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Review

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Multi-Link Vision stent vs. first-generation drug-eluting stents: systematic review and meta-analysis

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Summary

Background: Since its introduction, the cobalt chromium alloy MULTI-LINK VISION stent (MLV) has been extensively investigated thus leading to the largest amount of data so far available for a bare metal stent.

Aim and Methods: Systematic review and meta-analysis (according to Cochrane collaboration guidelines) aiming at summarizing the real world safety and efficacy of MLV stent. Endpoints of interest were: major adverse events [(MAE) combination of overall death and non-fatal myocardial infarction, MI], and target vessel revascularization (TVR). Rate of stent thrombosis was also assessed.

Results: Eleven studies finally retrieved totalling 5539 patients [7 study registries, 4243 patients and 4 randomized controlled trials (RCTs) comparing MLV vs. first generation of drug-eluting stent (DES) (paclitaxel or sirolimus eluting), (RCTs) 1296 patients]. Across study registries, at a mean follow-up of 11.1 months, MLV was associated with a 5.3% risk of MAE, 3% of death, 2.3% of MI and a 9% of TVR. Risk of ST was 0.5%. Compared to first generation of DES in RCTs, at a mean follow-up of 10.5 months, MLV achieved similar results in terms of MAE, death and MI. On the other hand, MLV was associated with a double risk of TVR [OR 2.01 (1.34–3.01), $P < 0.001$, number needed to treat 18 (13–40)]. Overall, in stent late loss with MLV was 0.81 mm (±0.51), while the in segment late loss was 0.61 mm (±0.5). Risk of stent thrombosis was equivalent. Of note, performance of MLV in terms of safety, efficacy and risk of repeat revascularization was quite consistent across all the published studies, despite inherent differences in study design, clinical setting, complexity of the lesions and ethnicity.

Conclusion: Compared to first-generation DES, MLV showed substantial equivalence with respect to hard clinical endpoints. Data are consistent in study registries and RCTs meaning that the overall performance of MLV is quite predictable and reproducible into the wide spectrum of clinical settings.

Introduction

Since their introduction in the mid-1980s, coronary stents dramatically changed the practice and perspective of interventional cardiology as well as the expectation and survival of thousands of patients.[1]

Huge efforts have been made worldwide in order to progressively ameliorate the technology and,

along with some necessary failures, several pivotal progresses were achieved.[1]

Bioengineering technologies led to the development of a cobalt–chromium alloy that has been used in the manufacture of surgical implants for use in contact with blood, soft and bone tissues[2] since decades.

In this context, a thin strut cobalt–chromium coronary stent has been developed in an attempt to maintain radiopacity and an optimal radial strength and recoil without compromising long-term patency compared to stainless steel thicker strut or gold coated stent.

The cobalt–chromium alloy MULTI-LINK VISION (MLV; Abbott Vascular) stent has been introduced into the market in 2003. Since then it has been investigated in different settings and compared with several alternative technologies in multiple study registries as well as randomized controlled trials (RCTs).

Aim of this study is to assess by means of systematic literature search and meta-analytic comparison, the 'real world' safety/efficacy of MLV compared to the first generation of drug-eluting stents (DES).

Methods

Study selection

BioMed Central and PubMed (updated to December 2010) were searched for studies comparing MLV vs. first-generation DES in coronary arteries and reporting clinical outcomes, according to an established method.[3] There were no language restrictions. Pertinent study registries were also searched. References of original and review articles were crosschecked, as well as presentations in major international cardiology meetings.

Data extraction and endpoints of interest

Two reviewers performed data abstraction blindly. Divergences were resolved by consensus or by a third reviewer. The endpoints of interest were the combined rate of major adverse events [MAE, defined as the cumulative risk of all cause death and non-fatal acute myocardial infarction (MI)], target vessel revascularization (TVR) and target lesion revascularization (TLR). Additional analyses were carried out according to single endpoints and the rate of stent thrombosis.

Data abstraction has been performed from registries and RCTs. The latter were pooled for meta-analytic purposes.

Meta-analytic methods

Data synthesis and analysis

Review Manager 4.2.5[4] was used. Review Manager is a comprehensive statistical and reviewing programme, developed and maintained by The Cochrane Collaboration, which includes *ad hoc* statistical tools for pooled estimate calculations, according to several methods.

