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# ACUCISE™ ENDOPYELOTOMY IN A PORCINE MODEL: PROCEDURE STANDARDIZATION AND ANALYSIS OF SAFETY AND IMMEDIATE EFFICACY

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**ABSTRACT**

Purpose: The study here presented was done to test the technical reliability and immediate efficacy of the Acucise device using a standardized technique.

Materials and Methods: 56 Acucise procedures were performed in pigs by a single surgeon who used a standardized technique: insert 5F angiographic catheter bilaterally up to the midureter, perform retrograde pyelogram, Amplatz super-stiff guidewire is advanced up to the level of the renal pelvis, angiographic catheters are removed, Acucise catheter balloon is advanced to the ureteropelvic junction (UPJ) level, the super-stiff guide-wire is removed and the contrast medium in the renal pelvis is aspirated and replaced with distilled water, activate Acucise at 75 watts of pure cutting current, keep the balloon fully inflated for 10 minutes, perform retrograde ureteropyelogram to document extravasation, remove Acucise catheter and pass an ureteral stent and remove guide-wire.

Results: In no case did the Acucise device present malfunction. The electrocautery activation time was 2.2 seconds (ranging from 2 to 4 seconds). The extravasation of contrast medium, visible by fluoroscopy, occurred in 53 of the 56 cases (94.6%). In no case there was any evidence of intraoperative hemorrhage.

Conclusions: This study revealed that performing Acucise endopyelotomy routinely in a standardized manner could largely preclude intraoperative device malfunction and eliminate complications while achieving a successful incision in the UPJ. With the guidelines that were used in this study, we believe that Acucise endopyelotomy can be completed successfully and safely in the majority of selected patients with UPJ obstruction.

**Key words**: kidney pelvis; ureter; ureteral obstruction; Acucise catheter; surgical procedures, minimally invasive

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## INTRODUCTION

Retrograde endopyelotomy by ureteroscopy or by Acucise catheter was recently reported as being the most cost-effective treatment for ureteropelvic junction obstruction (UPJO) (1). However, Acucise endopyelotomy has been reported in the literature as a risky procedure, due to either perioperative hemorrhage or technical complications in 0 - 36% of cases (2-11).

Technical complications include the fracture of the cutting wire inside the patient, balloon obstruction, and the inability of advancing the device to the level of the ureteropelvic junction (UPJ) (2).

To test the technical reliability of the Acucise device, 56 Acucise procedures were performed in pigs

by a single surgeon who used a standardized technique.

## MATERIALS AND METHODS

After the study protocol was approved by the Animal Studies Committee at Washington University School of Medicine in St. Louis, USA, 28 domestic sows were submitted to bilateral endopyelotomy with the Acuciseä device (Applied Medical, Rancho Santa Margarita, CA).

The pigs were submitted to a 16-hour oral fasting period. Next, a pre-anesthetic xylazine (1 mg/kg), telazol (1 mg/kg) and ketamine (1 mg/kg) solution was injected intramuscularly using a 20-gauge needle. Atropine sulphate (0.06 mg/kg) and sodium ceftiofur (ceftiofurato sódico) (3.0 - 5.0 mg/kg) were also administered intramuscularly. Intravenous access was performed and hydration with a saline solution was commenced (2 mL/kg weight/hour). Anesthesia was maintained throughout the procedure with 1.5 to 2.5% isoflorane; the animals' arterial pressure, heart rate and oxygenation were monitored continually.

