

Clinical Profile and Intervention Strategies for Resistant Coronary Lesions: A Cross-Sectional Study

Profil Clinique et Stratégies d'Intervention pour les Lésions Coronariennes Résistantes: Une Étude Transversale

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ABSTRACT

Introduction: Coronary artery disease (CAD) presents significant challenges across various age groups, often resulting in complex coronary lesions that are resistant to conventional treatment approaches. However, data on resistant coronary lesions in this demographic are limited.

Aim: To investigate the population characteristics and protocol for managing patients with resistant coronary lesions.

Methods: This retrospective cross-sectional study included 56 patients of all ages admitted to the cardiology department at the Farhat Hached University Hospital in Sousse between January 2020 and August 2023. Data collection was performed at the patient's bedside by a medical intern, followed by physical examination and blood sampling. Demographic characteristics, cardiovascular risk factors, and treatment modalities for resistant lesions were evaluated.

Results: Fifty-six participants aged 44 to 84 years were included in the study. A male predominance was observed (66.0%), with a mean age of 68.7 years. Diabetes (66.0%) and hypertension (80.3%) were the most frequently encountered risk factors, with a higher prevalence in men. Symptom onset was more common in individuals over 65 years old. Angina was the primary reason for consultation, with a predominance of coronary syndromes without ST-segment elevation. The majority of resistant lesions were monotoncular (73%), primarily located in the middle left anterior descending artery. Treatment techniques included the use of modified balloons (44.9%) and ablative techniques (52.1%), with high success rates respectively (84%) and (100%).

Conclusions: This study highlights the importance of cardiovascular risk factors in individuals with resistant coronary lesions and underscores the effectiveness of intervention techniques for treating them in this population.

Key words: Calcified coronary lesions, Rotational atherectomy, OPN balloon

RÉSUMÉ

Introduction: La maladie coronarienne (MC) pose des défis importants à différents groupes d'âge, entraînant souvent des lésions coronariennes complexes résistantes aux traitements conventionnels. Cependant, les données sur les lésions coronariennes résistantes sont limitées.

Objectif: Examiner les caractéristiques de la population et la prise en charge de cette population.

Méthodes: Une étude retrospective transversale incluant des patients de tous âges admis au service de cardiologie de l'hôpital universitaire Farhat Hached à Sousse entre janvier 2020 et août 2023. Les caractéristiques démographiques, les facteurs de risque cardiovasculaire et les modalités de traitement des lésions résistantes ont été évalués.

Résultats : Une prédominance masculine a été observée (66,0 %), avec un âge moyen de 68,7 ans. Le diabète (66,0 %) et l'hypertension (80,3 %) étaient les facteurs de risque les plus fréquemment rencontrés, avec une prévalence plus élevée chez les hommes. Le début des symptômes était plus fréquent chez les individus de plus de 65 ans. L'angine était la principale raison de consultation, avec une prédominance de syndromes coronariens sans élévation du segment ST. La majorité des lésions résistantes étaient monotonculaires (73 %), principalement situées dans la coronaire interventriculaire antérieure moyenne gauche. Les techniques de traitement comprenaient l'utilisation de ballons modifiés (44,9 %) et des techniques ablatives (52,17 %), avec un taux de succès élevé respectivement à (84 %) et (100%).

Conclusions: Cette étude met en évidence l'importance des facteurs de risque cardiovasculaire chez les personnes présentant des lésions coronariennes résistantes et souligne l'efficacité des techniques d'intervention pour les traiter dans cette population.

