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Coronary Stent Fracture: A Recently Appreciated Phenomenon with Clinical Relevance

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Abstract: In the stent era, in addition to restenosis, there are many important consequences deserving more attention. Firstly described in peripheral vascular interventions, it took several years for stent fracture to be known as an appreciable complication of coronary intervention. Especially with the introduction of drug eluting stents and the use of coronary stents in more complex cases, its prevalence has raised and new data have been published concerning its mechanism, predictors, diagnosis, clinical course and treatments. This review will discuss the available literature about stent fracture.

Keywords: Coronary stent, percutaneous coronary intervention, stent fracture.

INTRODUCTION

The role of stents in the coronary interventions is changing: the first generation stainless steel bare metal stents (BMS) bailed out flow-limiting dissection and recoil and inadvertently proved to decrease restenosis, the "Achilles' heel" of PCI. After this honeymoon for intervention, the unresolved obstacle addressed through the development of the drug-eluting stent (DES). DES, by itself faced with the many new important phenomenon: Endothelial dysfunction, edge effect, malapposition, late and very late stent thrombosis.

Stent thrombosis and fracture albeit infrequent [1-5], are now recognized as important complications of stenting. These surprisingly interconnected complications seem to occur especially after the DES implantation. Despite its low prevalence, stent fracture may be one of the main causes of target vessel revascularization (TVR).

This article will review the various aspects of coronary stent fracture.

INCIDENCE

Although stent fracture is a common complication in the peripheral vascular interventions [1], it remained unrecognized in percutaneous coronary intervention (PCI) for a long period of time. The reported incidence of stent fracture ranges between 0.8 and 19% [2-4]. This firstly may be due to the asymptomatic nature of stent fracture. In addition, in reported series, coronary angiography was performed in 60-90% of cases during follow up, thus is liable to potentially miss some instances of stent fracture [1, 2, 4]. Another explanation is that some studies have included only complete stent fractures [6-8] and neglecting partial ones [2]. Selection of different populations may also have impact on the reported incidence of stent fracture insofar this complication is more common in high-risk groups. Shaikh *et al.* analysed 188 patients with restenosis and found a high incidence rate of SF (18.6% of the study population) [4]. Furthermore, it seems that stent fracture does not happen equally in the different types of stents, so the incidence is likely to change with different stent types [1-4].

Diagnostic modalities have different accuracy to detect SF. Some studies have combined fluoroscopy and ultrasound [2] or fluoroscopy and computer tomography [9], influencing the rate of SF. (See the "Diagnosis" section for further detail).

With regard to these possible explanations, it is not surprising to see a much greater incidence of SF (29%) in a post-mortem DES registry [6]. Chakravarty *et al.* in their meta-analysis, reported a mean stent fracture incidence of 4.9% [5] and posited that the incidence correlated with procedural (stent type, deployment method, etc.) and lesional (vessel characteristics, native vs. graft, etc.) factors as well as diagnostic methods.

PREDICTORS AND MECHANISMS

Stent fracture came into recognition with the advent of the DES [4]. According to published data, the incidence of stent fracture in the BMS is inconsiderable [3, 10] and limited to the saphenous vein graft (SVG) [11, 12]. Excluding the Kawai *et al.* report showing a nonsignificant difference with respect to stent fracture between the BMS and the DES (4.4% for the DES and 1.3% for the BMS, p value = 0,078) [13], the bulk of the evidences have shown statistically significant differences between the two major stent types [1-5]. It has been suggested that a greater neointimal proliferation in the BMS reduces the risk of fracture [14, 15] or /and less radio opacity renders the diagnosis of fracture more difficult [4]. Besides, in routine practice, the BMS is usually not de-

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ployed for long and complex lesions, which are regarded as predictors of stent fracture [16].