After general anesthesia, the animals were placed in the dorsal lithotomy position. A cystogram was performed in order to identify vesicoureteral reflux (VUR). Flexible cystoscopy was performed and the ureteral orifices were identified; under fluoroscopic guidance, a 5F angiographic catheter was inserted bilaterally up to the midureter and retrograde pyelograms were done (Figure-1). If the collection system appeared normal, then an Amplatz super-stiff (0.035") (Microvasive, Natick, MA) guidewire was inserted into each angiographic catheter, and advanced up to the level of the renal pelvis. The angiographic catheters were then removed. Over the super-stiff guidewire, the Acucise catheter balloon was advanced to the UPJ level. The proximal third of the Acuciseä device was left in the renal pelvis and the distal two-thirds in the proximal ureter. With the Acucise device cutting wire turned laterally (Figure-2), as determined fluoroscopically, the super-stiff guidewire was removed and the contrast in the renal pelvis was aspirated and replaced with distilled water. If further visualization of the UPJ area was needed, then dilute nonionic contrast was used. The Acucise device was activated at 75 watts of pure cutting current and the balloon was filled with 2 cc of contrast. Activation of the cutting wire was continued throughout the inflation cycle, which required no more than 5 seconds. After 10 minutes with the balloon fully inflated to provide tamponade (Figure-3), the Acuciseä catheter was emptied and pulled back to the middle portion of the ureter. A retrograde ureteropyelogram was performed through the Acuciseä catheter in order to document the extravasation of the contrast through the previously incised area (Figure-4). After this, the Acucise catheter was removed and a 7F 20 cm ure-

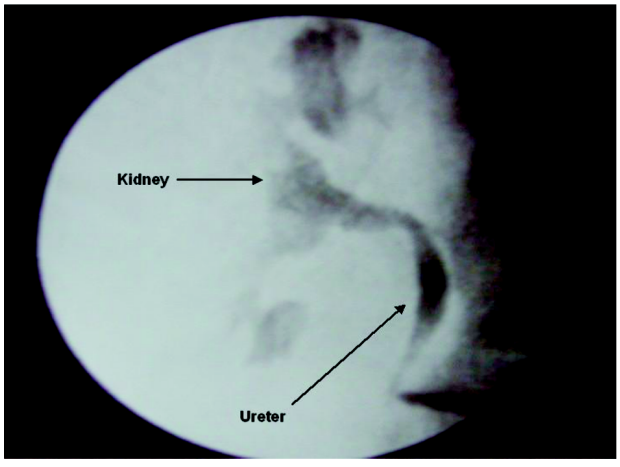


***Figure 1 –*** *Intraoperative fluoroscopy showing pyelogram with normal appearance of the collecting system.*

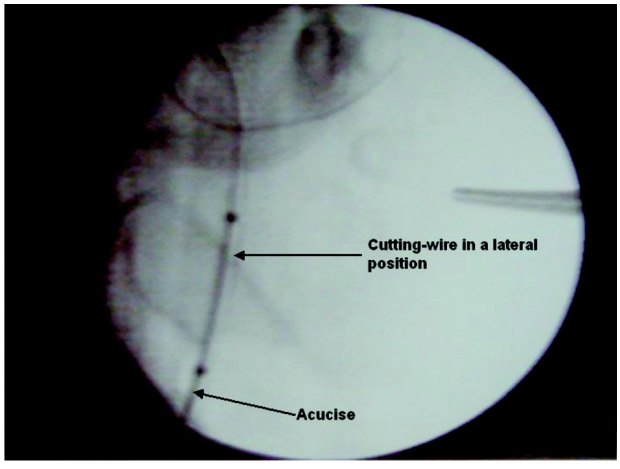


***Figure 2 –*** *Intraoperative fluoroscopy showing the Acucise device in place with the cutting wire in a lateral position.*