Statistical analyses

Odds ratios with 95% confidence intervals (95% CIs) were used as summary statistics. Binary outcomes from individual studies were combined with Der Simonian and Laird random-effect model, according to an intention to treat analysis. We also carried out the '*z*' test where z = estimated effect size/standard error of the estimated effect size, and the odds ratio (OR) considered on the log scale. As log (OR) has a unimodal distribution, the reported *z*-values were analysed to obtain a two-tailed '*P*', and hypothesis testing results were considered statistically significant at the 0.05 level.[5] Whereas appropriate, we also calculated the number needed to treat as the inverse of absolute risk reduction (ARR): NNT = 1/ARR.

We computed Cochrane Q heterogeneity test (H) by summing the squared deviations of each study's estimate from the overall meta-analytic estimate, weighting each study's contribution in the same manner.[6] We used the Q together with the resulting degrees of freedom (df) to calculate the proportion of variation due to heterogeneity [Inconsistency: $(I^2) = (Q - \mathrm{df})/Q$]. The degree of inconsistency among studies (I^2) was estimated with scores of <25%, between 25% and 75% and >75% representing, respectively, low, moderate or high inconsistency.[6]

Sensitivity analysis was performed by excluding trials one at time in order to assess the contribution of each study to the pooled estimates.[5]

The likelihood of publication bias was assessed graphically by generating a funnel plot for the combined endpoint of MAE and mathematically by means of Egger's test (*P* for significant asymmetry <0.1).[7]

This study is inspired by good practice guidelines from the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group[8] and the Cochrane collaboration Newcastle–Ottawa scale for assessing quality of cohort study.[5]

Results

Search result

The search algorithm resulted in 240 citations. We eventually appraised 11 studies, 4 RCTs comparing MLV stent vs. first-generation (paclitaxel or sirolimus eluting) DES[9,10,11,12] and 7 registries[13–19] totalling 5539 patients treated with percutaneous coronary intervention (PCI) for stable angina as well acute coronary syndromes. Any vessel size and AHA/ACC lesion type were present in the overall population, in which 21% of patients were diabetic (Figure 1). Main characteristics of included studies are shown in the Tables 1 and 2.

Overview of study registries and pooled outcomes

Overall, included patients were very well representative of the wide spectrum of patients undergoing PCI both in terms of clinical indication and lesion complexity. Moreover, included studies have been performed in the USA, as well as in the European Community and China.

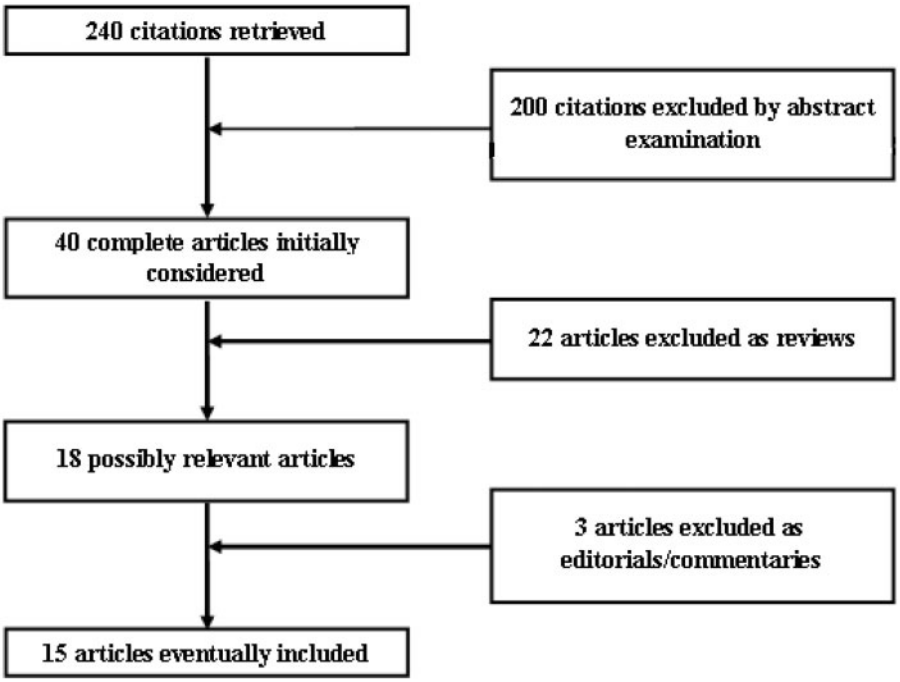

Figure 1. QUOROM flow chart showing the study selection process.

