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AMBULATORY ESWL MONOTHERAPY IN STAGHORN CALCULI

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ABSTRACT

Objective: To evaluate the efficacy of ambulatory extracorporeal shock wave lithotripsy monotherapy in the treatment of staghorn calculi.

Materials and Methods: Using piezoelectric lithotriptors (EDAP-LT01 or LT02), 268 staghorn calculi were treated. One hundred and forty three were complete and 125 were partial (65 filled the renal pelvis + one calyceal system, and 60 filled the renal pelvis + two calyceal systems).

Results: Eight patients abandoned the treatment, giving 260 available cases.

The overall stone free rate on ultrasound control was 53% (62% when controlled by x-ray), after an average of 6.1 sessions/stone. Cure rate was 92%, when including kidneys with clinically insignificant residual fragments (smaller than 2 mm occupying an area < 10 mm^2). Acute pyelonephritis was a frequent complication (11.5%), most often in association with dislodgment of the ureteral stent catheter. Loss of renal function occurred in one case.

Conclusion: The authors conclude that this treatment offers important advantages over open surgery or percutaneous nephrolithotomy, which should not be underestimated.

Key words: kidney; calculi; urolithiasis; lithotripsy; ESWL; staghorn calculi
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INTRODUCTION

When Extracorporeal Shock Wave Lithotripsy (ESWL) was first introduced in clinical practice in 1980, staghorn calculi, infected stones and hydronephrotic kidneys were considered not eligible for this modality of treatment. Within these last two decades, selection criteria for the treatment of urolithiasis have changed. Now, most centers accept ESWL as the first choice treatment for urinary stones, including staghorn calculi, either as monotherapy or in association with Percutaneous Nephrolithotomy (PNL). From the beginning of our experience, in 1987, we have used Ambulatory Extracorporeal Shock Wave Lithotripsy Monotherapy (AESWLM) in most cases of urinary stones. The results of our experience in 268 staghorn calculi are herein presented.

MATERIALS AND METHODS

Between October 1987 and December 1998, 8,100 ESWL sessions were performed for the treatment of 4,020 stones, using an EDAP LT01 and LT02 lithotriptors (both working simultaneously since 1997).

Two hundred and fifty seven patients had staghorn calculi, 11 of them bilaterally, for a total of 268 staghorn calculi treated. The average age of the patients with staghorn calculi was 44 years (4-77) and the female to male ratio was 2.95/1.

One hundred and forty two staghorn calculi were complete (Rocco 5), and 126 were partial (Rocco 4), 65 filling the renal pelvis plus one calyceal system, and 60 filling the renal pelvis plus 2 calyceal systems (1). The stone size varied between 20 x 25 mm to 141 x 82 mm and the area varied between 490 mm^2 to 2,700 mm^2, for an average of 1,050 mm^2.

Pyelocalyceal morphology was normal in 161 patients. Moderate hydronephrosis was present in 24 cases (14 complete and 10 partial calculi), one or more calyceal dilatations were present in 64 cases (37 complete and 27 partial calculi), in nine cases there was a giant hydronephrosis with marked impairment of renal function and 10 cases revealed evident signs of chronic pyelonephritis.

Seventy two patients had persistent urinary tract infections (UTI) and 10 patients had a solitary kidney. The ureteric and pyelocalycial morphology was analyzed in all patients by a previous intravenous pyelography (IVP). A double-J stent catheter was introduced before treatment in all but the first 17 cases. In all patients prophylactic antibiotics were administered, even in the cases with non infected stones. Treatment sessions were performed without anesthesia. With rare exception, almost all of the patients were administered analgesics or ansiolytics. Patients were put in dorsal or lateral decubitus, according to the stone portion chosen to be destroyed in the session (2). Taking advantage of the lithotriptor's small focus and its corrosive effect, several selective disintegrations were performed in each session. The mean frequency used was 3.8 c/s at 85-100% of power, and each treatment session lasted, on average, 58 minutes (20-70 min). All patients returned home after each treatment, going back to work the next day. Patients were told to adopt a position that would make the elimination of the fragments easier (3). The interval between the sessions was never less than 2 weeks. In cases with infectious stones and hydronephrotic kidneys or voluminous hydrocalyces the intervals were even longer. The double-J stent was changed whenever an obstructive pyelonephritis developed, when the patient complained of bladder symptoms or every three months. Ultrasonography and a final IVP were used to assess treatment results. The evolution of the treatment and its results, as well as the decision to suspend or continue it was made by the urologists of the ESWL Unity.

