



Intravascular Lithotripsy to Facilitate Carotid Stenting

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ABSTRACT

Severe arterial calcification can make balloon and stent expansion challenging. Severely calcified lesions are more likely to undergo recoil after balloon expansion or stenting. Intravascular Lithotripsy (IVL) is a potential solution for severe calcification limiting stent expansion or recoil in the Internal Carotid Artery (ICA). IVL has been rarely tried in ICA territory. ICA endovascular intervention is unique due to high risk of stroke and use of distal protection is mandatory to qualify for procedure re-impbursement. IVL is not approved in the ICA territory and not approved for treating under expanded stents. But, traditional calcium de bulking devices like Rotational or orbital atherectomy are dangerous in ICA territory while calcium scoring devices might fail. IVL can modify calcified plaque without direct mechanism for embolization. There have been reports of application of IVL in carotid self-expanding stenting. We have recently reported our experience in a Case Report in the use of IVL to both successfully dilate under expanded stents and stop the repeated lesion and stent recoil. IVL barring some limitations of requiring prolonged balloon inflations and lack of enough long-term follow may be further studied in the treatment of under expansion as well as recoil of self-expanding stents in carotid circulation.

Keywords: Carotid stenting; Severe calcification; Intravascular lithotripsy; Recoil

ABOUT THE STUDY

Arterial atherosclerotic plaques may become severely calcified in the intima and media due to inflammatory factors making balloon dilation challenging [1,2]. The atherosclerotic plaques can be particularly prone to getting calcified in patients with renal failure, diabetes and elderly age leading to severe Coronary Artery Calcification (CAC). The presence and extent of coronary calcification is very widely prevalent in the society and is often underestimated by angiography without using techniques like ultrasound [1]. The carotid arteries in particular have high propensity for severe calcification [1,2]. The calcification in the arteries is rock hard at times and stent expansion becomes difficult along with increase in complications like stent thrombosis, restenosis and stent recoil [3]. In these very hard calcified plaques, balloon dilation using noncompliant balloons up to highest possible pressures is frequently unsuccessful in optimal balloon expansion [4]. Calcification in carotid and other vascular territories may cause asymmetric expansion and stent deformation that may further lead to stent recoil and restenosis [5-7]. In the non-carotid circulation, there are atherectomy techniques to de bulk the calcium for successful stent expansion [7,8]. These include rotational and orbital atherectomy, but are very hazardous in the carotid arteries due to inherent embolization associated with the use of this de

bulking devices. In general, these techniques should be utilized before stenting [5]. The plaque scoring devices like Cutting Balloon or Angiosculpt can be utilized in the calcified carotid arteries and may reduce the risk of recoil [4]. The severity of calcified plaque volume influences both the likelihood of balloon expansion and the severe recoil [6]. Underexpanded carotid stents are associated with increased risk of in-stent restenosis as well as distal emboli [5,6,8,9].

However, a novel technique has emerged to treat lesions in the setting of severe vascular intimal and medial calcification [10]. This is shockwave Intravascular Lithotripsy (IVL) balloon. IVL uses the same technology as the ultrasound lithotripsy used to break kidney stones [11,12]. If the severely calcified rock like plaques in the intima and media could be shattered, balloon and stent expansion would occur [12]. The risk of recoil also would be lower due to fractures in the calcified plaque compressing the stent [8]. Two tiny electrodes called emitters inside a low-pressure standard angioplasty balloon create electric sparks which cause pressure wave forms equivalent to 50 atmospheres (atm). These waves shatter not only superficial but also relatively deep calcium. The product is not approved for carotid stenosis or under expanded stents but has been reported stents in the ICA and successfully expanded the stents and eliminated the recoil. The use of IVL in under expanded stents has been reported

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and use of IVL in ICA has been reported [13-15]. As noted, we reported the use of IVL in two layers of fresh stents in the carotid stenosis treatment [9]. This is the first report in the literature that two layers of fresh under expanded and persistently recoiled self-expanding carotid stents benefitted from Shockwave lithotripsy.