Table 1 Characteristics of study registries

Study	N	M/F (&)	Diabetes (%)	Prior MI (%)	MVD[a] (%)	Lesion type % [A, (B1, B2), C]
VISION registry	268	68/32	23	33	35	21/73/7
VIVE	429	77.2/22.8	28	35.2	38.2	4/93/3
REVE	518	NA	17.1	NA	53.7	(B/C lesion) 89.9
RISICO	143	76/24	22	57	32	5/81/14
DaVinci	1344	76/24	26.2	27.7	NA	11.9/79.3/8.8
COBALT	438	72.6/27.4	26.7	NA	72.8	(B2/c lesions) 41.4
REAL	1103	74.5/25.5	20.3	34.3	NA	(B2/c lesions) 61.5
Overall	4243	74/26	23.3	37.4	46.34	NC

[a]MVD = at least two vessels with >50% stenosis.
NC: Not Computable; NA: not available. See text for study acronyms.

Only follow-up angiography was clinically driven. Study registries have been considered and analysed according to follow-up length (as shown in Table 3) as COBALT (18) and REAL (19) reported results at 18 and 24 months, respectively. Conceivably, despite similar baseline patients' characteristics with respect to other study registries, a higher rate of event has been observed in both studies compared to those with shorter follow-up. Indeed, figures are presented for studies with follow up of 6–9 months and overall (Table 3). At a mean follow-up of 11.1 months, cumulative rate of major adverse cardiovascular events (MACE) was 5.3%, with inherent risk of all cause mortality and non-fatal MI of 3% and 2.3%, respectively.

Overview of RCTs and meta-analytic results

Patients enrolled in RCTs were predominantly affected by acute coronary syndromes. MISSION trial specifically enrolled patients with ST-elevation MI (11). RCTs have been exclusively performed in European countries and had a mean FU of 10.5 months. Besides MISSION trial, percentages of left main or multivessel disease, as well as other baseline characteristics of included patients were fairly homogeneous. Follow-up angiography has been done per-protocol in all but Basket trial (9). Overall, in stent late loss with MLV was 0.81 mm (±0.51), while the in segment late loss was 0.61 mm (±0.5).

Of note, the REAL registry (a large registry of coronary intervention performed in an Italian region) considered and followed not only those patients treated with MLV implantation but also those who received a first generation of DES.

Thus, as data have been published for both groups of patients of the REAL registry, we proceeded with the meta-analytic calculations also considering those data. Interestingly, ORs were substantially unchanged with of without the REAL data.

Specifically, when comparing MLV stent to first generation of DES, no difference was found in the risk of MAE [OR 1.35 (0.95–1.90), $P = 0.09$] (Figure 2), as well as in the risk of overall death [OR 1.17 (0.92–1.5), $P = 0.2$], and non-fatal MI [OR 1.42 (0.98–2.05), $P = 0.06$] (Figure 3).

Table 2 Characteristics of RCTs

Study	N	M/F (%)	Diabetes (%)	Prior MI (%)	Prior PCI/CABG (%)	ACS/SA (%)
BASKET	826	79/21	19	27	16/12	58/42
MISSION	310	77.8/22.2	9.6	3.9	1.6/1	100% STEMI
Spirit first	56	73/27	11	19	13 (overall)	79/21
Ortolani *et al.*[12]	104	76/24	16	29	16/2	62/38
Overall	1296	76/24	13.9	19.7	NC	74.5/25.5

ACS: acute coronary syndromes; CABG: coronary artery bypass graft; PCI: percutaneous coronary intervention; SA: stable angina; NC: Not Computable. See text for study acronyms.