RESULTS

All treatment sessions were well tolerated by the patients. Eight patients were lost to follow-up, and were excluded in the results. Classic surgery was performed in seven cases, since no fragments were eliminated after six sessions of ESWL. The number of sessions per case varied between 2 to 18 (average 6.1-8 in complete staghorn calculi, 4.3 in partial staghorn calculi with two calyceal groups involved, and 4.2 in the remaining partial staghorn calculi). The average duration of the treatment was 4.6 months (2-39 weeks per stone).

Complete destruction of the calculi without residual fragments was achieved in 161 (62%) of the 260 cases, when x-ray control was used. This result dropped to 138 (53%) when ecographic control was used (Table).

The success rate rises to 92%, if kidneys with clinically insignificant residual fragments (< 2 mm occupying an area < 10 mm^2) are included. There were no clinically significant differences between treatment results for the cases with complete vs. partial stag-

Table *- Final results for complete vs. partial staghorn calculi. The seven cases that shown no destruction are included in the group of residual stones > 2 mm.*

Final Results	Without Residual Stones		Residual Stones < 2mm < 10mm^2		Residual Stones > 2 mm > 10 mm^2
	Rx Control	Ecographic Control	Rx Control	Ecographic Control	Rx Control
Complete n = 134	76	63	41	54	17
Partial n = 126	85	75	37	47	4
Total n = 260	161 (62%)	138 (53%)	78 (30%)	101 (38.8%)	21 (8%)

horn calculi (Table). Among the nine patients with reduced renal function (and marked hydronephrosis), four became free of stones, two have residual fragments < 2 mm, and three have residual fragments > 2 mm < 10 mm. Thirty two (44.4%) of the 72 patients with persistent UTI became free of infection, 23 (31.9%) have infrequent episodes of UTI easily controlled by antibiotics, and 17 (23.6%) still need permanent antibiotic treatment. In 16 patients, a different bacterial species was detected.

The overall rate of severe complications was small. Three patients developed severe pyelonephritis (pain and temperature over 38ºC) associated with partial spontaneous dislodgment of the double-J stent catheter. Percutaneous nephrostomy was done in 2, both presenting marked hydronephrosis. The third patient lost his kidney as consequence of staying at home with fever for 2 weeks before returning to our center. Moderate pyelonephritis (temperature below 38ºC) occurred in 30 cases (11.5%) during the first three days after treatment, despite being under antibiotic therapy. Ten of these patients had a normal pyelocalyceal morphology (6 partial and 4 complete staghorn calculi), 20 had one or more calyceal dilatation (8 complete and 4 partial), and 8 had moderate hydronephrosis (5 complete and 3 partial). As a consequence of acute pyelonephritis, one kidney function was lost, severe functional impairment occurred in another, and moderate decrease was observed in four kidneys, all of them with infectious stones. Thirty cases of persistent "steinstrasse" (11.5%), 18 occurring in cases of complete and 12 in cases of partial staghorn calculi, were successfully treated either by ureteroscopic ultrasonic or ballistic lithotripsy (20 cases with 4 nephrostomies) or by "in situ" ESWL (10 cases). A case where a voluminous fragment became impacted in the middle third of the ureter needed open surgery, after an ureteroscopic failure. Massive calcification of the bladder end of the double J stent occurred in nine patients (3.5%), and was successfully treated by ESWL. The mean duration of hospitalization for patients requiring auxiliary procedures was three days. One hundred and twelve patients remain under our control. Sixty eight needed from 1 to 3 short sessions of ESWL over small recurrent calyceal calculi.

