International Journal of Clinical Urology
2020; 4(2): 68-72
http://www.sciencepublishinggroup.com/j/ijcu
doi: 10.11648/j.ijcu.20200402.18
ISSN: 2640-1320 (Print); ISSN: 2640-1355 (Online)

Prospective Randomized Study of Fixed Laser Setting Verses Variable Laser Settings for a Better Stone Free Rate

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To cite this article:
Chandra Mohan Vaddi, Siddalinga Swamy Panchekante Matha, Ramakrishna Paidakula, Soundarya Ganesan, Manas Babu, Hemnath Anandan. Prospective Randomized Study of Fixed Laser Setting Verses Variable Laser Settings for a Better Stone Free Rate. *International Journal of Clinical Urology*. Vol. 4, No. 2, 2020, pp. 68-72. doi: 10.11648/j.ijcu.20200402.18

Received: September 10, 2020; **Accepted**: September 25, 2020; **Published**: October 7, 2020

Abstract: OBJECTIVE: To assess the outcome of variable laser settings verses fixed setting on the stone free rate and complications. MATERIAL AND METHOD: We conducted a prospective, single-blind randomized controlled study. Solitary renal non lower pole stones 10 to 20 cm were included. A total of 113 Patients were randomly divided in to two groups. In group A, fixed laser setting was used at 1.0J energy and 12Hz frequency during the entire procedure. In Group B, variable laser settings were used; initial fine fragmentation was performed @ 1.0J X 12Hz. Once the residual stone reduced enough to wobble, the energy was reduced to 0.8 J and 8Hz. Settings were further reduced to 0.5J and 5Hz as required to complete the fragmentation process with minimal migration. RESULT: Group A had 58 patients and Group B 55 patients for analysis of perioperative variables. Stone free rate (<2mm) is in favor of systematic stone dusting with variable frequency (95.8% vs 83.6%, p=0.05). Post-operative fever and pain were not statistically significant between the groups (fever 10.3% vs 9.1%, p=1.00) (pain mean VAS 1/10 in group A vs 2/10 in group B). CONCLUSION: The solitary hard stones of 10 to 20 mm can be treated with more than 95% SFR using variable laser settings producing fine dust, without increase in significant postoperative complications or hospital stay.

Keywords: Retrograde Intra Renal Surgery, Dusting, Popcorn, Laser Settings, Stone Free Rate

1. Introduction

Endoscopic treatment for renal calculi has seen an increased trend towards retrograde intrarenal surgery (RIRS). With progressive advancements in technology even larger kidney stones are amenable to RIRS [1-3]. With larger stones, stone free rate (SFR) is reduced and in these cases laser settings play a major role. Many studies describe laser settings with respect to energy, frequency and pulse width but they have used fixed setting throughout the procedure [4, 5]. We observed that systematic painting of stone coupled with modifying the laser settings during the procedure tended to improve the SFR. We conducted a study to know the outcomes of fixed versus variable/modified laser settings. Primary outcome: comparison of SFR at 60 days between the two groups. Secondary outcome: comparison of Laser time and postoperative complications.

2. Material and Methods

We conducted this prospective single-blind randomized controlled study (duration - April 2019 to April 2020).

2.1. Inclusion Criteria

Consecutive adult patients (defined as age 18 or more) presenting with symptomatic solitary renal or upper ureteric calculus size 10-20 mm with computed tomography attenuation values ranging from 900-1500 Hounsfield units were included in the study.

2.2. Exclusion Criteria

Lower calyx stone, multiple calculi, pregnancy and kidney with anatomical abnormalities were excluded.

The study was approved by hospital ethical committee (study reg. no. ECR/230/INST/AP/2019/RR-16) and written informed consent were obtained from each participant before inclusion in the study. Block randomization technique was employed with block size of 4, 6 and 8 with 2 groups A and B. Randomization was revealed to the operating surgeon by opaque envelope just before surgery. In group A patients fixed laser settings were used throughout the procedure and in group B patients progressively decreasing variable laser settings were used.

2.3. Statistical Analysis

The sample size was calculated by assuming a hypothesized difference of 15% between both the groups, with confidence level of 95% and power of 80%. The minimum sample size per treatment arm required was 50. Expecting an attrition rate of about 20% we took a sample size of 60 per arm. Statistical analysis was performed using IBM-SPSS statistical software version 19. The normalcy of data was checked using one sample Kolmogorov-Smirnov test and found to be non-normal. Categorical variables were presented in percentages and tested for difference using Chi2 test and Fisher's exact test. Continuous variables were presented in median with interquartile range and analyzed using Mann-Whitney U test and Kruskal-Wallis test as applicable. P value <0.05 was considered statistically significant.