DISCUSSION

We are encountering increasing number of patients with severe calcification of the stenosed lesion sites including in the carotid circulation [1-3]. This makes lesion expansion difficult and makes lesions more likely to undergo severe recoil [4,7,8].

IVL can shatter calcified plaque without direct mechanism for embolization but is not approved for ICA application and not approved for under expanded fresh or old stents. We tried it as last resort in our case report with hard to dilate lesions and severe stent recoil in a long severely calcified lesion extending from distal common carotid to proximal ICA [9]. This was after failure of cutting balloon angioplasty followed by above the rated burst pressure balloon dilations with noncompliant balloon angioplasty. This was also after failure of two layers of closed cell self-expanding stents in stopping the lumen collapse from severe recoil. The stents looked much under expanded till the IVL was done [9]. IVL successfully dilated the artery and stopped the repeated lesion recoil and stent recoil. After the IVL, the lesion improved from 90% to 10% residual stenosis presumably due to modification of the calcified plaque (Figures 1 and 2) [9]. Shockwave lithotripsy balloon uses electric energy to vaporize the mixture of contrast and saline creating a pressure wave [10]. This device houses two tiny electrodes inside the angioplasty balloon creating electric sparks which cause pressure waves. The system consists of a generator that carries electric charge and connects to a catheter with a connecting cable [11]. The catheter has a 12-mm balloon and comes in various diameters. The balloon has two lithotripsy emitters and generates an electric spark that is readily visible on device activation outside the body. The spark generates shockwaves that modify the calcium in the arterial wall allowing increased vessel compliance and ability to dilate the stent at lower pressures. In our case report, this resulted in lesion expansion and elimination of lesion and stent recoil (Figures 3 and 4) [9].

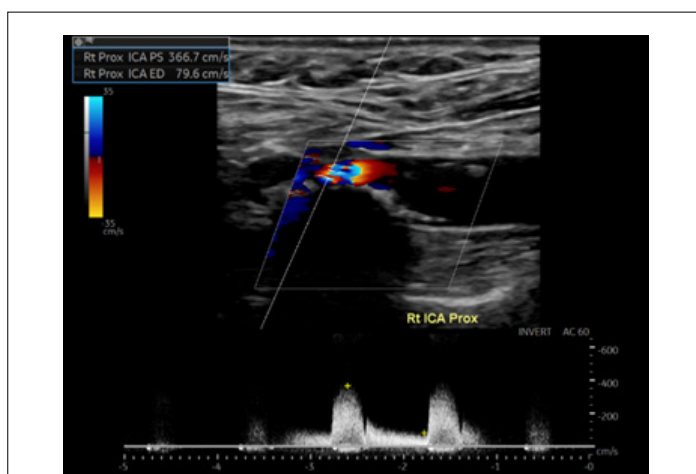


Figure 1: Carotid Doppler US before IVL showing severe shadowing distal to a severe stenosis due to calcification.

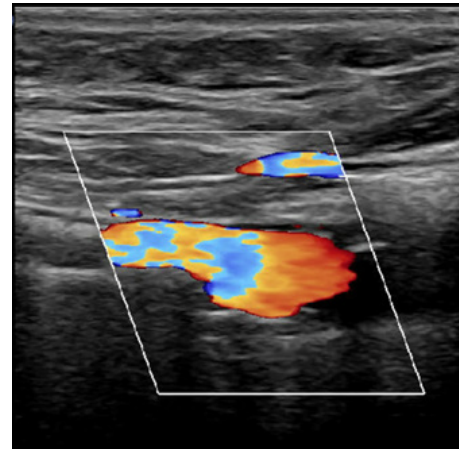


Figure 2: Post Intravascular Lithotripsy, the same lesion as in Figure 1 now has much modification of the severely calcified plaques resulting in much less shadowing and good stent expansion.