DISCUSSION

We have adopted the policy of trying ESWL in most cases of urolithiasis since we started using this treatment modality in 1987. Our experience shows good results in the treatment of staghorn calculi, with complete clearance of the stones in 53% of the cases, and clinically insignificant residual fragments in a further 38.8% of the cases. The majority of cases of big stones in voluminous hydronephrotic kidneys, usually considered not eligible for ESWL, were successfully managed by ESWL (Figures-1 and 2). The most common complication in our patients was acute pyelonephritis, which almost always occurred after dislodgment of the double-J stent. This is one of the disadvantages of the ambulatory regimen, as patients do not always follow the instruction of returning immediately to our center if some complication occurs.

Using an ambulatory regimen with short fragmentations, the number of sessions is higher but, on the other hand, the number of severe complications may be decreased, and almost all patients can go back to work on the day after the treatment. Besides, using short fragmentation with a piezoelectric lithotriptor and an interval of 2 weeks between the sessions, the probability of functional damage over the kidney is very small, since several papers in which a more powerful lithotriptor (Dornier HM3) was employed conclude that ESWL is harmless for the kidney (4-7). Figure-1 refers to a patient with a recurrence of staghorn calculi after two bilateral pyelonephrolitotomies, to whom any kind of treatment was denied in another center. This patient was submitted to 18 sessions in the right kidney and 14 sessions in the left kidney during 2 years, including 5 short sessions of 20 minutes on the right kidney and four in the left kidney. She was hospitalized during 2 days after the first session, in order to assess its consequences. Thereafter, all the treatments to both kidneys were ambulatory. She only stopped working on treatment days, and during 3 days after a moderate pyelonephritis. The patient referred to in Figure-2, only stopped working on treatment days and had no need for hospitalization. These two examples, like many others included in this series, testify the feasibility of AESWLM for staghorn calculi, even in complicated cases.