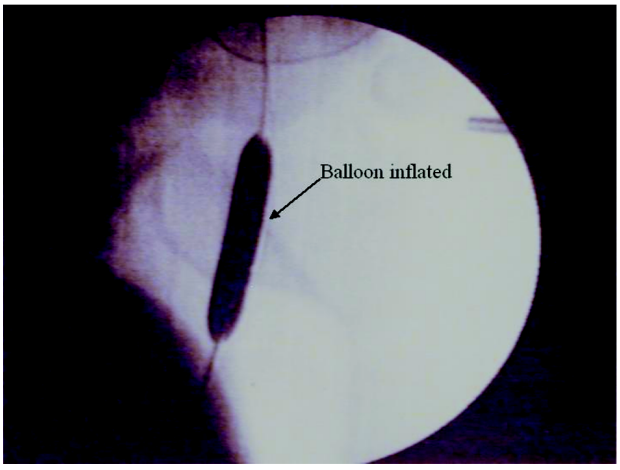


***Figure 3 –*** *Intraopertative fluoroscopy showing the balloon inflated just after electrosurgical activation of the "cutting" wire of the Acucise device.*

teral stent (Percuflex®, Microvasive, Natick, MA) was introduced over the super-stiff guidewire under fluoroscopic control. The proximal portion of the stent was positioned in the upper renal pole. After the correct positioning of the stent was confirmed via fluoroscopic images, the guidewire was removed and a 14F Foley catheter was placed in the bladder. The main steps of the Acucise endopyelotomy procedure are listed in the appendix.

If contrast extravasation was not observed, an 8/10F Amplatz dilator/sheath system was passed over the super-stiff guidewire. The 8F dilator was removed and a floppy tip guidewire was introduced into the 10F sheath alongside the super-stiff guidewire; the 10F sheath was removed. A flexible ureteroscope was passed over the guidewire up to the incision level; the guidewire was then removed. Under ureteroscopic view, the UPJ incision was observed and if peri-ureteral fat was seen, the flexible ureteroscope was withdrawn and a stent was placed, as previously described, over the super-stiff guidewire. If no incision was seen, then the cutting wire running over the Acucise balloon was cleaned with the back edge of a surgical knife, removing all of the charred material on it and the balloon was cleaned with repeated injection and aspiration of distilled water. The Acucise device was reintroduced and the entire procedure was repeated. The Acucise device was never reactivated during the same procedure without its having been removed and cleaned.

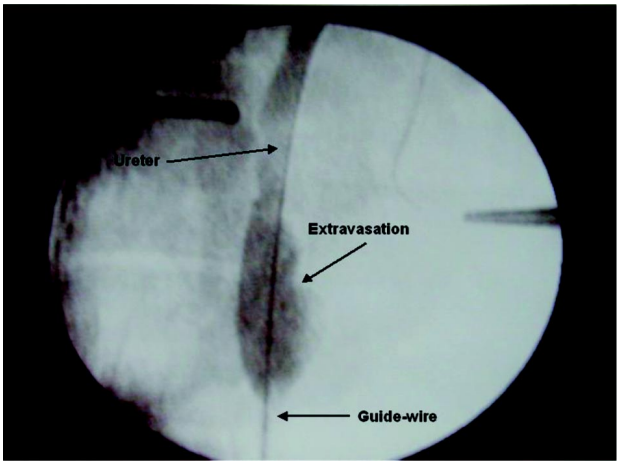


***Figure 4 –*** *Intraoperative fluoroscopy showing contrast extravasation after balloon deflation.*

Intra-operative hemorrhage was evaluated in terms of hemodynamic stability, by the presence of bruising in the flank, presence of a palpable mass, and subjectively through the interpretation of the color of the urine. The presence of clots in the urine was felt to represent significant bleeding that would require further therapy to control.

## Appendix

The 10 steps of the Acucise endopyelotomy:

1. Cystoscopy with ureteral orifices identification.
2. Insert 5F angiographic catheter bilaterally up to the midureter.
3. Perform retrograde pyelogram.
4. Amplatz super-stiff (0.035") guidewire is inserted into the angiographic catheter, and advanced up to the level of the renal pelvis.
5. Angiographic catheters are removed.
6. Acucise catheter balloon is advanced to the UPJ level: proximal third is left in the renal pelvis and the distal two-thirds in the proximal ureter.
7. The super-stiff guidewire is removed and the contrast in the renal pelvis is aspirated and replaced with distilled water.
8. Activate Acucise at 75 watts of pure cutting current (cutting for no more than 5 seconds).
9. Keep the balloon fully inflated for 10 minutes,

then empty the balloon, pull it and perform retrograde ureteropyelogram to document extravasation.