Mots clés: Lésions coronaires calcifiées, Athérectomie rotationnelle, Ballon OPN

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INTRODUCTION

Calcification of coronary arteries poses a significant challenge in interventional cardiology, affecting a substantial proportion of patients undergoing percutaneous coronary intervention (PCI) (1). With an aging population and rising comorbidities like diabetes and chronic kidney disease, the prevalence of calcified lesions is increasing (1,2). These lesions not only diminish the success rates of PCI but also heighten the risks of stent under-expansion, intrastent restenosis, and procedural complications (1,3). Moreover, their association with atherosclerosis underscores their predictive value for adverse cardiac events, even in asymptomatic individuals (3,4). Accurate diagnosis and effective management of calcified lesions are crucial for optimizing patient outcomes (2). Utilizing advanced imaging techniques like computed tomography (CT), coronary angiography, intravascular ultrasound (IVUS), and optical coherence tomography (OCT) enables precise lesion characterization and treatment planning (5). Integration of various diagnostic and therapeutic modalities is paramount for tailored patient care. In this article, we delve into the diagnostic strategies and treatment modalities for calcified coronary artery lesions, drawing insights from contemporary literature and our institutional experience.

METHODS

Our study is a retrospective cross-sectional analysis. We collected data from 56 patients of all ages who were hospitalized in the cardiology department at the Farhat Hached University Hospital in Sousse between January 2020 and August 2023. These patients were referred from outpatient cardiology clinics or the emergency department due to thoracic pain. They underwent diagnostic coronary angiography, revealing calcified coronary lesions resistant to treatment.

Inclusion Criteria

+Patients with chest pain and diagnostic coronary angiography showing calcified coronary lesions including de novo and intra-stent cases.
+The study included patients who underwent specialized percutaneous interventions for resistant lesions.

Exclusion Criteria

Incomplete data and poor record quality. Patients with non-calcified atherosclerotic lesions or those who refused coronary angioplasty were also excluded.

Study Protocol

In our study, data collection was conducted bedside by a medical intern following a physical examination and blood sampling. Subsequently, angiographic exploration and angioplasty were carried out by an experienced team of cardiologists in the cardiac catheterization

laboratory. Anamnesis for each participant included gathering information on gender, date and place of birth, personal medical history (such as angina, myocardial infarction, hypertension, and diabetes mellitus), family medical history (including cardiovascular diseases and diabetes mellitus), lifestyle habits (specifically tobacco consumption), and any functional signs like chest pain or dyspnea.

Physical measurements involved recording systolic and diastolic blood pressure levels in the morning from fasting individuals, along with anthropometric measurements such as weight, height, and waist circumference. Biological exploration encompassed a comprehensive biochemical profile, including measurements of total cholesterol, high-density lipoprotein cholesterol, triglycerides, and glucose levels. Blood samples were collected under fasting conditions and processed promptly in the laboratory.

Definitions used in our study included criteria for diabetes mellitus, hypertension, dyslipidemia, abdominal obesity, and smoking, which were based on established clinical guidelines and criteria.

In this study, calcium severity was defined based on angiographic assessment and was classified according to previous classifications (6,7). Calcium severity was categorized as follows:

- Mild: Presence of small, scattered calcifications without significant obstruction.
- Moderate: More extensive calcifications causing partial luminal narrowing or difficulty in balloon expansion.
- Severe: Extensive, dense calcifications leading to significant luminal narrowing or requiring advanced intervention techniques.

The angiographic exploration involved the utilization of both radial arterial and femoral approaches for coronary angiography. Lesion characteristics and severity were assessed, including the location and distribution of calcified coronary lesions, as well as the extent of coronary involvement.

The Judgment criteria of our study are :

- Prevalence of CVRF (cardiovascular risk factors) distribution in the studied population.
- Techniques used in resistant lesions and success rates with each technique

Statistical analysis of the collected data was performed using SPSS 18.0 software, employing various tests such as Pearson's chi-squared test, Fisher's test, and Student's t-test. Additionally, regression analyses were conducted to estimate independent predictive values of the parameters.

The objectives of our study encompassed a comprehensive review of diagnostic methods for resistant coronary lesions and a detailed description of plaque-modifying tools used in lesion preparation before stenting, with a comparative analysis against existing literature.