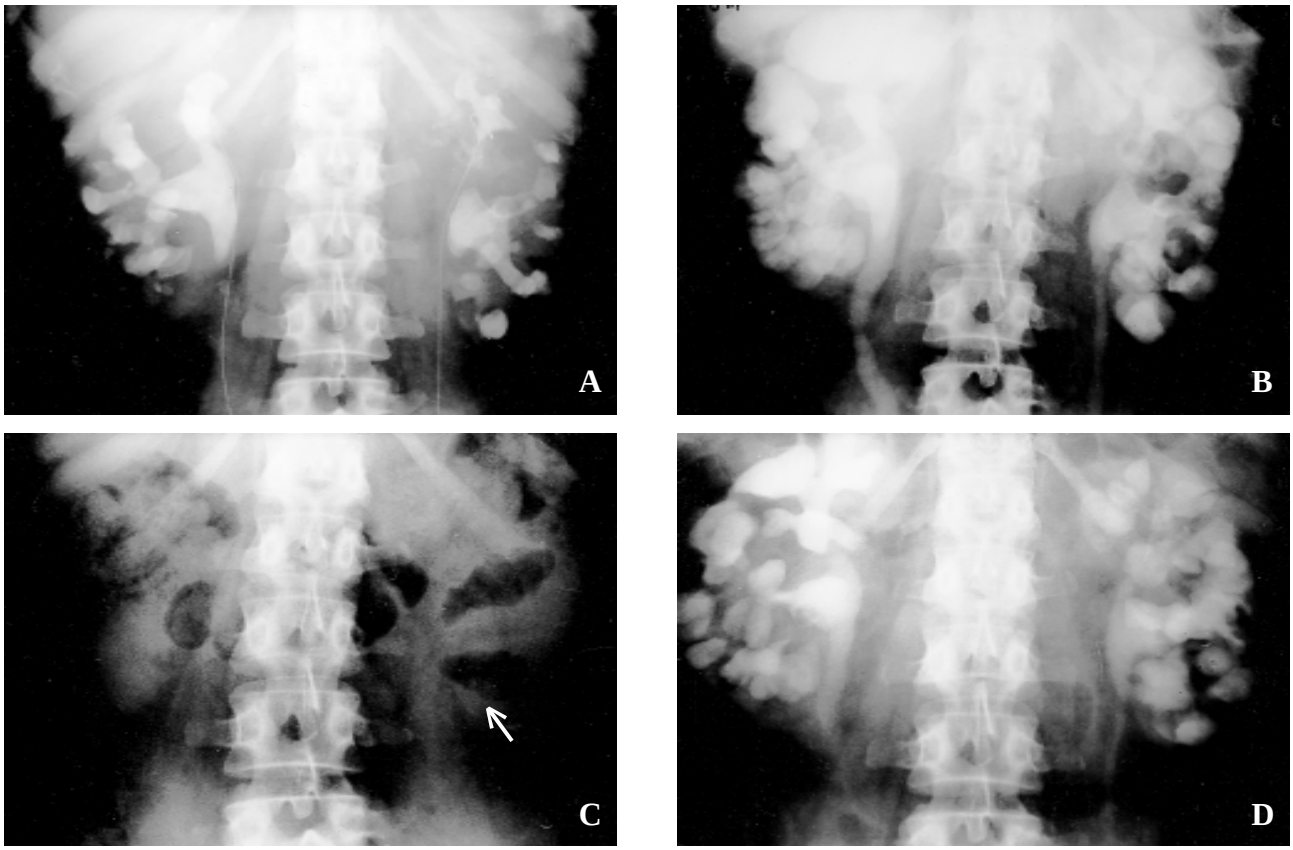

Figure 1 *- A) Voluminous recurrent bilateral staghorn calculi in a patient with two previous pyelonephrolithotomies performed three years before; B) IVP showing marked hydronephrosis and a reduction in the renal parenchyma; C) Final result with a little residual fragment in the lower calyx of the left kidney (arrow); D) IVP after treatment showing a marked reduction of the hydronephrosis and a partial recovery in the pyelocalycial morphology.*

As all patients are treated free of costs, we frequently perform short sessions on residual fragments, in order to accelerate their elimination, taking advantage of the recovery of the pyelocalyceal morphology and function (Figures 1-D and 2-D). The patients remain under follow-up, and prevention of recurrences is achieved performing short ESWL sessions whenever a stone is seen. None of the 112 patients that remain under our control developed staghorn calculi. However, as many patients were lost to follow-up, we are unable to know if there was any recurrence of staghorn calculi. We were also unable to correlate the results according to the stone composition, since many patients did not keep the fragments as they were told to. Literature results show that more than half of the patients with staghorn calculi can be successfully managed by ESWL monotherapy, with low morbidity (8-14). However, PNL is considered by many as the best treatment option in this setting, either alone or followed by ESWL **(**10,15-24**).** One of the claimed advantages of PNL is a shorter treatment time. According to Winfield (19), the cumulative total operative time to debulk staghorn calculi is 3.9 hours for partial ones and 9 hours for complete ones, with an average of 10 days of hospitalization. Given an average ESWL session duration of 60 minutes, these values are roughly equivalent to four and nine sessions, respectively, which is more than what we needed in an outpatient regime (6.1 sessions). However, in most of the papers reviewed by us, there is no detailed reference to the duration of PNL performed by other authors.

A lower rate of ancillary procedures is also claimed in favor of PNL. This observation is mainly

based on series where, the Dornier HM3 lithotriptor's high destructive effect was used to treat the stones on one to three sessions, separated by one to three days and where double J stents were often not placed (10,16,18,19,20,24). The use of double-J stents as a routine and the performance of less aggressive sessions separated by a minimum of 2 weeks (in order to allow a better clearance of fragments between sessions and to give time for renal recovery) reduced the need of auxiliary procedures in our series. On the other hand, the rate of severe complications with PNL is higher and not negligible, even in very experienced hands (10,17,19,20,24,28). The incidence of residual fragments is higher following ESWL than after PNL. However, the clinical relevance of this fact is not settled. On one hand, most patients with small residual fragments can be considered clinically cured, as they are asymptomatic, and their renal function is unaffected by the small fragments. Furthermore, even in the cases of infected stones, the incidence of subsequent urinary tract infections is unpredictable, and some times not directly related to the presence or absence of fragments, since in many recurrent cases, the bacterial species are not the same (25,26).

