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Diagnostic accuracy of in-stent coronary restenosis detection with multislice spiral computed tomography: a meta-analysis

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Abstract This study was designed to define the current role of multislice spiral computed tomography (MSCT) for the diagnosis of coronary in-stent restenosis using a meta-analytic process. Restenosis remains a limitation after coronary stent implantation and contributes to a substantial number of coronary re-assessments by conventional invasive coronary angiography (CA). We identified 15 studies (807 patients) evaluating in-stent restenosis by means of both MSCT (≥16 slices) and conventional CA until February 2007. After data extraction the analysis was performed according to a random-effects model. The analysis pooled the results from 15 studies with a total of 1,175 stents. A substantial number of unassessable stents (13%) were excluded from the analysis underscoring the shortcomings of MSCT. With this major limitation the diagnostic performance of MSCT for in-stent restenosis detection can be summarized as follows: the sensitivity and specificity were 84% [95% confidence interval (CI) 77–89%] and 91% (95% CI 89–93%), respectively, with positive and negative likelihood ratios of 12.2 (95% CI 6.6–22.6) and 0.23 (95% CI 0.17–0.31), respectively, and with a diagnostic odds ratio of 67.9 (95% CI 34.4–134.1). MSCT has shortcomings difficult to overcome in daily practice for in-stent restenosis detection and continues to have moderately high sensitivity and specificity. The diagnostic role of this emerging technology as an alternative to CA for in-stent restenosis detection remains limited.

Keywords MSCT · Computed tomography · Restenosis · Stent · Invasive angiography · Coronary angiography · Meta-analysis

Introduction

Coronary artery disease requiring revascularization is increasingly treated by percutaneous coronary intervention (PCI) due to the successful introduction of coronary stent implantation [1]. Indeed, by reducing acute major complications and the incidence of restenosis compared with conventional balloon angioplasty, stents are used in almost all PCIs currently [2]. Following the recent introduction of drug eluting stents associated with even further reduction in the occurence of in-stent restenosis, we can anticipate a substantial increase in the number of patients considered for PCIs and with subsequent stent implantation in the future. However, in-stent thrombosis and excessive neointimal hyperplasia may still occur causing partial or complete in-stent obstruction [3, 4]. Whereas the clinical diagnosis of acute in-stent thrombosis is frequently easy, that of in-stent restenosis remains sometimes more difficult and needs invasive diagnosis by means of conventional coronary angiography. Because a substantial number of these invasive coronary angiograms are not followed by intervention, multislice spiral computed tomography (MSCT) of coronary arteries has been thought to be able to play a role as a non-invasive tool to exclude in-stent

restenosis and thus act as a gatekeeper before considering conventional invasive diagnostic procedures [5, 6]. Using a meta-analytic process, we have conducted a systematic review of all studies comparing MSCT and conventional invasive coronary angiography for the diagnosis of in-stent restenosis, in order to define the current diagnostic performance of MSCT in this setting.

Materials and methods

Search strategy

Database searches for English-language articles published until November 2006 were performed in MEDLINE, Cochrane librabry and BioMed Central databases. We combined the medical subject headings for *computed tomography*, *multislice computed tomography* (*MSCT*), and *coronary angiography*, with the exploded terms *stent and restenosis* and scanned references in retrieved articles and reviews. The retrieved studies were carefully examined to exclude potentially duplicate or overlapping data. Meetings abstracts were excluded, as they could not provide adequately detailed data and their results might not be final. Only papers evaluating the presence of in-stent restenosis by both conventional invasive coronary angiography (CA) and MSCT in the same subjects were included.

Study eligibility

We included a study if (1) it used MSCT as a diagnostic test for in-stent restenosis, with >50% diameter stenosis selected as the cut-off criterion for significant restenosis, using conventional invasive angiography and quantitative coronary angiography as the reference standard; (2) it used the latest-generation of MSCT (≥16 slices); (3) and it reported cases in absolute numbers of true positive (TP), false positive (FP), true negative (TN), and false negative (FN) results or presented sufficiently detailed data for deriving these figures. Studies were excluded if they were performed (1) only in patients after coronary artery bypass graft surgery, (2) in a subset of patients with prior heart transplant.

Data extraction

The following information was extracted from each study: first author, year of publication, and journal; study population characteristics, including sample size (number of subjects evaluated with both tests, number of patients excluded); number of stents evaluated and excluded from the analysis; gender; mean age (and standard deviation); mean heart rate (and standard deviation); relative timing of the two imaging procedures and whether or not evaluation of one test was blind to the result of the other; technical characteristics of the MSCT, including type and brand of machine used; and rate of beta-blocker usage. Two investigators performed the data extraction independently. Discrepancies were solved by a third investigator and global consensus. The study quality conformed to the QUADAS guidelines [7, 8].

Data synthesis and statistical analysis

Categorical variables from individual studies are presented as *n/N*(%) and continuous variables are presented as mean with (standard deviation) SD. Measures of diagnostic accuracy are reported as point estimates [with 95% confidence intervals (CIs)]. By means of TP, TN, FP, and FN rates, we computed sensitivity, specificity, positive and negative likelihood ratios and diagnostic odds ratios as previously described [9]. We computed all statistics for individual studies, and then combined them using a random-effects model. Between-study statistical heterogeneity was also assessed using the Cochran Q chi-square tests. Weighted symmetric summary receiver operating characteristic plots, with pertinent areas under the curve, were computed using the Moses-Shapiro-Littenberg method [10, 11].

