Intravascular Lithotripsy vs Cutting Balloon for Severe Coronary Calcification

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Purpose: This study compared the efficacy and safety of the Cutting Balloon (CB) and the novel intravascular lithotripsy (IVL) in severely calcified coronary lesions.Methods: This study was a prospective, single center, randomized controlled trail. Eligible patients were randomly assigned to receive CB or IVL treatment. The primary endpoint was procedural success, defined as successful stent implantation with <30% residual stenosis. Calcium morphology was evaluated by optical coherence tomography (OCT).Results: A total of 152 patients with severe coronary artery calcification were enrolled (74 in CB group and 78 in IVL group). The baseline characteristics of groups were comparable between groups. Procedural success rate was higher in IVL group as compared to CB group (96.2% vs 86.5%, p<0.05). The calcification fracture rate and minimal lumen area (MLA) increase assessed by OCT were shown in Table 1. There was no significant difference in safety endpoints in two groups.Conclusion: This study demonstrates that coronary lesion preparation using IVL is significantly more effective than CB in achieving acute luminal gain.

Table 1. Serial OCT measurements and safety endpoints in two groups

	CB group (N=74)			IVL group (N=78)		
	Pre-CB	**Post-CB**	**Post-Stent**	**Pre-IVL**	**Post-IVL**	**Post-Stent**
At MLA site						
Lumen area, mm^2	2.04±0.72	2.64±0.69	5.65±1.79	2.16±0.98	3.21±1.12	6.98±2.48
Area stenosis	79.4±13.6	58±20.6	27.4±11.9	80.2±16.5	49.0±27.6	20.5±10.4
Calcium angle, °	172.2±92.0	151.4±62.7	142.1±68.9	184.2±87.9	140.8±59.4	120.7±86.8
Calcium fracture rate	/	45, (60.8)	48, (64.9)	/	58, (74.4)	66, (84.6)
Residual stenosis, %						
<50%			73, (98.6)			78, (100%)
<30%			64, (86.5)			75, (96.2%)
Safety endpoints						
Severe dissection			3, (4.1)			1, (1.3)
Perforation			0, (0)			0, (0)
Abrupt closure			1, (1.4)			1, (1.3)
No-reflow			0, (0)			0, (0)