Amongst the various types of the DES, the sirolimus Stent (SES) is the main convict [1-5]. Although there are few investigations reporting equal frequencies of stent fracture in the different types of the DES [13], the majority of the available studies underscore a higher frequency of SF in SES [1-4]. Chakravarty *et al*. [5] and Chhatriwalla *et al*. [17] found that more than 95% of their stent fracture cases had occurred in the Cypher Stent, and Lee *et al*. in their analysis 3636 of Cypher Stents and 1162 Taxus Stents in 530 patients, reported a stent fracture prevalence of 1.9%, all in the Cypher Stents [1].

Several hypotheses have been proposed for this predilection. The interaction between stent and vessel geometry during stent implantation is considered the most important factor in the pathophysiology of SF. Stents change the vessel geometry, thus creating a new vessel angulation. This geometric distortion imposes a considerable mechanical force, increasing metal fatigue and finally the likelihood of stent fracture [4, 18]. In this context, stent flexibility which influences the vessel geometry appears to be directly related to fracture resistance. In DES group, the least flexible device undergoing bench testing for flexibility (Cypher) was the most susceptible to stent fracture [19]. Also, the fact that the SES enjoys relatively high radio opacity is believed to enhance the possibility of fracture diagnosis [3]. There is currently a paucity of data in the existing literature on the rate of stent fracture in the new generation of the DES [18]; nonetheless, the incidence appears to be lower [5, 18, 20]. A recent large consecutive series of everolimus-eluting stents demonstrated stent fracture in 2.9% of lesions [21]. In this report, fracture was evaluated angiographically, with only ~50% of patients having intravascular ultrasound evaluation (IVUS) and the analysis was performed at 6-9 months following stent deployment. Both the early time course for evaluation (6-9 months) and the use of IVUS in only ~50% would tend to underestimate the true prevalence of stent fracture in this population [21].

It should be noted that the flexibility/comformability and fracture resistance has been addressed in the design of new generation of stents. The new platinum chromium everolimus-eluting stent (PROMUS Element) with "a modified scaffold design" try to create a more flexible and fracture resistant stent [22, 23].

Apart from stent type some other stent characteristics play role in stent fracture. Longer stents are thought to be more vulnerable to fracture [2, 15, 17]. Doi *et al*. reported that in their two groups of patients, fracture was more frequent in the group with longer stents (45.2 ± 23.0 vs. 28.5 ± 14.9 mm, p value =0.0003) [15] and Park *et al*. found a similar difference in terms of the correlation between the stent length and stent fracture in their two patient groups (55.25 ± 22.26 mm vs. 40.07 ± 25/51 mm, p value =0.005) [18]. Radial force is believed to be more pronounced in longer stents, (not) least in the mid-part of the stent, and it increases metal fatigue and consequently the rate of fracture [4, 5, 18].

Overlapping stents by enhancing "axial stiffness" possibly increases the risk of stent fracture [1, 9, 24-26]. A 60% rate of fracture in overlapped stents was observed in one study [3], and elsewhere, higher frequencies of restenosis along with fracture were reported in overlapped stents [27]. Excessive pressure during stent deployment, balloon post-dilation and resultant damage to the stent strut has also been blamed for a rise in the risk of stent fracture [3, 7, 15, 18, 25, 28]. This notion was borne out by the Park *et al*. study, which found a higher maximal inflation pressure in the stent fracture group (13.42 ± 3.86 atm vs. 11.62 ± 3.39 atm, p value =0.015) [18].

The stent and balloon diameter [4, 16, 18, 24, 28], number of the implanted stents [18], residual post-stenting stenosis [18], smaller minimal lumen diameter, and greater acute gain and late loss [18, 29] are some other procedural predictors. Park *et al*. demonstrated a significant relation between the number of the implanted stents and stent fracture (2.17 ± 0.19 vs. 1.61 ± 0.91, p value =0.005) [18], and Kim *et al*. showed a higher incidence rate of stent fracture in lesions with smaller minimal lumen diameters before the procedure (0.38 ± 0.55 vs. 0.71 ± 0.46 mm, p value =0.04) and larger acute gain (2.28 ± 0.39 vs. 1.44 ± 0.60 mm, p value =0.001) and late loss (0.81 ± 0.49 vs. 0.42 ± 050 mm, p value =0.001) [29].

