Original Article

Benefits of accurate and guided endoureterotomy versus ureteral balloon dilatation in the management of ureteral strictures—comparative animal study

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Background: Endoscopic treatment of ureteral strictures provides a minimally invasive approach with a shorter hospital stay and less postoperative pain. There are different therapeutic options, the dilatation balloon and endoureterotomy with holmium yttrium-aluminum-garnet (Ho:YAG) laser are the most used. To assess histological changes after endoureterotomy in the ureteral stricture treatment comparing Ho:YAG laser endoureterotomy versus balloon dilatation endoureterotomy.

Methods: The subjects used were a total of 48 female pigs. The initial assessment consisted of an endoscopic, nephrosonographic, and contrast fluoroscopic evaluation of the urinary tract. Subsequently, a model of ureteral stricture was performed. Three weeks later, the ureteral stricture was diagnosed and treated. Then animals were randomly assigned to two groups (group A, Balloon dilatation endoureterotomy and group B, Holmium laser retrograde endoureterotomy) in which a double-pigtail ureteral stent was placed for 3 weeks. Follow-up assessments were performed at 3–6 weeks. The final follow-up was completed at 5 months and included the pathological study.

Results: In terms of therapeutic effectiveness, the overall success was 81.2%. The success rate was 91.7% in group B and 70.8%in group A without statistical significance. No evidence of vesicoureteral reflux nor urinary tract anomalies were observed. Histological assessment showed statistical significance in overall score, lamina propria fibrosis and serosal alterations in group A with higher histological changes.

Conclusions: The overall histopathological score after ureteral stricture treatment in an animal model showed better remodeling of incised ureteral wall healing after Ho:YAG laser endoureterotomy. Laser endoureterotomy tends to have higher success rate compared to balloon dilatation.

Keywords: Endoureterotomy; holmium yttrium-aluminum-garnet (Ho:YAG) laser; balloon dilatation

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Introduction

A ureteral stricture (US) is a decrease in ureteral caliber. This condition can have multiple origins, such as after endourological procedures, impacted stones, pelvic or abdominal surgeries (gynecological, urological, digestive, vascular), infectious or inflammatory diseases, radiation or even an idiopathic origin. US is mainly a benign and idiopathic condition (1,2).

Patients with US can develop symptoms depending on grading of hydronephrosis and duration (3). The classic symptoms of US are low-back pain, nausea, vomiting, urinary tract infection, etc. Although patients are often asymptomatic, ,the diagnosis of US is based on the medical history, blood test, urinalysis and imaging test, which can reveal renal insufficiency, hydronephrosis, metabolic acidosis or urinary tract infection (1-5).

Treatment ranges from ureteral stent or nephrostomy insertion, through minimally invasive treatment as endourological procedures, to reconstructive surgery. This obviously depends on the clinical situation, when a patient presents with acute sepsis or medical emergency, this usually requires an urgent urinary diversion before definitive treatment. Otherwise, an uncomplicated US can be managed by an elective/delayed definitive treatment (1-7).

Technological advances in the endourology field have promoted the implementation of endoureterotomy for the treatment of US in recent decades, especially in selected cases (3,6). There are different endourological techniques, such as holmium yttrium-aluminum-garnet (Ho:YAG) laser, balloon dilatation endoureterotomy, Acucise® balloon endoureterotomy, cold endoureterotomy and monopolar hot electrocautery. However, Ho:YAG laser endoureterotomy and balloon dilatation have greater diffusion in the latest scientific literature (1,4,8).

Ho:YAG laser endoureterotomy enables an accurate and guided incision by direct visualization, although with a mild thermal effect on surrounding tissues. Conversely, balloon dilatation endoureterotomy does not transmit a thermal effect, but it does not enable accurate control of the performed incision. Besides, the endourological control of balloon dilatation endoureterotomy is carried out with fluoroscopy, which does not allow direct visualization of endoureterotomy incision (4,9-11).

The aim of this paper was to assess histological changes after endoureterotomy in US treatment comparing Ho:YAG laser endoureterotomy versus balloon dilatation endoureterotomy in an animal experimental study. This study aimed to determine which of the most utilized endourological techniques in clinical practice is associated with greater success and less damage to the ureteral wall after healing, which may be related to these outcomes in human subjects. We present this article in accordance with the ARRIVE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-222/rc).

Highlight box

Key findings

- Holmium yttrium-aluminum-garnet (Ho:YAG) endoureterotomy provides great success in benign ureteral strictures.

What is known and what is new?