10. Remove Acucise catheter keeping the guide-wire in place, pass an ureteral stent, and remove guidewire.

## RESULTS

A total of 56 retrograde endopyelotomies were performed by the same surgeon (C.A.) using the Acucise device. The average weight of the animals was 50.2 Kg (ranging form 40 to 65 Kg). On average, the procedure to complete bilateral Acucise incisions lasted 46 minutes (ranging from 35 to 85 minutes). The procedure was completed successfully in all cases. All animals survived the procedure.

### Device Function

In no case did the Acucise device present a malfunction. In one case, the device was activated accidentally while it was still outside of the animal; it still functioned well when placed inside the animal. In all cases, the passage of the Acucise device over the super-stiff guidewire up to the UPJ was achieved with no difficulty. In 4 cases, access to the UPJ had to be obtained first with a Terumo hydrophilic guidewire, as the super-stiff guidewire did not progress to the renal pelvis. In these cases, a 5F angiographic catheter was passed over the Terumo guidewire, following which the Terumo guidewire was removed and a super-stiff guidewire was then passed through the 5F angiographic catheter and then coiled in the renal pelvis. The 5F catheter was then removed and the procedure was performed as described. The electrocautery activation time was 2.2 seconds (ranging from 2 to 4 seconds). The area that was charred on the electrocautery wire was measured immediately after the procedure and it was 17.5% (ranging from 3.3% to 40%).

### Intra-Operative Success

The extravasation of contrast, visible by fluoroscopy, occurred in 53 of the 56 cases (94.6%). In the 3 cases without extravasation, flexible ureteroscopy revealed no incision and the Acucise device was replaced and reactivated, as described. This resulted in successful extravasation in all 3 cases.

### Intra-Operative Hemorrhage

In no case was there any evidence of intraoperative hemorrhage. All animals remained hemodynamically stable; there was neither flank bruising nor a palpable mass in any of the animals. After the procedure, urine color was evaluated subjectively: clear urine in 28.6% (8 of 28) of the cases, pink urine in 67.8% (19 of 28) of the cases, and reddish urine without clot formation in 3.6% (1 of 28) of the cases.

The double-J ureteral catheter was introduced successfully in all animals, however, in 2 cases; a 22 cm stent had to be placed due to the length of the ureter.

## COMMENTS

In this series, we successfully performed 56 consecutive Acucise endopyelotomies in a porcine model without finding any device malfunction or any intraoperative complications, including significant bleeding. However, the pig may be a less severe model than the clinical situation since the pig ureter has less surrounding fat. Also, the UPJ area in all of the animals was presumably normal and unaffected by crossing vessels. Nonetheless, the standard technique described seemed to largely preclude technical problems with the device and was effective in providing a satisfactory incision in nearly 95% of cases. We have no explanation for the 3 initially unsuccessful cases; however, in all 3 a second placement and activation was successful.

A potential problem may be the activation of the electrocautery at an inappropriate moment through inadvertent operation of the cautery pedal. This may be done by the surgeon himself, by an assistant, or perhaps even by someone circulating in the room. To avoid this problem, the electrosurgical machine should be placed on stand-by until the surgeon is ready to make the incision. Immediately after the incision is made, the electrosurgical unit should be placed back into a stand-by mode. Also, the surgeon must check to make sure that the electrosurgical machine is set on pure cutting current and never coagulation or blend

current. Either of the latter would not only preclude an incision but would likely also result in scarring at the UPJ.