Although there have been a few reports showing no specific predilection for the location of stent fracture [1], the right coronary artery (RCA) appears to be favoured [1, 5, 18, 29, 30]. In a meta-analysis on stent fracture, the incidence rates of this complication in the RCA, left anterior descending artery (LAD), left circumflex artery (LCX), SVG, and left main artery were 56.4%, 30.4%, 10.9%, 1.7%, and smaller than 0.01%, respectively [5]. In another review of eleven studies, Lee *et al*. noticed that 54% of all fractures were reported in the RCA [3]. The higher rate of stent fracture in the RCA may be due to its tortuosity and sharp angularity, which increases metal fatigue during a cardiac cycle [2, 3, 18]. In their review, Lee *et al*. reported excessive tortuosity in most cases of stent fracture [3], and Shaikh *et al*. explained that tortuosity increased the flexion points during a cardiac cycle and consequently led to stent fracture [4]. Ino *et al*. having meticulously analyzed the hinge motion angle of vessels during systole and diastole, and concluded that a greater degree of motion induces a higher degree of metal fatigue [2]. Furthermore, they have reported that the degree of the hinge motion of the RCA was greater than that of the LAD or LCX (31.0 ± 3.º vs. 22.8 ± 4.9º) and stated that stenting changes the vessel angulation, thereby creating different mechanical forces which might increase metal fatigue. Different angulations have been proposed as measures of increased mechanical forces [8, 29, 31]. The mean measured angles in the Chang *et al*. study was 67º [26], which differed from that in the Shaikh *et al*. study (≥75°) [4] and the one in the Yang *et al*. and Umeda *et al*. studies (≥ 45°) [8, 31]. Researchers believe that the higher incidence of stent fracture in the SVG stems from the same mechanism [7].

Halwani *et al*. in their detailed study, showed that the calcification of plaque increases the risk of stent fracture [32]. In addition, ostial [33] and bifurcation lesions [28] are reported as the predictors of stent fracture.

Whereas a number of studies have reached the conclusion that patient-related predictors and coronary artery dis-

ease risk factors do not increase the risk of stent fracture [4, 5], Park *et al*. demonstrated that hypertension and chronic kidney disease were correlated with stent fracture [18].

In a meta-analysis on stent fracture, overlapping stents, stent length, and stenting in the RCA were the only significant predictors of this complication [5]. Elsewhere, after a multivariate analysis, Park *et al*. found that stent length, use of the SES, minimum stent diameter, and maximal inflation pressure were the only significant predictors of stent fracture [30]. And finally, Kuramitsu *et al*. who analyzed SF in a new generation of DES (everolimus-eluting stent), found ostial lesion and lesions with hinge motion, tortuosity, or calcification as independent predictors of SF [21].

CLASSIFICATION

Diagnostic modalities have helped devise different classifications for stent fracture over the years [1, 25, 29-31]. In the fluoroscopic classification, stent fracture is graded with regard to the number of the fractured struts seen during angiography: single strut fracture as type I; ≥2 strut fracture as type II; ≥2 strut fracture with deformation as type III; fracture with transection but no gap as type IV; and fracture with a gap within as type V [6, 34].

Park *et al*. reported the incidence of stent fracture in the above-mentioned types as follows: 50% type I; 7.7% type II; 38.4% type III; 3.9% type IV; and 0% type V [18]. Nakazawa *et al*. in their thorough assessment, showed that most stent fractures were types I, II, and III [6]. Also in the report of Kuramitsu *et al*. 97 % of SF in the everolimus-eluting stent were classified as type II and III [21]. There are also other classifications for the grading of stent fracture, which are on the basis of intravascular ultrasound (IVUS) [35] or computed tomography (CT) scan [28].