- Both balloon dilatation endoureterotomy and Ho:YAG laser endoureterotomy are techniques for the treatment of ureteral strictures most used.
- Ho:YAG laser endoureterotomy presents less histological damage with direct impact of healing and success rate.

What is the implication, and what should change now?

- Ho:YAG laser endoureterotomy has not shown greater ureteral histological damage, in addition to providing advantages such as versatility and mandatory fluoroscopy in the minimally invasive treatment of ureteral stenosis.

Methods

Forty-eight healthy female pigs weighing 35–40 kg were used in this study. The experimental protocol was approved by the Minimally Invasive Surgery Center's Ethical Committee for Animal Research (No. IEND207). This Committee also certified that the research study was carried out following the guidelines for animals used for scientific purposes (Directive 2010/63/EU-European Commission).

Phase I: *US animal model*

After the collection of blood and urine samples, the sterility of the urine was evidenced. Subsequently, the degree of dilation of the upper collecting system was assessed with ultrasound control, according to the Society for Fetal Urology (SFU) guidelines (12). To evaluate vesicoureteral reflux (VUR), simulated voiding cystourethrography (SVCUG) was performed at baseline, and at 3 and 6 weeks, with a final follow-up at 20 weeks. To perform SVCUG, a bladder catheter was placed into the urinary bladder and filled. The bladder was manually compressed until the pressure reached 50 cmH_2O for

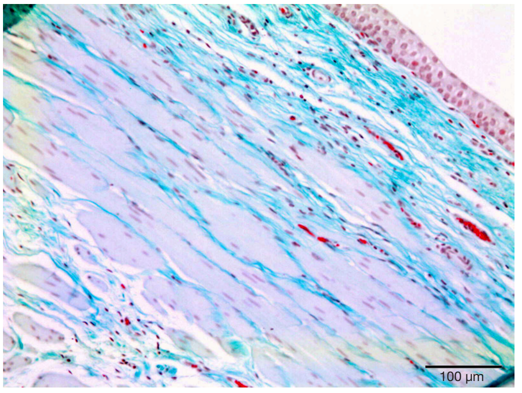

Figure 1 Masson's trichrome stain (20×). Group B. Urothelium undamaged. Mild fibrosis of muscle layers. Muscle fiber bundles properly oriented. Group B: Holmium laser retrograde endoureterotomy.

60 seconds to simulate micturition (13,14). Serum urea, creatinine levels, urinalysis and urine culture were assessed during all study phases.

In this experimental study, the right kidney and ureter were assessed morphologically, and functional parameters were determined by intravenous urography (IVP), retrograde ureteropyelography (RUPG) and ureteroscopy. The contralateral kidney and ureter were used as controls without US.

Once the urinary tract was evaluated, an experimental laparoscopic stricture model was created in the proximal right ureter with a short-term biodegradable ligature. Ureteral ligation was performed by manual laparoscopic knotting, resulting in the unilateral stricture model. The type of established US is fibrotic and short (<2 cm). A validated stricture model was performed (15-18).

Phase II: *US treatment*

Three weeks later, the US was developed and diagnosed (14-16). The upper urinary tract was evaluated again (ultrasonography, urea and creatinine serum levels, IVP, RUPG, urinalysis and urine culture). Once the imaging studies had confirmed the existence of obstructive uropathy, animals were randomly distributed into two homogeneous groups, depending on the endourological techniques performed. All procedures were performed by the same surgeon. A posterolateral ureteral incision was performed to avoid blood vessel injury, and the incision extends from 5 mm distal and proximal to the US.

- ❖ Group A: Balloon dilatation endoureterotomy (Uromax Boston Scientific, 12 Fr × 4 cm, rated burst pressure 20 atm).
- ❖ Group B: Holmium laser retrograde endoureterotomy (Ho:YAG laser: Storz Calculase II of 20 W Fiber 365 µm with 1.2 J/10 Hz) (17). A semi-rigid ureteroscope (Storz. 7-9.9Ch. 43 cm) is used.

A full-thickness incision of the stricture segment was confirmed by extravasation of contrast medium in the case of balloon dilatation endoureterotomy and visualization of periureteral fat in the case of holmium laser retrograde endoureterotomy. A 7Fr polymeric ureteral double pigtail stent was placed in all groups for a three-week period (Universa® Soft, 22 cm, Cook® Medical).