Table 3 Outcomes of study registries with follow-up duration of 6–9 months and overall

Study	N	FU (m)	MAE (%)	Death (%)	MI (%)	TVR/TLR (%)	ST
VISION registry	268	6	5 (1.8)	3 (1.2)	2 (0.8)	11 (4.3) TVR	0
VIVE	429	6	3 (0.6)	2 (0.5)	1 (0.2)	6 (1.4) TVR	0
REVE	518	6	3 (0.5)	2 (0.4)	1 (0.19)	21 (4.2) TLR	NA
RISICO	143	6	8 (5)	4 (2.9)	4 (2.9)	8 (5.8) TVR	0.7
DaVinci	1344	9	38 (2.8)	18 (0.8)	20 (1.5)	130 (9.7) TVR	0.2
Pooled 6–9 months FU	**2702**	**6.6**	**57 (2.1)**	**29 (2.2)**	**28 (1.9)**	**176 (6.5) TVR**	
COBALT	438	18	27 (6.1)	18 (4.1)	9 (2)	52 (11.9) TVR	NA
REAL	1103	24	143 (13)	79 (7.2)	64 (5.8)	150 (13.6) TVR	1
Pooled	**4243**	**11.1**	**5.3**	**3**	**2.3**	**9**	**0.5**

The first row in bold typeface indicates results at 6–9 months, the second row in bold typeface indicates results at longest follow up.

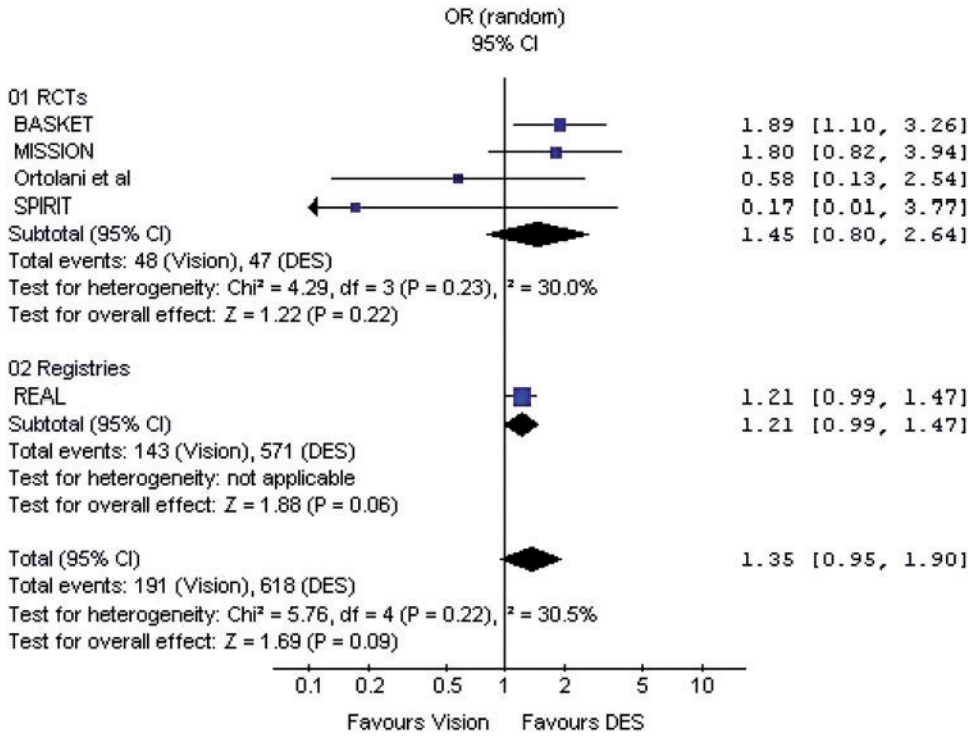

Figure 2. Overall analysis of the risk of MAE at the longest follow-up available. Single study ORs and 95% CIs are shown by squares and lines. Overall OR with 95% CI shown by diamonds.