On the other hand, the higher risk of stone re-growth from the residual fragments is not as important when dealing with a non-invasive and tolerable therapy (ESWL) as it is when an invasive method

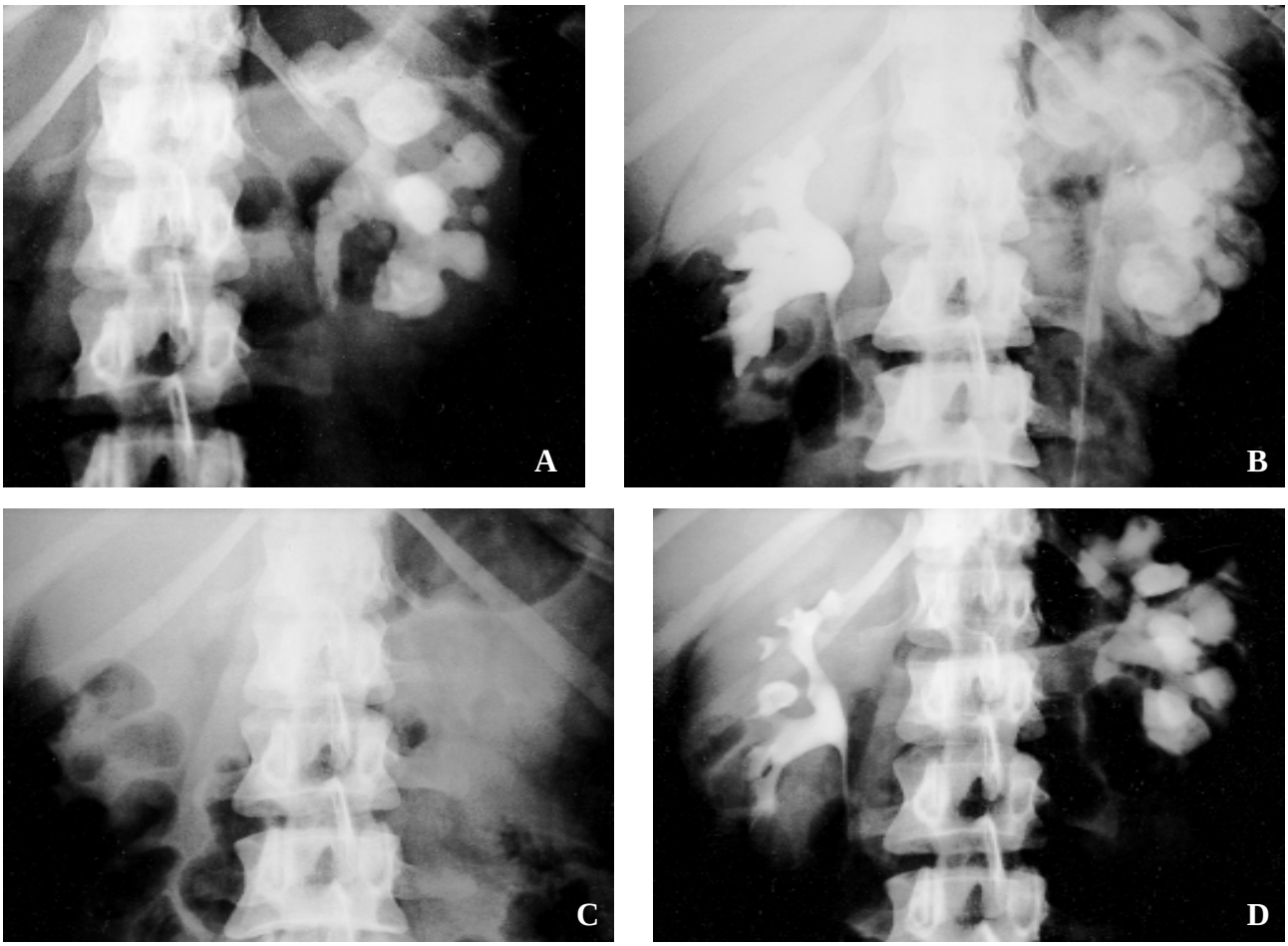

Figure 2 *- A) Voluminous recurrent staghorn calculi in a patient with a previous pyelonephrolithotomy performed eight years before; B) Voluminous hydronephrosis on the IVP with marked reduction in renal parenchyma; C) The final result with no residual fragments; D) The IVP one year after treatment showing a marked reduction of the hydronephrosis with improvement of the renal function and partial recovery of the pyelocalycial morphology.*