CLINICAL PRESENTATION

Doi *et al*. observed equal frequencies of stent fracture at one year and a year after stent implantation [15], but some reported series, regarded stent fracture as a late stent failure phenomenon. They stated that the incidence of stent fracture has been directly correlated with time duration from stent deployment and explained that geometry distortion of the vessel wall is more pronounced with time. Surprisingly, the one year comparison of the two different stent platforms (platinum chromium vs. cobalt chromium) with regard to flexibility in PLATINUM Trial, showed no significant differences [22], but the two year analysis of the trial were in favour of the more flexible one (platinum chromium) [23]. The possible explanation could be that SF was more pronounced after one year of stent implantation.

Stent fracture is usually associated with binary restenosis, thrombosis, aneurysm, embolization, ischemic events, and target lesion revascularization (TLR) and could thereby increase morbidity and mortality [3].

Several studies have reported a rise in in-stent restenosis (ISR) in tandem with stent fracture [4, 7, 31], in a wide range of 10-90 % [16, 28]. It has been hypothesised that stent fracture renders local drug delivery at the stent site uneven and impaired [7, 8]. In contrast, Halkin *et al*. reported that in their series, stent fracture usually occurred long after drug delivery had been terminated and that ISR could not have been caused by the proposed mechanism [36].

Is this type of restenosis significantly harmful? Chakravarty *et al*. in their meta-analysis, concluded that as much as stent fracture could be asymptomatic, the probability of ISR and TVR exhibited an upward trend amongst the reviewed studies [5]. Ino *et al*. also reported that ISR and TVR after stent fracture were not allied to major adverse cardiac events (MACE) [2]. Lee *et al*. reported that their cases of ISR were focal and limited to stent fracture types III and IV, half of them asymptomatic, and that there were no cardiac deaths [37]. Park *et al*. also showed a greater incidence of binary restenosis in their group of patients with stent fracture (one patient with stent fracture presented with non ST-elevation myocardial infarction [NSTEMI]), but there was no difference in terms of clinical manifestation between patients with or without stent fracture [18]. In contrast, other investigations have suggested that stent fracture could be potentially harmful [17]. Chhatriwalla *et al*. reported a 6% incidence rate of STEMI and 42% of NSTEMI in their stent fracture population [17], and Nakasawa *et al*. reported that all their cases of fatal stent fracture were in stage V [6], although there was a low risk of adverse events with low-grade stent fracture.

Aneurysm is more common with complete stent fracture, and a combination of stent fracture and aneurysm is normally expected to happen one year after stenting [15]. And finally, stent thrombosis, albeit apparently uncommon [1, 6], has also been proposed as a complication of stent fracture [3, 6, 17, 38]. Thrombosis by SF can be seen at any time, and was reported as a risk factor for late stent thrombosis. It has been suggested that direct contact of free metal to luminal surface can cause platelet activation [39].

Kuramitsu *et al*. also reported an increased risk of TLR and MI caused by SF following everolimus- eluting stent implantation (5.1% versus 0.4%; P=0.018 and 25.6% versus 2.0%; P<0.001, in SF and non-SF group respectively) [21]. Stent thrombosis was also more common in the SF group than in the non-SF group (5.1% versus 0.4%; P=0.018) [21].

DIAGNOSIS

The existing literature abounds with imaging modalities suggested for optimal diagnosis of stent fracture. Most of the relevant studies have utilized fluoroscopy with or without contrast injection: while some maintain it as the best possible way to diagnose stent fracture [40] (Fig. **1**), others urge that complimentary modalities be drawn upon [37, 41]. Ino *et al*. argued that some cases of stent fracture were only detected by plain fluoroscopy and that contrast injection might mask them [2].

Some innovative designs have increased the accuracy of flouroscopic diagnosis. One of these novel methods is Stent Boost (StentBoost Substract, Phillips Healthcare, Best, Netherlands), which employs a marker balloon to detect stent fracture [42].