After three weeks, the ureteral stent was cystoscopically removed, and reassessment was performed with IVP, percutaneous ultrasound, and RUPG. According to the animal model scientific literature, three weeks is enough time for adequate healing and a decrease in ureteral oedema (14-16). A urine culture by cystocentesis was taken just before the removal of the ureteral stent and the administration of prophylactic antibiotic. Intramuscular prophylactic enrofloxacin was administered to all study animals on the day before and 2 days after each study phase.

Phase III: *end-study evaluation and post-mortem studies*

The final outcome was performed at five months by urinalysis, ureteroscopy, cystoscopy, ultrasonography and contrast fluoroscopy. Once the follow-up imaging studies were complete, necropsies were performed in all cases, removing the kidneys, ureters, and bladder *en bloc*. Sections of the healed ureteral segments were obtained and stained with hematoxylin and eosin, periodic acid-Schiff (PAS) and Masson's trichrome stains. The histopathological evaluation was performed by a single pathologist blinded to the two randomized groups. The histopathological score was validated and included the items: urothelial resurfacing, lamina propria fibrosis, fibrosis in the muscular layer, muscle layer integrity, and serosal alterations (14,16-18). Finally, each parameter was graded according to the following scores: 0= no histopathological changes; 1= mild changes; 2= moderate changes; and 3= severe changes (16-18) (*Figures 1-3*).

Global success after endoureterotomy was defined as absence of a US, hydronephrosis and obstructive uropathy on ultrasound and fluoroscopic evaluation, as well as relief of signs.

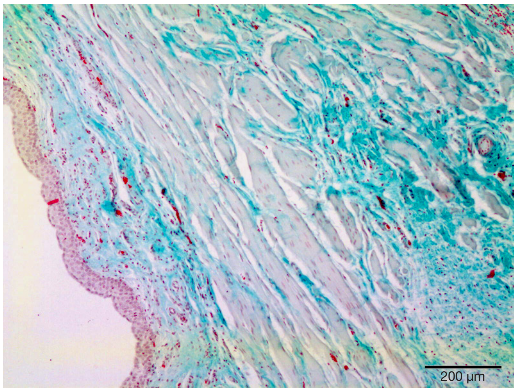

Figure 2 Masson's trichrome stain (10×). Group A. Moderate fibrosis of the lamina propria and severe fibrosis of the muscle layer. Group A: Balloon dilatation endoureterotomy.

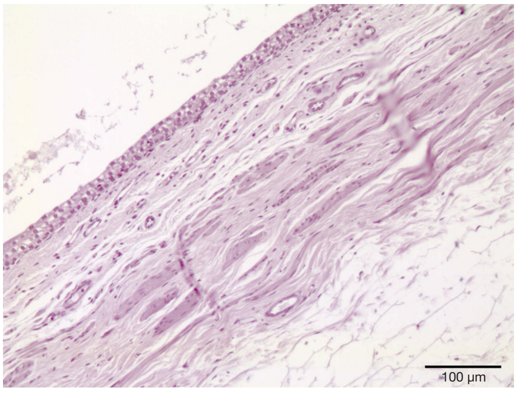

Figure 3 Hematoxylin-Eosin stain (20×). Group B. No damage to the ureteral wall. Mild loss of integrity of the muscular layer. Group B: Holmium laser retrograde endoureterotomy.

Statistical analysis

the determination of the sample size was carried out with a hypothesis contrast with the means, obtaining a total of 24 animals for each group (0.05 level of significance; 95% statistical power). The histological data on ureteral damage was formulated as mean ± standard deviation (SD). The histological scores underwent statistical analysis with Student's *t*-test and Fisher's exact test. The normal distribution of variables was confirmed using the Kolmogorov-Smirnov test. Differences were considered significant at P<0.05.

Results

Phase I

Animals did not show ureteral abnormalities or VUR. Blood tests showed creatinine and serum urea were within the range for porcine species. None of the urine cultures were positive.

Phase II

After creating the experimental US model, all animals were diagnosed with US within three weeks. The grade of hydronephrosis evidenced was II–III in all subjects. The features of US were single and short (defined as less than 1.5 cm). In this phase, none of the animals showed ureteral abnormalities except US. Subsequently, three weeks after ureteral stent retrieval, 36 of 48 animals (75%) had a negative urine culture, and 12 of 48 (25%) had a positive urine culture.

Phase III

After performing endoureterotomy, the overall success rate was 81.2%. The success rate was higher in Ho:YAG laser endoureterotomy (91.7%) than balloon dilatation endoureterotomy (70.8%), although without statistical significance (P=0.068), but the odds ratio (OR) 95% CI (OR =4.39) evidenced a dependency between the success rate and the type of endourological technique. The histopathological overall score found significant statistical differences between the assessed endourological techniques (P<0.05) (*Table 1*); laser endoureterotomy involved less histopathological ureteral damage. When the histological score of the different ureteral layers was assessed, there were significant differences between groups, with lamina propria fibrosis and serosal alterations (*Table 1*).

