INTRODUCTION

Percutaneous coronary intervention (PCI) technology continues to advance, and the use of coronary artery stents is the treatment of choice for significant coronary lesions, their use resulted in better outcomes than those produced by balloon angioplasty alone and lower rates of complications peri- and post-procedural (1). The introduction of coronary artery stents has greatly decreased the mortality and the necessity of

ORIGINAL PAPER

BARE METAL STENTS SIZE: CORRELATIONS WITH CORONARY STENT RESTENOSIS

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SUMMARY

Introduction: The coronary stents use for the ischemic heart diseases interventional treatment, has decreased the incidence of postprocedural complications compared to the classic balloon angioplasty. Knowledge of technical factors associated with subsequent risk of angiographic recurrences can guide the strategy for selection of the patients and the type of stent to be implanted.

Methodology: The aim of this study is to identify the technical characteristics of “bare metal” stents made of cobalt chrome alloy or stainless steel which are associated with a higher risk of restenosis during the first year after implantation. A total number of 808 coronary stent segments were angiographically analyzed, 472 (58.42%) of them presenting imaging criteria of restenosis. It was evaluated the relationship between the size of implanted stents (combination diameter / length) and the presence of restenosis at control angiography.

Results: The obtained data show that the use of stents with a diameter ≤ 2.5 mm and length 15-28 mm or stents with small diameter (≤ 2.5 mm), average diameter (2.5 to 3.25 mm) and long length (> 28 mm) is significantly associated with restenosis after stenting (p < 0.001).

Conclusions: Decreasing the diameter of the implanted stent or increasing the length of metallic material at the level of vascular wall is associated with a higher risk of clinical and imagistic recurrence. Clinical follow-up of these patients is required to be more frequent.

Abbreviations: BMS: bare metal stent, DES: drug eluting stent, OD: odd ratio, PCI: percutaneous coronary intervention

Key words: stent diameter, stent length, in-stent restenosis

RéSUMÉ

Dimension des stents “en métal nu”: corrélations avec la resténose du stent coronarien

Introduction: L’utilisation de stents coronariens dans le traitement interventionnel de la cardiopathie ischémique a diminué l’incidence des complications post-procédurales par rapport à l’angioplastie classique à ballonnet. La connaissance des facteurs techniques associés au risque subséquent de récidive angiographique peut guider la stratégie de sélection des patients et le type de stent à implanter.

Méthodologie: Le but de cette étude est d’identifier les caractéristiques techniques des stents «en métal nu» en alliage de chrome cobalt ou en acier inoxydable qui sont associés à un risque plus élevé de resténose au cours de la première année suivant l’implantation. Un nombre total de 808 segments de stent coronaire ont été analysés angiographiquement, 472 (58,42%) d’entre eux présentant des critères d’imagerie de resténose. On a étudié la relation entre la taille des stents implantés (diamètre / longueur de la combinaison) et la présence de resténose à l’angiographie témoin.

Résultats: Les résultats de l’étude montrent que l’utilisation d’endoprothèses ayant un diamètre ≤ 2,5 mm et une longueur de 15-28 mm, ou des petits diamètre (≤ 2,5 mm), un diamètre moyen (2,5 à 3,25 mm) et une longue longueur (> 28 mm) Sont significativement associés à une resténose après stent (p < 0,001).

Conclusions: La diminution du diamètre du stent implanté ou l’augmentation de la longueur du matériau métallique au niveau de la paroi vasculaire est associée à un risque plus élevé de récidive clinique et imagiologique. Le suivi clinique de ces patients doit être plus fréquent.