2.4. Procedure

All patients underwent standard evaluation including imaging with non-contrast computer tomography, routine laboratory evaluation with urine culture, complete blood count, creatinine and random blood sugar. Pre-operative counseling included discussion of surgical options, risks and benefits of each approach. If the patient chose RIRS, study protocol was discussed in addition. All patients underwent DJ stenting 2 weeks before the scheduled date of RIRS to passively dilate the ureter for easy placement of access sheath.

Upon inclusion, patients received preoperative antibiotic in loading dose (based on hospital antibiogram) within 60 minutes before the surgery. If urine culture showed infection or colonization it was treated pre-operatively. All procedures were performed under general anesthesia by a single surgeon (VC) experienced in RIRS procedure. A 9.5/11.5Fr, 28cm ureteral access sheath (Cook medical, Indiana, USA) was placed by standard method. Stone visualized with flexible ureterorenoscope (Flex X2, Karl Storz, Tuttlingen, Germany) and fragmented with Holmium: YAG laser (Quanta 30W, Milan, Italy) using 200 micron laser fiber (Quanta systems Q1, Milan, Italy) with fixed long pulse duration. Irrigation with sterile normal saline (NS 0.9%) was performed by assistant using 50ml syringe.

Patients were randomly divided into two groups based on type of laser settings used in the procedure. In group A, fixed laser setting is used at 1.0J energy and 12Hz frequency during the entire procedure. Even if the stone fragments and started to wobble the same laser settings continued till the stone reduced to fine fragments which are deemed appropriate for spontaneous passage. Decision of basketing in group A was semi objective, based on size of fragment in relation to size of laser fiber. After doing popcorn for certain duration, if any large fragments (subjective) were present they were retrieved with 2.2 Fr N Circle Nitinol Tipless basket (Cook Medical, USA).

In Group B patients variable laser settings were used; initial fine fragmentation is produced with painting technique which was performed @ 1.0J X 12Hz. We decided these settings for painting technique after using 30 W Quanta laser machine over a period of 10 yrs. The settings may differ with other machines. The lasering procedure involved systematic surface painting and maintaining profile of the calculus as much as possible avoiding fragmentation into larger pieces (Figure 1). Laser fiber is in non-contact mode with the stone most of the occasions. Once the residual stone reduced enough to wobble, the energy was immediately reduced to 0.8J X 8 Hz (6.4 W). Settings were further reduced (upto 0.5J X 5Hz; 2.5W) as required to complete the fine fragmentation process with minimal migration. End point of fragmentation was fine dust.

3.5 Fr, 26 cm DJ stent was placed in both the groups in all the cases at the end of the procedure.

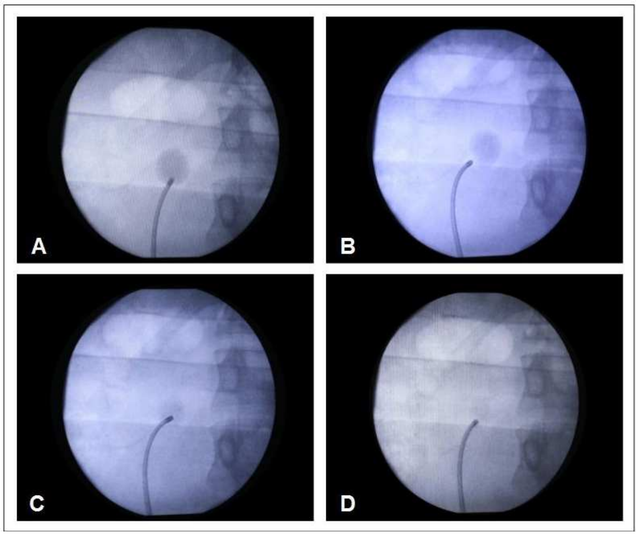

Figure 1. *The lasering procedure involved systematic surface painting maintaining profile of the calculus as much as possible avoiding fragmentation into larger pieces.*

2.5. Postoperative

Patients once stable were discharged on first postop day. Postoperative pain was measured on visual analog scale (VAS score 0 – 10). Postoperative fever was considered to be due to urinary tract infection unless proven otherwise, evaluated and treated with standard care. DJ stent was removed after 2 weeks in both the groups. Repeat imaging was not performed before removal of DJ stent.

A plain CT KUB was performed in all the patients at two months. Any residual fragment 2mm or more in size was considered as failure of procedure. Reporting of CT scan was done by single radiologist (blinded).

3. Results

Group A had 58 patients and Group B 55 patients for analysis of perioperative variables (Figure 1). However, 3 in group A and 7 in group B were lost to follow up after DJ stent removal. Patients preoperative and perioperative data is provided in table 1.

Stone free rate was better with Group B which was statistically significant (83.6% group A vs 95.8% group B. p=0.05). Duration of lasering time was higher in Group B. Overall pain score was low Independent of the groups.