At a mean follow-up of 12.8 months, including the REAL registry, MLV was associated with a significantly higher risk of TVR [OR 1.64 (1.38–1.96), $P<0.001$]. Of note, when considering RCTs only, this difference is even higher in favour of DES with an OR of 2.01 (1.34–3.01) with an absolute risk of 6% and 12% for DES and MLV, respectively. Thus absolute risk reduction can be calculated as 0.06 and subsequent number needed to treat (1/ARR) as 18 (13–40). The latter would imply that the allocation of 100 patients to DES implantation would save 5–6 TVR with respect to MLV (Figure 4). TLR was not computable for lack of data.

Although a small number of events has to be acknowledged, in terms of stent thrombosis, there was no difference between MLV and first generation of DES [OR 1.03 (0.56–1.88), $P=0.94$] (Figure 5, A).

Study registries vs. RCTs

From the comparison of study registries and RCTs (Table 4), a significant difference has been observed in terms of the rate of non-fatal MI and MAE.

RCTs have been performed more recently than study registries, perhaps they have adopted the new definition of peri-procedural MI. It is now widely accepted that the latter clearly had the effect of increasing the diagnosis and incidence of peri-procedural MI as well as of spontaneous MI.[20,21]

As a consequence, differences seen in terms of non-fatal MI and MAE could be entirely explained by different endpoint definitions.

The rate of all cause mortality, TVR and ST were quite similar.

Quality of included studies and assessment of possible biases

No heterogeneity with an overall very low inconsistency has to be acknowledged (I^2) across all the meta-analytic calculations.

Exclusion of one RCT at a time did not alter the results.

The assessment of possible sources of bias is reported in Table 5. Very good overall consistency has to be acknowledged among reviewers rating the quality of the studies. Included patients were well representative of the 'real-world' scenario according to the incidence of risk factors and baseline characteristics. The presence of 'incomplete data', whereas applicable, has been thoughtfully addressed, and no 'selective reporting' has to be acknowledged.

Overall, the quality of the registries has to be acknowledged as poor (i.e. high likelihood of biases) compared to RCTs, which had a good internal validity (i.e. low likelihood of biases).