Mots-clés: diamètre du stent, longueur du stent, resténose intra-stent

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emergent coronary artery bypass grafting below 1% (2). Moreover, continuous development and technological progress in PCI industry in recent decades allowed many improvements in stent design and delivery system including low profile, increased radial force, flexibility which promoted more frequent use of stents in the treatment of coronary artery disease. Instead, the presence of metallic material in the coronary artery vessel wall triggers a cascade of physiological events, in response to the permanent presence of "foreign body", which led to the description of a new pathology called "restenosis in stent". Risk factors that may influence the development of restenosis after stent implantation are multiple and variable depending on the type of stent, morphology of coronary lesions, certain clinical or periprocedural parameters (3). Knowledge of clinical and angiographic variables, genetic factors or significant technical shortcomings that are correlated with risk of restenosis may help to guide selection of patients and to identify optimal type of stent to be implanted. The presented study aims to analyze the relationship between the size (stent diameter related to its length) of the "bare metal" stents (BMS) and the risk of restenosis in the first year after stent placement.

**Material and Methods**

The study was conducted in the Department of Interventional Cardiology of Army’s Center for Cardiovascular Disease "Academician Vasile Cândea" Bucharest on a group of patients who underwent angioplasty with "bare metal" stents for coronary heart disease.

The study group is formed from patients treated percutaneously with BMS implantation, who were sent to our department from January 2005 to December 2013 with indication of repeated angiography based on clinical arguments.

**Inclusion criteria:**
- patients with complete interventional revascularization with "bare metal" stent who underwent invasive angiographic evaluation within one year following the initial procedure.

**Exclusion criteria:**
- patients who had at least one drug eluting stent (DES) simultaneously implanted;
- patients with stents in arterial or venous coronary grafts;
- patients with initial suboptimal postprocedural results;
- patients with major cardiac events in the first month after implantation;
- patients with incomplete data acquisition.

Coronary angiography was performed according to standard operating protocols, each lesion being examined in at least two orthogonal projections. Data regarding the size of the implanted stents have been collected from medical records. In stent restenosis was defined in terms of angiographic criteria as recurrent restenosis with percentage diameter ≥ 50% within the stent level or within its 5-mm proximal and distal edges. Stent length (the stented segment length) was determined from the manufacturer reference chart for balloon inflation at nominal pressure. When multiple stents were implanted for long coronary lesions ("overlapping stents"), it was defined as the sum of individual lengths. Stent diameter was defined as its minimal diameter specified by manufacturer at nominal pressure. When performing post-dilation, it was defined as the diameter of the balloon used (according to compliance chart at nominal inflation pressure provided by manufacturer).

Statistical analysis was performed with the following software: IBM Statistical Package for Social Sciences 22 (SPSS) and S-PLUS 8. We calculated OR and 95% CI to estimate relative risk assuming the fact that odds ratio over-estimate this risk.

**Results**

During the study period 512 eligible patients with implanted stents for coronary ischemic heart disease were identified. Based on angiographic examination data, they were divided into two groups: patients with angiographic restenosis in at least one stent implanted (398 patients, 77.7%) and patients without invasive criteria for in-stent restenosis (114 patients, 22.3%). The average time from initial procedure to invasive control evaluation was 210 (± 35) days for the first group and 280 (± 40) days for the second group.

A total number of 808 coronary stented segments were angiographically analyzed, 472 (58.42%) of them presenting imaging criteria for restenosis and 336 (41.58%) showing stents without restenosis. Most of them (351; 43.4%) had a diameter of 2.5 to 3.25 mm followed by those with a diameter ≤ 2.5 mm (248; 30.7%) and those with a diameter ≥ 3.25 mm (209; 25.9%). The stent length was another angiographic analyzed parameter. Thus, most frequently we found coronary segments with stented length of 15-28 mm (407; 50.4%), followed by those with length ≤ 15 mm (224; 27.7%) and length > 28 mm (177; 21.9%). We also analyzed distribution of implanted stent based on their size and location. The most frequent stents with average size (2.5 to 3.25 mm/15-28 mm) were located at the level of left anterior descending coronary artery (table 1).