IVUS has enjoyed a rise in its use for the diagnosis of stent fracture in recent years. As opposed to a limited number of studies reporting a low diagnostic yield [43], the majorities have acknowledged the efficacy of IVUS as a diag-

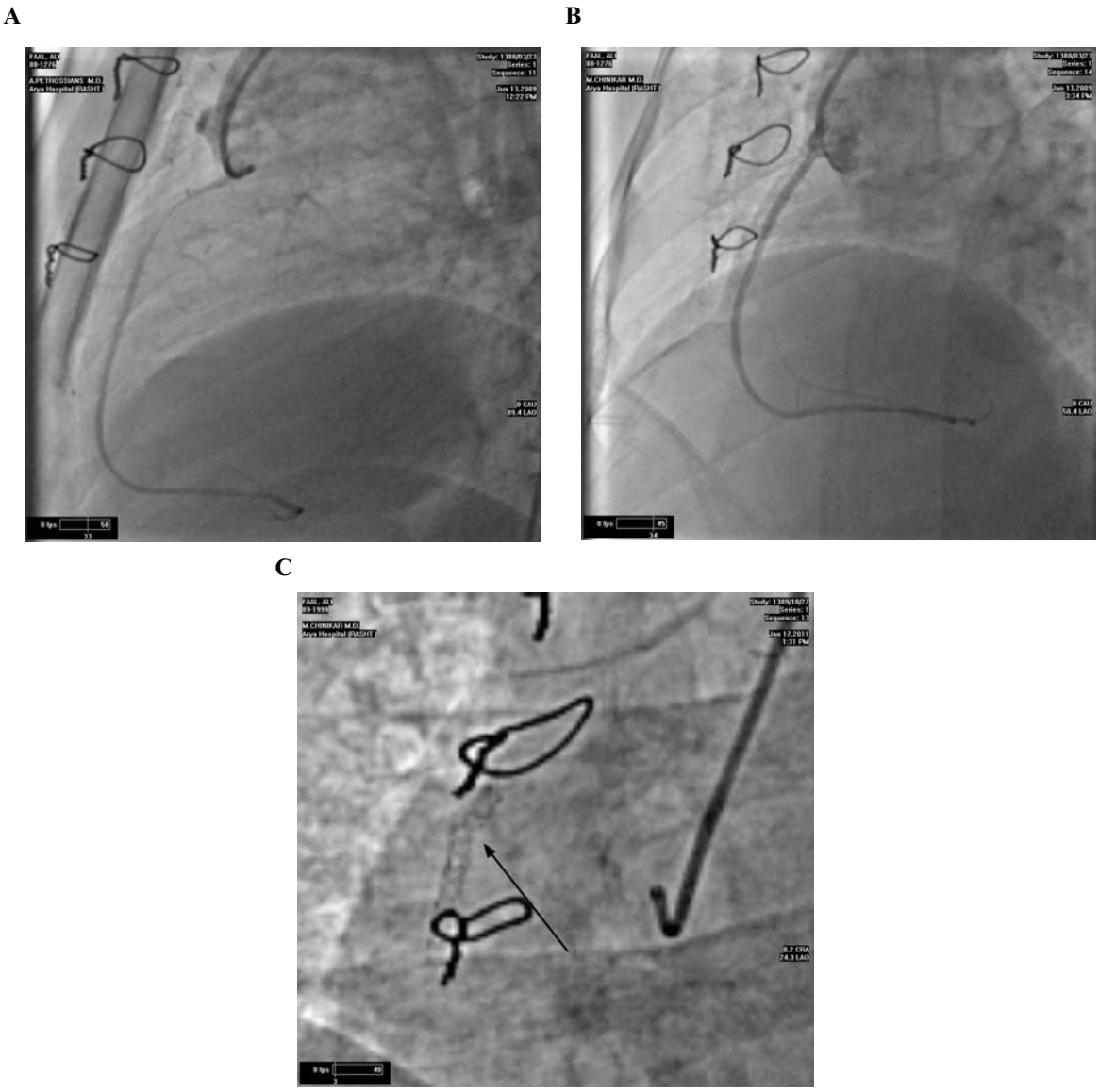

Fig. (1). Percutaneous coronary intervention was performed on a saphenous vein graft lesion (**A**). A Cypher stent was deployed with apparently satisfactory result (**B**). Nine months later, the patient hospitalized for an episode of acute coronary syndrome. Stent fracture was detected on fluoroscopy at the proximal third of the stent (**C**).

