and restricture occurs in 89% of cases [6]. In our study, the recurrence rate was 30% for the cold knife group during the 9-month follow-up period and this rate increased to 33% after 18 months.

Low success and high recurrence rates of cold knife urethrotomies make urologists search different types of therapeutic alternatives for stricture treatment. Lasers have been used in urethrotomies instead of cold knife since 1984. Laser types are Nd:YAG, argon and diode and Ho:YAG and KTP [7]. In a recent study, low-power holmium laser urethrotomy was compared with the cold knife technique [8]. The operative time of the laser group was shorter than that of the cold knife group (16.42 ± 8.04 vs. 23.83 ± 5.47 min; p < 0.001). The recurrence rates for the laser and cold knife groups were 19 and 46.7%, respectively. The recurrence-free rates of both groups at the 3rd month were similar (p = 0.122). In addition, the recurrence-free rates at 6, 9 and 12 months were significantly higher in the laser group (p = 0.045, 0.027 and 0.04, respectively). There was no statistically significant difference between the 2 groups in terms of the preoperative and the 1st-, 6th- and 12th-month postoperative Q_{max} values. Similar to these results, our recurrence-free rate for the PlasmaKinetic group was 14% during the 9-month follow-up period, which was statistically significant compared with the cold knife group (30%). We also believe that as regards the cost-effectiveness of the treatment, PlasmaKinetic vaporization of the fibrotic tissue has a significant advantage over laser therapies.

Another energy source used for urethrotomies is PlasmaKinetic. Plasma creates an electrically conductive cloud when radiofrequency energy contacts tissue [9]. An advantage of PlasmaKinetic is cutting the tissues at a much lower average temperature (as low as 50°) than conventional electrocautery [10]. As a result of this, thermal damage of the surrounding tissue is less than 1 mm. The main goal for using the PlasmaKinetic system is to vaporize the fibrous tissue. There are 2 available designs on the market: braided-tip (Plasma-Cut) for finer fibrous tissue and spring-tip (Plasma-Cise™) for more dense fibrous tissue removal. The main difference between the PlasmaKinetic and cold knife urethrotomies is not only incision of the fibrous tissue but also evaporation, so that the recurrence of fibrotic tissue can be decreased [11–14]. In our study, the mean recurrence rate of the cold knife group (30%) was statistically higher than the PlasmaKinetic group (14%) at the end of 9th month (p < 0.05). In our opinion, the main reason of this difference is not only

incision of the fibrous tissue but also vaporization of the fibrotic tissue during the PlasmaKinetic procedure. Nevertheless, we found no statistical difference between the 2 groups in terms of the recurrence rate at the end of the 18th month (cold knife: 33%, PlasmaKinetic: 37%). This showed us that the outcome of the stricture did not change and fibrotic tissue reformed between the 9th and the 18th month.

Basok et al. [15] reported the first clinical experience with PlasmaKinetic and searched the effectiveness and outcomes of urethrotomies in 22 patients; 17 patients (77.3%) were recurrence-free during the mean follow-up period of 14.2 months; on the other hand, 5 (22.7%) developed strictures during the same period. In our study, 86% of the patients were recurrence-free during the 9-month follow-up period and this value decreased to 63% at the end of 18 months. Our results can be accepted as similar to those of Basok et al. [15] as we did not check the patients at the end of the 14th month. The results might have matched if we had had an opportunity to check the patients at the same time.

Conclusions

PlasmaKinetic urethrotomy is a safe and effective method for the management of urethral stricture disease. When compared with cold knife conventional therapy, it provides a better recurrence-free rate during the early period. Nevertheless, the outcome of the stricture did not change and fibrotic tissue reformed between the 9th and the 18th month.

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