Figure 1 Group A had 58 patients and Group B 55 patients for analysis of perioperative variables.

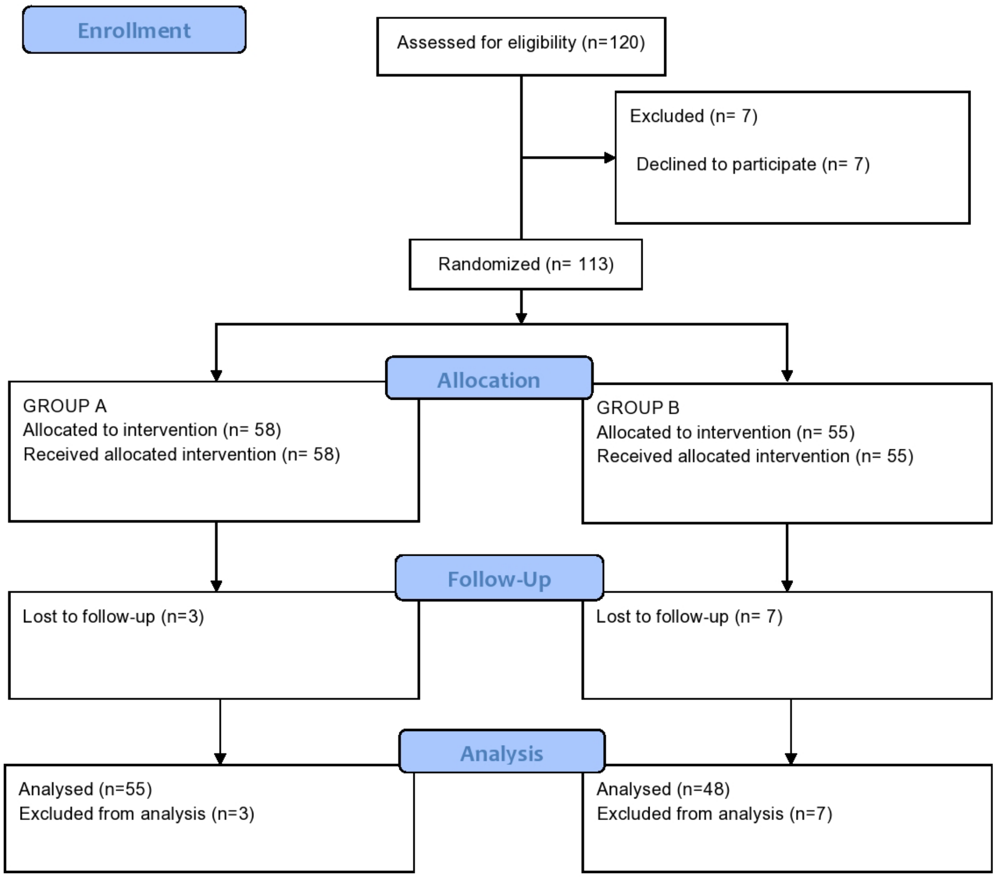

Figure 2. *Consort diagram: Group A had 58 patients and Group B 55 patients for analysis of perioperative variables.*

Table 1. *Patients preoperative and perioperative data.*

		Group A (n=58)*	Group B (n=55)*	p value
Age (years)		43 (21 to 70)	43 (20 to72)	0.51
Sex	Male	63.8%	69.1%	0.55
	Female	36.2%	30.9%	
Stone size (mm)		12	13	0.27
Stone location	Ureter	15	14	0.98
	Pelvis	22	22	
	Upper calyx	11	11	
	Middle calyx	10	8	
Lasering time (min)		38 (28.8 to 45)	62 (45 to 75)	<0.0001
Basketing during procedure		12%	0%	0.013
Post-operative pain	VAS	1 (0 to 2)	2 (1 to 3)	0.046
Post-operative fever		10.3%	9.1%	1.00
Post-operative hematuria		18.9%	10.9%	0.23
Post-procedure hospital stay (hours)		20.8 (20.2 to 22.7)	20.8 (20.0 to 22.4)	0.68
Success rate	Overall	83.6%	95.8%	0.05

* Except for calculation of success rate. In that case group A n=55, group B n=48.

4. Discussion

Our RCT revealed good SFR in systematic stone painting with variable laser settings when compared to fixed laser settings (95.8% vs 83.6%). This was achieved without any basket-retrieval in the variable setting group (0 versus 12% in group A). Although this did involve an increased lasering time (by appx 24min) and somewhat increased post-operative pain (median difference of 1 on a 10-point VAS); nevertheless, postoperative hospital stay was not increased (median 20.8 hours in each group).