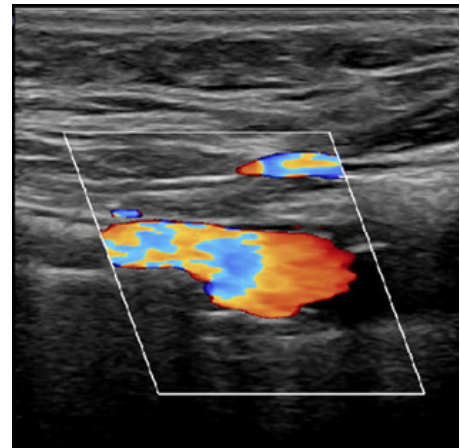


Figure 3: Intravascular lithotripsy balloon is in place at the site of poor carotid stent expansion and the severe calcified plaque is indicated by the dotted area.

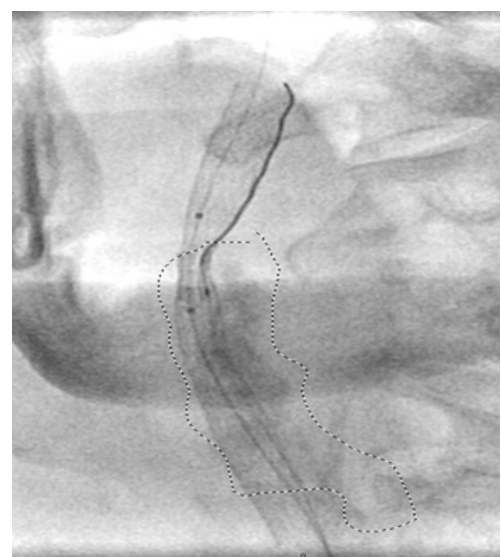


Figure 4: Well expanded Intravascular Lithotripsy balloon and the stent appear better expanded.

Recoil is a problem after balloon angioplasty alone in severely calcified lesions but may be seen in stented lesions as well [4,7,8]. However, if the hard-calcified plaques leading to lack of expansion and subsequent recoil could be shattered, the balloon and stent expansion would occur and recoil after balloon and stent treatment would be mitigated. In general, for under expanded stents, Shockwave lithotripsy is probably the best option because presence of previous stent is a relatively contraindication for other calcium removing procedures like rotational atherectomy or orbital atherectomy because of possibility of burr entrapment. In internal carotid circulation, atherectomy is not possible due to inherent micro embolization leading to strokes and TIAs.

IVL has been rarely applied in Carotid circulation but never in under expanded or recoiled fresh stents except for our case report [9,13,15]. As noted, endovascular intervention in our case report had failed due to lack of balloon expansion initially but later, the balloons did expand at the rated burst pressure [9]. Yet, severe lesion recoil was undermining the angiographic results and even two layers of X act stents were under expanded on angiography due to stent recoil until IVL was done. IVL solved the two problems of poor lesion expansion and vessel recoil by effectively modifying the calcified plaque [9]. The currently approved indications for IVL are limited to native vasculature. The previous literature except for our case report had focused on the ability of IVL to expand the lesions but not on the elimination of stent recoil that can be related to modification of the severe vascular calcification [7-9,13,15].

Our report and others' work illustrates the ability of shockwave lithotripsy balloon to treat severely calcified carotid stenosis that suffers from lack of dilation or elastic recoil even after two layers of fresh under expanded stents [9,13,15]. Carotid stenting can induce bradyarrhythmias and hypotension from carotid baroreceptor activation during balloon dilation and IVL does require prolonged balloon inflations, which theoretically could produce more hemodynamic changes during carotid IVL [13,15]. Also, prolonged follow up is limited in applications of IVL in carotid stent procedure. Hence, barring these limitation that can be addressed by further research, IVL can be useful in carotid stenting.

CONCLUSION

Severe calcification can compromise carotid stenting procedures due to difficulty in balloon dilation that is part of carotid stenting procedure. Hence, carotid stenting can be limited by severe calcification of the carotid stenosis site due to stent under expansion. Additionally, lesion recoil and carotid stent recoil can be worsened by severe lesion calcification. However, calcification can be modified by IVL making it easier for balloon expansion in otherwise undilatable lesions and also reduce the degree of recoil of the lesion site. Our recent case report along with other recent reports as referenced above indicate the success of IVL in facilitating carotid stenting procedures.

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