RÉSULTS

Epidémiologic, clinical and échographic characteristics of the study population

The demographic profile of the study population, comprising 56 individuals aged between 44 and 84 years, revealed a slight male predominance, with 66.0% being male and 33.9% female. Regarding age distribution, the mean age was 68.7 years, with the majority of individuals (67.8%) being over 65 years old. Although women tended to be older on average, this age difference between genders was not statistically significant.

Analysis of various cardiovascular risk factors indicated a noteworthy prevalence of diabetes, affecting 66.07% of the population, with a slight male predominance (59.4%). Hypertension was highly prevalent, observed in 80.35% of individuals, with a significant male bias (60%) and particularly prevalent among those over 65 years old (68.8%).

Tobacco use was prevalent in 62.5% of patients, with a significant predominance among males (94.2%) and a higher prevalence in individuals over 65 years old (62.8%). Obesity, defined as BMI ≥ 30 kg/m², was present in 26.7% of patients, with a notable predominance among females. A sedentary lifestyle and stress were observed in 62.5% of patients, with a higher prevalence among males and a concentration among individuals over 65 years old. Similarly, coronary heredity was present in 44.6% of patients, with a male predominance and a concentration among individuals over 65 years old.

Dyslipidemia affected 78.5% of patients, with a slight male predominance and a higher prevalence among individuals over 65 years old. Pre-existing coronary artery disease was prevalent in 67.8% of patients, primarily treated with coronary angioplasty (63.1%).

Clinical presentation (Table 1)

Angina pain emerged as the primary symptom prompting consultation. A predominance of coronary syndromes without ST segment elevation was most commonly observed, accounting for 31 cases (55.3% of patients presenting with pain), with a significance level of $p=0.002$.

Table 1. Different clinical presentation of enrolled patients.

	Staff	Pourcentage
CCS	20	35,7%
NSTE	31	55,4%
STEMI	5	8,9%
Total	56	100%

CCS: Chronic coronary syndrome, NSTE: Acute coronary syndrome without ST elevation, STEMI: acute coronary syndrome with ST segment elevation.

Diagnostic Methods of Resistant Lesion

The diagnosis of resistant lesions was primarily conducted through coronary angiography alone in 55 patients, accounting for 98.2% of cases, with only one patient diagnosed by coronary CT angiography followed

by coronary angiography (1.8%).

Characteristics of Resistant Lesion

Localization of the Lesion (table 2)

In our study, there was a predominance of patients with monotroncular lesions (excluding the Left Main Coronary Artery) observed in 41 patients, constituting 73% of the total population, with a p-value of less than 0.001. Additionally, 6 patients exhibited bitroncular lesions (10.3%), and 9 patients had lesions including the Left Main Coronary Artery (16.1%).

Table 2. Lesion localization in enrolled patients.

	Staff	Pourcentage
Monotroncular	41	73,2%
Bitroncular	6	10,7%
Main left lesion	9	16,1%
Total	56	100%

Nature of the lesion (table 3)

The total number of lesions amounted to 69 observed within the 56 patients included in this study. Among these 69 resistant lesions, 55 cases were native lesions (79.7%), while 14 cases were intrastent restenoses (20.2%), indicating a significant difference with a p-value of 0.001.

Table 3. Nature of the lesion of enrolled patients.

	Staff	Pourcentage
Native calcified lesion	55	79,7%
intra stent Restenosis	14	20,3%
Total	69	100%

Treatment Techniques

*Types of Techniques Used:

Several techniques were employed to treat the different resistant lesions. Notably, modified balloon-based methods were utilized in 31 cases (44.9%), including GRIP TT[®] TM and OPN[®] TM balloons. Other treatment modalities included ablative techniques in 36 lesions (52.2%), primarily using Rotablator. Additionally, in two cases (2.9%), a combination of treatment techniques was employed.

We note that 13 lesions are treated with GRIP TT[®] TM. This technique was used for 7 native lesions and 6 in-stent restenoses, with no significant difference.

We note that 18 lesions are treated with OPN NC[®] TM balloon. Regarding the type of lesion, a predominance of native lesions was observed, with 13 cases.