Passing the Acucise device all the way up into the collecting system seems to facilitate rotation of the catheter, thereby making it easier to put the cutting wire into a directly lateral position. Also, draining the contrast and urine from the renal pelvis and replacing it with distilled water and nonionic contrast, if needed, may be an important factor since urine and ionic contrast solutions conduct electricity thereby decreasing the concentration of the electrosurgical current at the site of the cutting wire. Lastly, remaining faithful to the 10-minute balloon inflation period at 24F after cutting wire activation is another fundamental point, since the 24F Acucise balloon may tamponade smaller vessels and minimize post-operative bleeding.

The preferred treatment for UPJO has always been open dismembered pyeloplasty, with success rates above 90% (12-17). Endoscopic treatments are represented by the antegrade or retrograde endopyelotomy (EP). Antegrade endopyelotomy is performed through a percutaneous renal access, while the retrograde EP may be done with the Acucise catheter or through ureteroscopy, either a rigid ureteroscope with a cold knife or electrosurgical probe or a flexible ureteroscope with a Holmium laser or electrosurgical probe. Regardless of the endopyelotomy technique, for primary UPJ obstruction, a lateral incision at the UPJ is done in the impaired area to reduce the chance of bleeding (18).

The advantages of endopyelotomy techniques over open surgery include less intense post-operative pain, less hospitalization time and a quicker return to normal activities (3). However, the endopyelotomy techniques classically present a lower success rate, ranging from 70 to 89% (8,19-22). Recently, several factors that impact negatively on endopyelotomy have been identified. While controversial, these are generally thought to include any of the following: a) The presence of anterior crossing vessels; b) Grade III or IV hydronephrosis; c) An area of stenosis > 1cm in length and d) Renal function of the affected kidney of < 20%. In one study, using selective criteria for the application of endopyelotomy, a success rate of 92.8% was reported with an average follow-up period of 54 months (23,24).

Among the options for treating UPJ obstruction, according to a recent survey in the United States, the preferred methods were open surgery (43%) and Acucise endopyelotomy (42%) (25). However, Acucise endopyelotomy continues to be questioned in the literature due to concerns over adverse effects (2,23). The post-Acucise endopyelotomy transfusion rate ranges from 1 - 9%; among these patients, nearly half required embolization and there have been cases of nephrectomy performed for ongoing bleeding. There have been no deaths from Acucise endopyelotomy reported in the literature to date (2). We believe that much of these problems are truly avoidable and indeed, since using a lateral direction for deploying the cutting guidewire, we have seen only one episode of bleeding over the past 5 years. Similarly, Kim and associates have noted no subsequent episodes of bleeding after adopting a policy of directing the cutting wire laterally (11,18). In addition, the use of spiral CT scans has largely eliminated the use of the Acucise device in the face of crossing vessels, thereby further increasing its safety (18). Also, the suggestions in this article have all but eliminated device malfunction in our experience. Finally, it is important to realize that the current Acucise device is smaller (i.e. 10F over the balloon portion) than the original device which was used by investigators who reported some of the higher incidences of bleeding or device malfunction. Also in those earlier experiences, the incision was routinely being made posterolateral and the presence and location of crossing vessels was not known preoperatively (18).

## CONCLUSIONS

This study revealed that performing Acucise endopyelotomy routinely in a standardized manner could largely preclude intraoperative device malfunction and eliminate complications while achieving a successful incision in the UPJ. We emphasize factors such as delivering the device over a super-stiff guide

wire, replacing urine/contrast medium in the renal pelvis with water/nonionic contrast, making a lateral incision, activation of the electrosurgical current for the least time possible, avoiding inadvertent reactivation by keeping the electrosurgical device on stand-by mode, keeping the Acucise balloon inflated at 24F for 10 minutes after making the incision, and device reactivation only after refurbishing the device by removing char and cleaning the balloon. With these guidelines, we believe that Acucise endopyelotomy can be completed successfully and safely in the majority of selected patients with UPJ obstruction.

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