An increasing trend towards RIRS is noted for the renal stone management in the last decade. The SFR of RIRS is equivalent to PCNL in stone size <20mm with added advantage of shorter hospital stay and lower risk of complications[3]. As the stone size increases, the SFR decreases when compared to standard PCNL [1, 2]. Various techniques like painting, chipping, perforation, dusting, popcorn etc., are suggested to improve the SFR. Most of the studies mention high frequency low energy and long pulse width for dusting. Medium frequency, high energy and short pulse width is used for faster ablation of the stone [4, 6-10].

Emilian E et al [7] studied *in vitro* stone fragmentation by popcorn method in 144 tests where in combinations of 0.5 to 1.5 J, 10 to 20 and 40 Hz, and long and short pulses were tested for 2 and 4 minutes. In each test the laser setting was fixed there was no change in the laser setting.

Li Roger et al [11] compared different laser settings in In vitro calyceal and ex vivo porcine ureteral models. In calyceal model, 0.6J/5Hz, 0.2J/15Hz, and 0.2J/50Hz were compared and in ureteral model 0.6J/5Hz and 0.2J/15Hz. They used fixed laser setting for each calculi. They concluded that in ureter it should be performed using the low-energy, moderate-frequency dusting setting to minimize retropulsion and maximize efficiency. In the renal calyx, there was no difference with laser settings.

We observed with experience of >1000 cases, when the stone is large and hard, then energy and frequency which is used for faster ablation also produce dust initially. Especially when the laser fiber is just away from the surface of the stone. But as the stone volume decrease, the same settings break the stone into pieces. Once the stone is made into pieces, it is difficult to do painting or dusting. In such cases random firing, that is keeping the laser fiber in the center of the fragments procedures popcorn effect. This would lead too many fragments. There fragments may migrate into other calyces or get unnoticed in the sea of dust thus decreasing the SFR. This could be the reason for very low SFR in our Group A patients.

To avoid this we used high laser settings which initially helped to reduce the stone volume faster. The moment wobbling occurs; slowly both energy and frequency are reduced to continue painting and then produce fine dust. During the last part of the lasering where the stone is very tiny we used 2.5 W from the periphery to the center making fine dust. Ultimately we never did random firing or basketing in group B patients. Sometimes we used irrigation to completely clear the dust.

Having worked with different laser machines and settings we believe that it may not be appropriate to fix the laser settings for dusting or popcorning. In fact it would depend on the hardness, volume, size and location of the stone as well as characteristics of particular machine.

Very few studies comparing basketing/ fragmentation versus dusting are described.

Chew et al [12] enrolled 59 patients and followed for 3 months (N=36 Basketing, N=23 Dusting). Significantly more laser energy was used in the dusting group. Operative time was longer in the basketing group. The stone free rate of 89.1% in the basketing group and 60.9% in the dusting group. Even though the dusting group had longer operative time and low initial residual rates, with time there was no difference between the groups in readmission or intervention. The reasons for low SFR in dusting group in this study was not explained.

Gamal Saad [13] compared dusting and fragmentation for less than 2 cm renal stones. Group 1 (23 cases) were dusted with low power (0.2-0.4 J) high frequency (20 to 30 Hz). Group 2 (23 cases) were fragmented with high power (1-2J) and low frequency (4-5Hz). The stone free rate in group 1 was 86%and in group 2 was 89%. Group 2 had longer operative time when compared to group 1 (57+_9 min vs 73+_13 min, p=0.001). They have used fixed laser setting and had more operative time in fragmentation group probably due to use of basket. We have compared the lasering time in our study, which was more in group B dusting group (by appx 24min); however, it translated into high stone-free rates without added complications.

Even though the systematic painting technique with variable laser settings is very useful for 1 to 2 cm hard stones, it has certain limitations. The major limiting factor is the time taken to dust completely in more than 2 cm hard stones. This classical painting is also not possible in the inferior calyceal stone where entire surface of the stone is not visualized. Similarly when multiple stones are present it may take much longer time to dust each stone. The technique of continuous painting over the stone without breaking the stone is also techniquely demanding.

With our promising results, in experienced hands and laser settings according to the laser machine, using systematic painting with variable laser settings would achieve higher SFR particularly in larger stone widening the scope of RIRS over PCNL. However, larger studies enrolling patients with stones larger than 20 mm would be required before it can be recommended in larger stones and also reproducing the same effect of laser settings in different laser machines is also challenging.

5. Conclusion

The solitary hard stones of 10 to 20 mm can be treated with more than 95% SFR using variable laser settings producing fine dust, without increase in significant postoperative complications or hospital stay.

Acknowledgements

We thank Dr Pavan, Dr Devendera department of anesthesiology Preeti urology and kidney hospital, Dr Ravi, Dr Ganesh and Dr Anil for maintaing the data, Mr Shreedhar for operative assistance.

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