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Introduction & Objectives: Extracorporeal shockwave lithotripsy (ESWL) and flexible ureteroscopy (RIRS) are generally considered as two valid alternative first-line options for stones up to 2 cm located in the kidney. The objective of our study was to compare the outcomes of the two techniques in the treatment of renal stones.

Materials & Methods: We designed a prospective clinical trial with balanced randomization (1:1) between the 2 arms of treatment (ESWL vs RIRS), according to stone location (inferior calyx vs other sites) and size (6-10 mm vs 11-15 mm vs 16-20 mm). 150 patients were included from April 2012 to April 2018, presenting a single renal stone from 6 to 20 mm. A total of 143 patients have been treated so far and have the first follow-up consultation available. Primary endpoint of the study was to investigate the successful outcomes of the 2 treatments after 30 days (defined as totally stone-free patients - SF-0, or presenting clinically insignificant fragments up to 5 mm - SF-5), based on US and KUB X-ray performed by an independent and blinded Radiologist. Secondary endpoints were: difference between complication rates (according to Clavien-Dindo classification), outcomes according stone location and stone size, long-term outcomes. Ethical Committee approval was obtained.

Results: RIRS outcomes resulted superior to ESWL at the imaging evaluation after 30 days (SF-0 51,5% vs 25,7%, $p=0.002$; SF-5 77,3% vs 55,7%, $p=0.006$). Considering stone location, RIRS proved to be significantly superior to ESWL when treating stones located in all renal sites (SF-5 74,4% vs 52,3%, $p=0.03$), except for the lower calyx (SF-5 81,5% vs 61,5% $p=0.09$). Considering stone size, RIRS had significantly better stone-free rates than ESWL when treating stones >10 mm (SF-5 76.9% vs 50%, $p=0.03$), while no significant differences were found for stones between 6 and 10 mm (SF-5 78.8% for RIRS vs 62.2% for ESWL, $p=0.1$). No significant differences between RIRS and ESWL were shown considering complication rate (6.1% vs 9.6%, $p=0.3$).

Conclusions: RIRS showed better outcomes than ESWL and should be considered the first treatment option for renal stones between 11 and 20 mm. Both RIRS and ESWL proved to be viable alternatives, with comparable rate of complications, for the treatment of kidney stones up to 10 mm.