nostic modality and even proposed stent fracture classification based on it [1, 5]. Yamada *et al*. showed that IVUS was more reliable than angiography [44] and posited that the high ability of the metallic strut for the reflection of ultrasound must be the reason for the superiority of IVUS.

Multislice CT scan is another diagnostic modality in the medical armamentarium for the detection of stent fracture [28, 43, 45-47]. All the studies using CT scan for diagnosis have underlined its high accuracy in comparison with angiography [43, 45]. Pang *et al*. reported an overall accuracy, sensitivity, and specificity of 84.1%, 80.7%, and 100%, respectively, for CT scan compared to 73.9%, 77.2%, and 58.3%, respectively, for conventional angiography [43].

Finally, optical coherence imaging has also been reported as a diagnostic modality for revealing stent fracture [38].

A review of the literature on a comparison between the different modalities for diagnosis of stent fracture yields the following observations. Pang *et al*. compared 64-slice CT scan, conventional angiography, and IVUS and the result was superiority of CT scan [43]. Hecht *et al*. asserted that CT scan and IVUS were both highly valuable for detecting stent gap [28]; an important determinant for ISR, stent fracture, and overlap failure, so considering the noninvasiveness of CT scan, it could be a valuable modality for diagnosis and prognosis.

TREATMENT

There is no consensus for treatment of stent fracture. Many consider stent fracture benign and usually asymptomatic, accompanied by a negligible incidence rate of cardiac events and, therefore, advocate only the continuation of antiplatelet therapy [37], while others opt for treatment and apparently 1-2% of TVR procedures are undertaken for lesions with stent fracture [18]. Lee and coworkers in their study conclude that if patients with SF continued the dual anti-

platelet therapy irrespective of symptoms, a low MACE would occur [37]. Sianos *et al*. report an immediate symptom relief following re-stenting in lesion with SF [24]. Park *et al.* in their series of SF only treated patients with SF who were complicated by ISR and a decreased fractional flow reserve [18]. Other patients in their series were only followed and they had an excellent clinical course.

As far we know, stent fracture could result in ISR. There are three approaches regarding stent fracture with ISR. Some tend to leave asymptomatic ISR without treatment and reserve intervention for symptomatic ISR [25]. Others choose to treat stent fracture with ISR irrespective of symptoms [37]. Lee *et al*. presented an algorithm for the treatment of stent fracture [37]. They proposed the continuation of antiplatelet therapy regardless of ischemic symptoms and suggested intervention for the following patients: a) symptomatic or asymptomatic ISR with > 70% stenosis and b) symptomatic ISR with 50-70% stenosis, which shows positive results in physiological stress test with or without IVUS. Balloon-only, BMS, and DES have all been applied for the treatment of stent fracture; the usage of the DES, however, seems to be more reasonable. Of note some studies have suggested the use of Paclitaxel-eluting stents in the SES fracture [25].

CONCLUSION

Since its first case report in 2004 [24], stent fracture has gradually been recognized as an important complication of coronary stenting. Stent fracture may have a low overall clinical incidence and benign course, but under no circumstances should underestimate its potential consequences. Usage of the SES, length of the stent, and stenting of the RCA are amongst the major contributors. Stent fracture is usually diagnosed during fluoroscopy, but CT scan and IVUS seems to have more advantages in the detection of this complication.

For all the research conducted thus far, there is still no consensus about the treatment of stent fracture; nevertheless, the DES has conferred favourable results in symptomatic lesions.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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