In this study, less ureteral damage was associated with a higher success rate after endoureterotomy, with significant differences (*Table 2*).

In phase II, a positive uroculture presence had no impact on the overall success rate. However, positive uroculture was significantly associated (P<0.05) with greater lamina propria fibrosis, without relation to either the overall

Table 1 Histopathological score according to endourological techniques and ureteral layer

Ureteral histopathological score (0–3)	Urothelial resurfacing	Ureteral wall inflammation	Lamina propria fibrosis	Fibrosis in the muscular layer	Muscle layer integrity	Serosal alterations	Overall score
Group A (N=24)	1.38±0.82	0.92±0.58	1.21±1.06	1.54±1.10	1.71±0.85	1.71±1.04	1.40±0.53
Group B (N=24)	1.29±0.99	1.13±0.90	0.46±0.77	1.67±0.96	1.5±093	0.17±0.48	1.03±0.52
P	0.754	0.346	0.008	0.678	0.425	0.0001	0.018

"*T* Student" analysis. Data are presented as mean ± standard deviation. Group A: Balloon dilatation endoureterotomy. Group B: Holmium laser retrograde endoureterotomy.

Table 2 Histopathological overall score according to overall success and failure rate

	Success (mean ± SD)	Failure (mean ± SD)	P
Ureteral histopathological score (0–3)	1.09±0.45	1.75±0.67	0.001

"*T* Student" analysis. SD, standard deviation.

histopathological score or the endourological technique after ureteral stent removal.

Discussion

US is a condition for which incidence has increased after endourological procedures in recent years because of ureteral manipulation, potentially rising by up to 11% after an endourological procedure in some papers (3,5). The gold standard treatment is reconstructive surgery, whether by an open, laparoscopic or robotic approach. However, technological and material advances in endourology, as well as reduced hospital stay, surgical time, postoperative morbidity and recovery have made endoureterotomy an adequate option in selected patients (2,4,9). The overall success rate after endoureterotomy depends on careful selection of US (4,9,19-22). Likewise, benign, short length (<2 cm), short duration, no ischemic and renal function >20% of US have reported better outcomes after endoureterotomy (4,9,19-22). The success rate after endoureterotomy is about 80%, even up to 100% with the appropriate selection of US patients (4,9).

The success rate after endoureterotomy relies on healing by second intention. In the current study, an extensive analysis of the ureteral layer after healing by second intention showed long-term histopathological changes after endoureterotomy in US treatment. Although, some studies have been performed in a canine model, indicating ureteral regeneration (23,24), an experimental model in porcine species has anatomical, histological and physiological similarities with humans (25,26).

The success rate after balloon dilatation is about 50–76% (4,10,27). Limitations of these studies were mainly the lack of histological assessments of the kind of ureteral remodeling. These weaknesses in the scientific literature were dealt with in our study and provided useful information about the impact on ureteral healing after endoureterotomy. Unfortunately, clinical studies show heterogeneity of patient selection, such as the kind of US, without archiving an appropriate patient cohort (1,4,10). The best results were provided with iatrogenic and no anastomotic US, as after iatrogenic endoscopic procedures the rate was up to 85% (4,7,28).

Likewise, short length (<2 cm) and short duration US showed higher success rates (1,4,8,9). US in our experimental study was of a short length, benign and short duration, suitable features for endourological techniques. In this study, the success rate after balloon dilatation endoureterotomy was 70.8% and showed greater histopathological changes with regard to the Ho:YAG laser endoureterotomy group. However, Figenshau *et al.* did not show histological changes between endourological techniques (balloon dilatation, hot electrocautery monopolar and Acucise®) in the same ureter in a porcine model (16). Figenshau *et al.* performed their study in the same ureter; in contrast, in our study was performed as an endoureterotomy for US. Consequently, histopathological changes after endoureterotomy took place in the ureteral segment, with fibrosis that differed from native tissue. Such a significant difference could explain ureteral layer remodeling with greater histopathological changes and fibrosis in US. Therefore, the Figenshau study cannot be extrapolated to clinical practice for US and our study.