Success rates were with respectively for Modified ballon techniques (84%) and (100%) for Ablative technique.

Table 4. different resistant lesion techniques used in enrolled patients.

	Staff	Pourcentage
Modified ballon only	31	44,9%
Ablative technique only (ROTA)	36	52,2%
Association	2	2,9%
Total	69	100

DISCUSSION

Pathogenesis of Coronary Calcifications and Epidemiology and Risk Factors

The pathogenesis of coronary artery calcification (CAC) involves complex interactions between phosphate and calcium metabolism, leading to the formation of hydroxyapatite deposits within the arterial wall. Risk factors such as aging, diabetes, hypertension, dyslipidemia, and renal dysfunction contribute to the development and progression of CAC. (8–10) Studies have shown that patients with chronic kidney disease, particularly those requiring hemodialysis, exhibit more extensive calcification in coronary lesions (8). Hypercalcemia, hyperphosphatemia, and secondary hyperparathyroidism further exacerbate CAC formation (11). Additionally, genetic factors, and microRNA dysregulation play roles in promoting vascular smooth muscle cell transformation into an osteoblast-like phenotype. Despite a lack of association between dietary calcium intake and CAC, age, male sex, and Caucasian ethnicity remain significant predictors of CAC prevalence and severity. Understanding these pathophysiological mechanisms is crucial for developing effective therapeutic strategies.

The risk factor analysis in our series aligns with existing literature. CAC predominates in males (66%), with a peak age above 65 years (67.8%). Diabetes is found in 66.07% of patients, hypertension in 80.35%, tobacco use in 62.5%, and dyslipidemia in 78% of patients.

Imaging techniques

Tomodensitométrie (CT) is the sole non-invasive test with high sensitivity and specificity for detecting and quantifying calcium in coronary lesions (12). Large-scale observational CT studies have established calcium scores, providing prognostic value in predicting ischemic cardiac death [(13,14)] The latest American College of Cardiology study indicates that non-invasive measurement of coronary artery calcium (CAC) scores is reasonable for cardiovascular risk assessment in asymptomatic intermediate-risk patients (15). As the CAC score increases, it loses sensitivity and gains specificity in predicting coronary artery disease.

Angiography has low to moderate sensitivity compared to IVUS and CT for detecting CAC but is highly specific. Angiographic CAC is often classified into three groups: none/mild, moderate, and severe. The accuracy of coronary angiography in identifying high calcium content

is suboptimal, particularly in cases of in-stent restenosis. A pivotal study by Mintz et al. showed that coronary angiography identified calcium in only 38% of cases, with detection appearing to depend on the degree of calcification arc (60% for moderate calcifications and 85% for severe calcifications). (9)

Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are the two main intravascular imaging modalities (16,17) Since calcium causes reflection of ultrasound, coronary artery calcification (CAC) typically appears on an intravascular ultrasound (IVUS) image as a hyper-echoic arc combined with a deeper acoustic shadow cone.

IVUS has a sensitivity of 90% and a specificity of 100% for identifying calcified plaques, with calcium arc >180° predicting stent under-expansion.

Compared to IVUS, optical coherence tomography (OCT) has a 10 times higher image resolution and is capable of remarkably characterizing individual structures of the coronary wall, plaque composition (presence or absence of thrombus, calcium, dissections, etc.), and proper stent placement, for example, identifying edge dissection or malapposition/underexpansion. However, identifying calcium on OCT is challenging in cases of non-homogeneous plaques (fibro-lipid-calcific) and if the calcium deposit is deep or under a lipid or necrotic core. Despite these limitations, OCT appears to be more precise than IVUS for defining calcium burden, as it provides additional measurable parameters beyond the degree of calcific arc, such as calcific surface, thickness, length, and three-dimensional volume (18,19).

Concerning our study, it is noteworthy that the diagnosis of coronary artery calcification (CAC) was primarily made using coronary angiography (55 out of 56 patients), with only one case where tomography was followed by coronary angiography. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) were not utilized despite their undeniable diagnostic contribution.