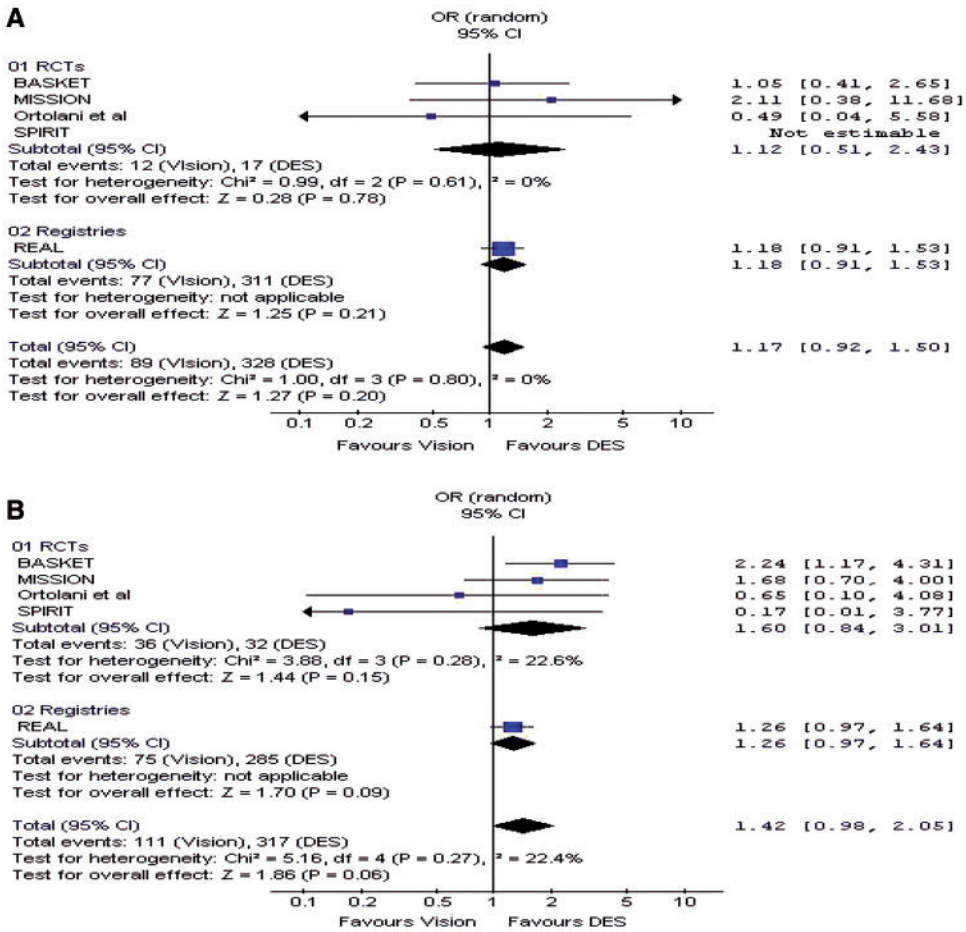

Figure 3. Overall analysis of the risk of (**A**) all cause death and (**B**) non-fatal MI. Single study ORs and 95% CIs are shown by squares and lines. Overall OR with 95% CI shown by diamonds.

The Funnel plot for all studies according to the risk of MAE (Figure 5, B) showed an overall symmetry within the 95% CI. Moreover, Egger's test for the risk of MAE further confirmed the absence of small study/publication bias as '*P* for asymmetry' was 0.13.

Discussion

The cobalt–chromium alloy MLV stent has been challenged worldwide with every type of lesion, clinical syndrome and patient's baseline risk. In study registries and then in RCTs against first generation of DES, MLV showed a good and consistent performance. Compared to first-generation DES, it was associated with a doubled risk of failure leading to repeat revascularization, however, in terms of major events, it provided substantially equal results.

The story of interventional cardiology begun in late 1970s when the first balloon coronary angioplasty has been described.[22] Extensive technological progresses led this pioneer technique to be surpassed, in the mid-1980s, by coronary stents. The need for a coronary stent was driven by the observation of acute vessel closure and high rate of restenosis.

However, the early success and complication rates seen with the first bare metal coronary stents[23] were not always competitive with those of routine balloon angioplasty. A wide implementation of coronary stenting technique took place only after the publication of some pivotal studies,[24,25] together with initial evidences suggesting the need for dual antiplatelet therapy.[26] By 1999, coronary stenting was performed in the vast majority of the PCI procedures,[27] notwithstanding inherent problems and concerns such as the risk of subacute thrombosis and in-stent neointimal hyperplasia. The former is currently managed with adjuvant pharmacological therapy, i.e. dual antiplatelet therapy. The latter has been brilliantly overcome by the DES technology.[28]

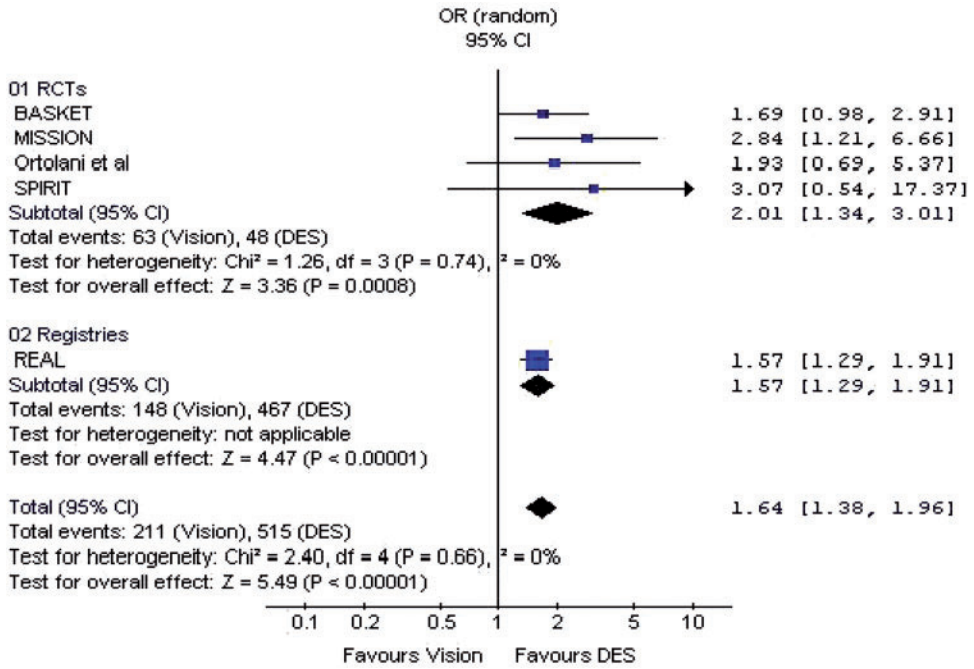

Figure 4. Overall analysis of the risk of TVR at the longest follow-up available. Single study ORs and 95% CIs are shown by squares and lines. Overall OR with 95% CI shown by diamonds.