was used. In fact, such re-growths can easily be controlled by short ESWL sessions. In cases where a complete stone clearance is considered necessary, we believe that ESWL should be tried first, and, if residuals remains, PNL with a flexible nephroscope (with which a free stone's rate of about 85% can be obtained may then be used (12,15,27).

This appears to be a much more sensible option than trying PNL in the first place, as more than 50% of patients are rendered totally free of stones with ESWL and can therefore be spared the higher risks of PNL with a high rate of blood transfusions (0.3 to 50%) and their inherent and potential risks of hepatitis and AIDS contamination (10,16-20,24,28,29).

CONCLUSIONS

1)- Piezoelectric ESWL as ambulatory monotherapy for the treatment of staghorn calculi has shown in our center to be a highly valuable option, affording a 53% stone free rate for an average number of 6.1 sessions per stone, and an overall success rate of 91.8% when kidneys with clinically insignificant residual fragments < 2 mm are included. 2)- The ultrasonic control is a more accurate method to detect residual fragments. 3)- The recurrences of staghorn calculi can be avoided with a close follow-up of the patients, performing ESWL when the residual fragments grow, or when a new small stone appears, as occurred in 68 of the 112 patients under follow-up. 4)- Given the good results obtained in our experience, all staghorn calculi, even massive ones, should be given an opportunity of being treated by ESWL. 5)- In a small number of cases ESWL is ineffective, and these stones have to be treated by invasive techniques.

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EDITORIAL COMMENT

Whether the author's conclusions are justified depends primarily upon what one is satisfied with. The overall stone-free rate in this series, at 53 percent, is the same as the stone-free rate of 50 percent identified in the analysis of the papers published up to 1993 reported in the AUA Guidelines Report on the Management of Staghorn Calculi. Those 50 percent results were achieved using, for the most part, an unmodified HM-3, a very different and considerably more powerful machine than the Piezoelectric lithotrite used in this study. Most people regard being stone free as the sine qua non for the management of infected stones. I do not believe that the authors have made the case that leaving these patients with stony infected stony material behinds represent a satisfactory option in the average patient, although I would certainly concede that there are occasional patients in whom even residual stones may represent a distinct improvement over the original staghorn status.

There is no unanimity of opinion as to what a "clinically insignificant fragment" is. This disagreement extends not only to the size of such fragments, but to the numbers of such fragments and the only unquestioned and incontrovertible, widely accepted, way to measure "success" and "cure" are stone-free rates. The reality is that the stone-free rates in this study are unimproved over the last 15 years, and it has taken using this lithotrite longer to achieve these results. Further, many of these patients were unfortunately lost to follow-up, and while I believe that it is safe to assume that most of these stones were struvite stones, the stone analysis was apparently not available in many of these patients.

I certainly respect that treatment of these patients is free to the patient, yet it is nevertheless true that such shock wave treatment still represents a cost center somewhere in the medical system, even if this may be buried in the budget of the National Health Service. Such large numbers of treatment must have some morbidity physically or psychologically in the patient population. As I read this paper, while I am enormously impressed with the large number of patients seen, the reality is that many of these patients were unavailable for follow-up and that of the ones that were residual stones grew and new stones appeared in some 50 percent of the patients treated.

My own view is that this group of patients would have been better being treated in a percutaneous-based practice where the stone-free rate would have been far higher and obtained far more expeditiously. That while percutaneous surgery has its own risk, the stone-free state could be achieved without the multiple treatments, double-J stent placement, and risks of sepsis that attended this group.

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