Treatment techniques

The available techniques for treating coronary artery calcification (CAC) can be classified into two groups: ablation techniques and balloon-based techniques. The first group includes rotational atherectomy (AR), orbital atherectomy (AO), and excimer laser; these techniques theoretically ablate calcium to promote stent expansion (20–22). Balloon-based techniques do not eliminate calcium but aim to increase plaque elasticity and allow stent expansion by fracturing the calcified component at one or more sites (23).

Lithoplasty is the latest balloon-based technology available for treating coronary artery calcium (CAC). The system consists of a semi-compliant balloon equipped with two emitters placed both proximally and distally, generating shock waves (1 per second) propagating through the coronary wall, fracturing the calcium within the coronary artery while minimally interacting with the adventitia. It is a highly effective technique for lesion preparation before stent implantation, combined with ease of use. Balloon-based techniques include cutting balloons (CB)

and scoring balloons (SB), offering controlled lesion dilation and incisions in calcified plaques, respectively (24,25). High-pressure non-compliant balloons (HPNB), like OPN® TM, are used for lesion preparation and stent post-dilation, especially in challenging cases (26).

In our study, unlike what is commonly reported in the literature where the use of modified balloons is less frequent, this technique was notably present in 44.9% of patients using OPN® TM and GRIP TT® TM type balloons, with a high success rate both in native lesions and in in-stent restenosis (27). Optimal AR success factors include calcific eccentricity, arterial lumen size, burr size, and guide wire bias (28).

AR complications such as burr entrapment, dissection, and perforation can be minimized by optimal manipulation (29). AR may still be the only available technique for non-crossable calcific lesions, but clinical trials have not consistently shown long-term benefits (30). For instance, the ROTAXUS trial comparing AR + DES versus standard DES angioplasty in moderately to severely calcified lesions found AR associated with immediate luminal gain but greater late in-stent luminal loss (at 9 months) with neutral effect on restenosis (31). Another trial, PREPARE-CALC, found AR superior in procedural success compared to modified balloon strategy and not associated with excessive late lumen loss at 9 months (32). However, interpretation is debatable due to lack of precise clinical criteria and reliance on angiography alone for calcification severity assessment.

In our study, rotational atherectomy was the sole ablative technique used, comprising 36 lesions (52.1% of total lesions). It was preferentially used for non-crossable native lesions, proximal lesions, and moderately tortuous lesions, with a remarkable 100% success rate.

Uncrossable lesions remain the main limitation of lithoplasty, and it has been proposed that combining the lithoplasty balloon with atherectomy (AR) could allow for superior lesion preparation. (33,34)

In contrast to the literature, our study employed a combination of RA and OPN® TM balloon in two cases of in-stent restenosis, resulting in procedural success.

Study limitations:

Our study represents a pioneering effort in exploring the diagnosis and management of coronary artery calcification (CAC), offering valuable insights into interventional cardiology. It underscores the importance of long-term patient monitoring and suggests the establishment of a national CAC registry. However, limitations such as a relatively small sample size and the unavailability of intracoronary imaging techniques hindered comprehensive analysis and comparison with existing literature, rendering our findings primarily observational. Additionally, the absence of certain therapeutic procedures, like lithotripsy and atherectomy, due to their recent adoption globally and high cost within the community, highlights the need for further research and resource accessibility to optimize CAC management strategies.

CONCLUSION

In summary, our study underscores the significance of cardiovascular risk factors in individuals with resistant coronary lesions. We observed a predominance of males, with diabetes and hypertension being prevalent risk factors. The majority of lesions were monotoncular, mainly in the middle left anterior descending artery. Despite these challenges, intervention techniques such as modified balloons and ablative procedures yielded a high success rate. Moving forward, a tailored, multifaceted approach is crucial for optimizing outcomes in this vulnerable population. While our study has limitations, further research is warranted to validate our findings and refine therapeutic strategies for resistant coronary lesions.

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