Some reports show that DES are used in up to 75% of PCI procedures, at least in some regions of the USA. On the other hand, this percentage varies widely across USA and also when compared to worldwide data where use of DES can drop to 35%.[29]

There are several regional, clinical and economical reasons for this inconsistency. Overall, they confirm that bare metal stent (BMS) are still widely used in contemporary practice.

Benefits of DES are their significant reduction in repeat revascularization compared with use of a BMS, whereas their adverse effects relate to the increased risk of very late ST and the requirement for prolonged dual antiplatelet therapy.

Of note, benefits of DES are not universal. The advantage in terms of reducing restenosis depends on lesion characteristics, and the magnitude of benefit is greater in high risk lesions.[30]

Moreover, risk of stent thrombosis is also variable.

For patients whose risk of restenosis is relatively low (i.e. non-diabetic, vessel diameter $\geqslant 3$ mm), and/or the risk of ST is relatively high (poor compliance to medical therapy), a BMS should be preferred. Ultimately, an evaluation of the overall risk/benefit ratio cannot neglect the cost/effectiveness issue. A recent systematic review concluded that the cost effectiveness of DES was unfavourable compared with that of BMS at 1 year. While being associated with a higher initial cost, DES did not increase survival and provide an overall small relative reduction of restenosis.[31]

Results of our systematic review and meta-analysis actually provide insights in the performance of MLV as a paradigm for any other BMS. Unlike the MLV, none of the commercially available BMS has been extensively investigated, however, observations and consensus over the years tried to summarize which are the clinical and angiographic features useful for a thorough decision process. The choice between a BMS and DES should rely on the expected event rates and the present manuscript aims at providing a 'Real World' analytical basis for treating physicians both when selecting the appropriate stent and consenting the patients before the procedure.

Limitation of the present study

A limitation inherent to all meta-analyses is the potential heterogeneity among studies, in terms of protocols, patients and sample sizes, and the unavailability of patient-level data.

However, the primary disagreement that arises in meta-analyses is whether to incorporate between-study variation (heterogeneity and inconsistency) in estimating summaries of effect size. In presence of significant heterogeneity, it may be more appropriate to analyse results using both methods.