Using angiographic data, we analyzed the relationship between in-stent restenosis presence and the implanted stent size (diameter and stent length) (table 2, fig. 1).

It was found that stents with diameter ≤ 2.5 mm and 15-28 mm length, stents with small (≤ 2.5) or average (2.5 to 3.25) diameter and length > 28 mm presented more frequent imagistic criteria for restenosis at angiographic control (p < 0.001). The association of stent length ≤ 15 mm with an average diameter (2.5 to 3.25 mm) was significantly related to angiographic absence of in stent restenosis (p = 0.014). This relationship was maintained even for the stents with large diameter (≥ 3.25 mm) and small (≤ 15 mm) or medium (15-28 mm) length.
Thus, stents with diameter ≤ 2.5 mm and 15-28 mm in length were associated with an estimated risk of restenosis of 3.8-fold higher. Also, combinations of the stents with small diameter (≤ 2.5) and long length (> 28 mm) and those with average diameter (2.5 to 3.25 mm) and long length (> 28 mm) presented a similar risk (table 3, fig. 2).

**DISCUSSION**

Our observations are consistent with many research which shows that an increased stent length represents an important predictor of angiographic restenosis and correlates with the degree of vessel injury and neointimal reaction (4, 5, 6, 7). From the beginning of interventional treatment it was confirmed that, when using stents, there is a linear relationship between their length and angiographic recurrences of restenosis at 6-9 months follow-up (6). Corroborating data from six randomized trials Mauri L et al. showed that the stented segment length is an independent predictor of in-stent restenosis. Each 10 mm is associated with an absolute increase of 7.7% of the percent diameter restenosis observed in BMS at 6-9 months (7).

The diameter of the reference vessel or the implanted
The stent remains a parameter strongly associated with restenosis phenomenon (8, 9). These observations are confirmed by ultrasound studies that showed that minimum luminal area calculated immediately postprocedural is an independent predictor of restenosis for both DES and BMS stents (10). Implantation of BMS stents in vessels with small diameter is associated with an increased risk of restenosis and need for subsequent revascularization (3, 5, 6, 11, 12, 13). One explanation would be that, for a certain degree of neointimal accumulation, luminal reduction of over 50% can be correlated with stent diameter and residual post-intervention stenosis degree (11). In line with these observations, our data confirm that by decreasing the diameter of the metallic prosthesis the risk of subsequent in-stent restenosis increases.

Using data from several randomized trials Feyter PJ et al. constructed a reference chart to correlate luminal area and stent length measured by intravascular ultrasound with coronary lesions. It was demonstrated, that when luminal area related to a certain stent length increases, the risk of restenosis diminishes (14). In our study, we made a similar diagram correlating the presence or absence of in-stent restenosis with the size of implanted stents. According to it, the length of the stent less than 15 mm appears to cancel the increased risk of restenosis given by the presence of a diameter ≤ 2.5 mm. Similarly, the favorable restenosis effect of the stent length > 28 mm is cancelled by using a stent with diameter ≥ 3.25. In fact, our diagram shows that increasing the stent diameter with respect to a specific stent length the risk of restenosis decreases in the same fashion. The favorable effect of large stent diameter was confirmed by BASKET-PROVE trial (PROspective Validation Examination) results. Using BMS for large vessels stenting involves a risk of stent restenosis comparable with DES (15). Our results are also supported by data from the Cardiac Care Network of Ontario registry showing that DES are effective, especially, in patients with thin vessels (< 3 mm) and long lesions (≥ 20 mm). At the same time, BMS remains a viable alternative for large vessels with short lesions (16).

**CONCLUSIONS**

Bare metal stents size represents an important factor that can be correlated with the risk of late restenosis. In-stent restenosis rate is reduced using stents with larger diameter and shorter length.

**REFERENCES**

8. Farooq V, Räber L, Gogas BD, Serruys PW. In-stent restenosis. In Percutaneous Interventional Cardiovascular Medicine The