The advantages of Ho:YAG laser endoureterotomy are accuracy, as well as longitudinal and guided incision in US with localized thermal effects, i.e., only 0.4 mm (21,29). Furthermore, it causes less peripheral tissue and blood vessel damage, since it generates limited vaporization of fibrotic tissue (30). Because of Ho:YAG laser can be used in flexible ureterorenoscopes, this allows access for US and unified stone treatment. The Ho:YAG laser endoureterotomy success rate in selected cases can reach up to 90% (4,9,21). Features that decrease the success rate are impacted stones, ischemic or malignant US, length >2 cm or renal failure (4,9,19-22). The European Association of Urology guidelines on laser technologies recommends Ho:YAG laser for benign [Level Evidence (LE): 3], even as a first line treatment, although the panel considers open surgery as the gold standard. In the case of US recurrence after endourological techniques, they propose reconstructive surgery (29). The follow-up can confirm that endoureterotomy treatment failure was from 1.6–3 to 9–18 months, according to the scientific literature (30). The follow-up in this present study was 5 months, which is adequate and reasonable for the assessment of endoureterotomy treatment failure.

There are no comparative studies of balloon dilatation and Ho:YAG laser endoureterotomy with regard to the success rate and histopathological changes. Balloon dilatation endoureterotomy has no thermal effects, and it does not require the use of an ureteroscope, which may be unavailable, above all in pediatric patients. Conversely, balloon dilatation endoureterotomy requires the use of fluoroscopic and radiological exposure (4,10). In the case of Ho:YAG laser endoureterotomy, it is required to use an ureteroscope and there is a mild thermal effect. However, Ho:YAG laser endoureterotomy is the preferred option and the most commonly used treatment because of incisional control and its versatility with concomitant stone treatment (4,9).

The results in the present study show that Ho:YAG laser endoureterotomy leads to fewer histopathological changes to the ureteral wall, such as lamina propria fibrosis and serosal alterations, which may be related to the higher success rate with regard to balloon dilatation endoureterotomy. In the case of balloon dilatation endoureterotomy, in contrast to Ho:YAG laser endoureterotomy, there were no guided and accurate ureteral wall rupture, which may be related to the greater degree of histopathological damage in the serosal layer due to the lack of endoureterotomy incision control. Consequently, we have seen less histological damage in Ho:YAG holmium laser endoureterotomy, resulting in easier and more accessible healing by secondary intention. The thermal effect of the holmium laser does not generate a detriment to ureteral healing, either because its dispersion capacity is slight, and the control over the incision allows treating only the desired area of USs. Sometimes endorupture with balloon dilatation can occur in an area with fewer factors that favor healing by secondary intention, such as in a more fibrotic area, and less vascularization.

The clinical impact after endoureterotomy is remodeling of the ureteral segment; this must be balanced, since worse ureteral layer healing will lead to a higher probability of re-stricture. In contrast, the presence of a short remodeled ureteral segment does not have an impact on urine bolus flow and ureteral peristalsis. In clinical practice, an aperistaltic ureteral segment is not significant since urine bolus flow is not concerned with short length segments. However, we did assess which endourological techniques showed less histopathological damage during ureteral healing.

Our data show that less histological damage is associated with a higher success rate because healing by secondary intention with less damaged tissue has a higher probability of success. At the same time, these data are consistent with the characteristics of the most successful US that will present after endoureterotomy: short length, non-ischemic strictures and short duration (4,9,14,19,21,22).

The ureteral healing can be affected by bacterial colonization (31), and other studies have also shown a relation with a higher chance of endoureterotomy treatment failure (14,25). In this study, a higher histopathological score in lamina propria fibrosis corresponded with positive urine culture, which may be indirectly related to the overall histopathological score and the overall success rate after endoureterotomy. Lamina propria fibrotic changes are related to the overall success rate.

Among the limitations in our study are the use of an animal model; although it was well-accepted and developed, we could not identify different levels of pain or other signs. Regarding the availability of diagnostic techniques, the lack of an isotopic renogram meant we could not assess renal function. The follow-up time was adequate for some researchers, but other researchers have extended the onset of recurrences with a longer duration.

Conclusions

The overall histopathological score after US treatment in an animal model showed better remodeling of incised ureteral wall healing after Ho:YAG laser endoureterotomy. Laser endoureterotomy tends to have higher success rate compared to balloon dilatation.

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Footnote

Reporting Checklist: The authors have completed the ARRIVE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-222/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-23-222/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-222/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The experimental protocol was approved by the Minimally Invasive Surgery Center's Ethical Committee for Animal Research (No. IEND207). This Committee also certified that the research study was carried out following the guidelines for animals used for scientific purposes (Directive 2010/63/EU-European Commission).

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