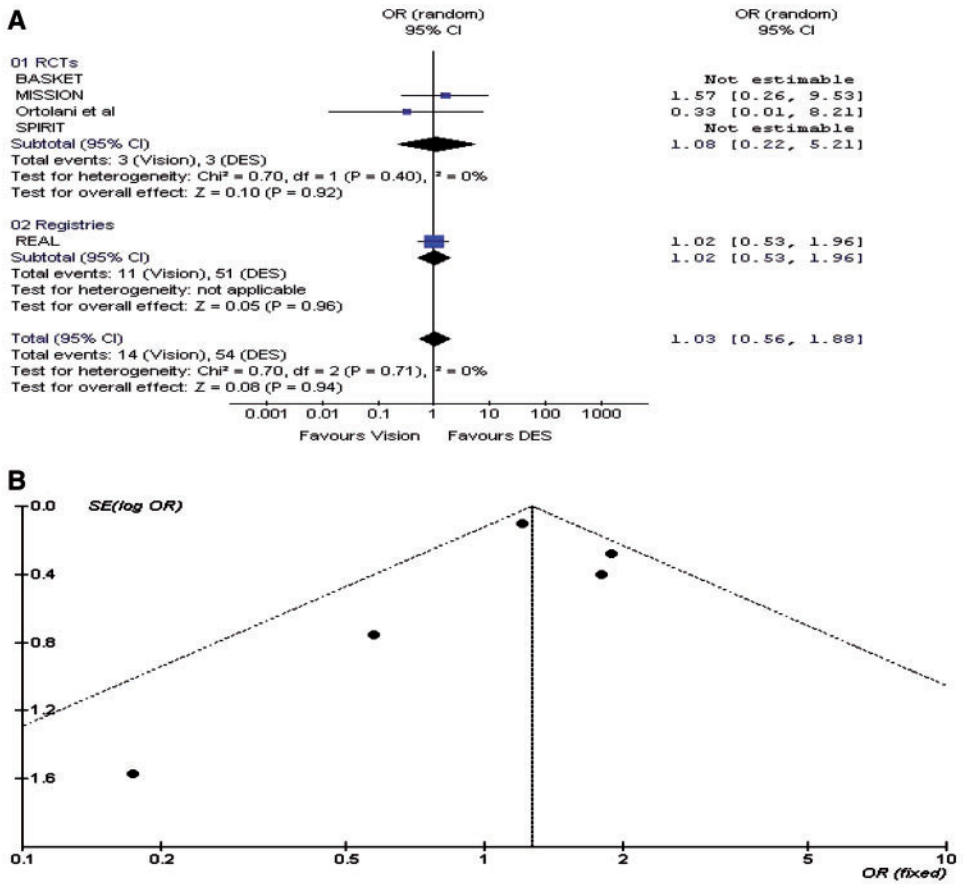

Figure 5. (**A**). Overall analysis of the risk of Stent Thrombosis at the longest follow-up available. Single study ORs and 95% CIs are shown by squares and lines. Overall OR with 95% CI shown by diamonds. (**B**). Funnel plots of included studies according to MAE rate. Dotted lines represent 95% CI. SE (Log OR): standard error of the log transformed OR.

Table 4 Head-to-head comparison of Study Registries and RCTs

	MAE (%)	Death (%)	Non Fatal MI (%)	TVR (%)	ST (%)	FU (m)
RCTs	9.3	2.3	7	12.2	1	10.5
Study registries	5.3	3	2.3	9	0.5	11.1

A statistically significant result with the fixed-effect model indicates that there is an effect in at least one of the studies, and the overall result is an average measure of treatment effect of the studies in the analysis.

On the other hand, the random effects tends to give a more conservative estimate (i.e. with wider confidence intervals) indeed data are presented according to the latter.

The retrospective designs of some of the included studies, the lack of adjusted ORs in some reports, some discrepancies in duration of follow-up and the obvious use of different DES have to be acknowledged as possible limitations of this analysis. They are all impossible to overcome due to the design of the included studies. Ultimately, the potential risk of selection bias is unavoidable in registry studies.

Avenues for future research

The next theoretical step should probably be a RCTs in which the population would be selected as appropriate for BMS and then randomized to different devices in order to appraise whether one performs better than another or they are substantially equivalent. On the other hand, this trial would practically be complicated by the large sample size required and the need for an accurate clinical and angiographic risk stratification to achieve homogeneity and avoid confounding factors.

Table 5 Assessment of bias

	Sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective reporting
VISION registry	NA	NA	NA	No	No
VIVE	NA	NA	NA	No	No
REVE	NA	NA	NA	No	No
RISICO	NA	NA	NA	No	No
DaVinci	NA	NA	NA	No	No
COBALT	NA	NA	NA	No	No
REAL	NA	NA	NA	No	No
BASKET	Computerized	Adequate	Adequate	No	No
MISSION	Computerized	Adequate	Adequate	No	No
SPIRIT FIRST	Computerized	Adequate	Adequate	No	No
Ortolani *et al.*[12]	Computerized	Adequate	Adequate	No	No

NA: not available.

Conclusions

MLV is by far the most extensively investigated bare metal stent. This systematic review and meta-analysis aims at summarizing all the available evidences supporting its use. Despite the inclusion of complex lesions, a high percentage of diabetic patients and acute clinical settings, cobalt–chromium alloy MLV stent showed a very low rate of failure leading to repeat revascularization, perhaps a substantial equivalence with first-generation DES in terms of major endpoints. These highly consistent and reproducible findings across different studies are crucially important in those cases when the risk/benefit ratio favours BMS over DES.

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