Sources of clinical and statistical heterogeneity were explored by means of subgroup analyses and meta-regression [12]. Specifically, we performed stratified analyses according to publication year, sample size, number of interpretable stents, and 16 vs 64 slices. Statistical computations were performed with SPSS 13.0 (SPSS, Chicago, Ill.) and MetaDiSc [13], and significance testing was at the two-tailed 0.05 level.

Results

The reviewing process is described in Fig. 1. Database searches identified 199 potentially relevant citations. After title/abstract assessment, we retrieved 35 studies as complete reports, from which 20 were excluded because (1) they did not employ MSCT or ≥16 slices MSCT; (2) they looked only at grafts or at atherosclerotic plaque assessment; (3) they had overlapping data; (4) they were in a language other than English; (5) it was impossible to find or calculate absolute figures from presented data; overlapping or duplicated publication was obvious; or (6) no systematic angiographic control was performed. Thus, we included 15 of these studies in the systematic review [14–28]. All studies were published between January 2004 and February 2007, or were in press, or ahead of publication and then available on a dedicated journal website in February 2007. Table 1 presents demographic data and details on included studies.

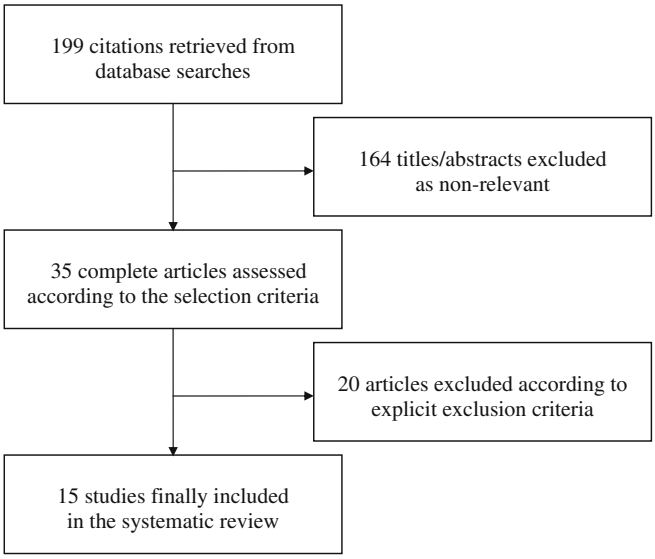

Fig. 1 Flow diagram of the reviewing process

In-stent restenosis meta-analysis

As shown in Figs. 2, 3, 4, 5 and 6, the analysis pooled the results from 15 studies with 807 patients, corresponding to 1,175 stents and showed after exclusion of the analysis of 13% of unassessable stents that, in comparison with invasive coronary angiography, MSCT for in-stent restenosis detection had a sensitivity of 84% (95% CI 77–89%), a specificity of 91% (95% CI 89–93%), a positive likelihood ratio of 12.2 (95% CI 6.6–22.6), a negative likelihood ratio of 0.23 (95% CI 0.17–0.31), and a diagnostic odds ratio of 67.9 (95% CI 34.4–134.1). The summary receiver operator characteristic curves are shown in Fig. 7. Statistical heterogeneity was found for specificity ($P<0.001$) and positive likelihood ratio ($P<0.001$).

Additional analyses

We explored sources of clinical and statistical heterogeneity by performing subgroup analysis for the number of slices in each CT scan. While a 64-slice CT scan should be more accurate than a 16-slice one, we did not find significant results by interaction testing. Specifically, for 16-slice CT scans, we found a sensitivity of 82% (95% CI 72–89%), a specificity of 92% (95% CI 88–94%), a 16.1 (95% CI 5.1–50.6) positive likelihood ratio, a 0.25 (95% CI 0.16–0.37) negative likelihood ratio, and a 69.9 (95% CI 30.3–161.4) diagnostic odds ratio. For >16-slice CT, we found a sensitivity of 85% (95% CI 76–92%), a specificity of 91% (95% CI 88–94%), a 10 (95% CI 5.5–18.2) positive likelihood ratio, a 0.20 (95% CI 0.11–0.33) negative

Table 1 Characteristics of included studies

Study	Slices (*n*)	MSCT (brand)	Patients (*n*)	Stents (*n*)	Male (%)	Mean age in years (SD)	Mean heart rate in bpm (SD)	β-blockers (%)	Unassessable stents (%)
Schuijf, 2004 [14]	16	Toshiba	22	68	95	62 (7)	65 (11)	77	26.5
Cademartiri, 2005 [15]	16	Siemens	51	76	82	60 (12)	57 (3)	67	2.6
Kitagawa, 2005 [16]	16	GE	16	21	76	66 (8)	56 (8)	90	–
Gilard 2005 [17]	16	Philips	29	29	70	63 (10)	66 (8)	100	6.9
Kefer, 2006 [18]	16	Philips	50	73	80	64 (9)	61 (8)	88	5.5
Chabbert, 2006 [19]	16	Siemens	114	121	76	67 (11)	53 (-)	92	10.7
Watanabe, 2006 [20]	16	Siemens	31	42	87	64 (10)	54 (6)	81	17
Ohnuki, 2006 [21]	16	Siemens	16	20	69	65 (10)	67 (9)	–	5
Gilard, 2006 [22]	16	Philips	143	232	71	68 (10)	64 (12)	83	45.6
Gaspar, 2005 [23]	40	Philips	65	111	69	63 (12)	–	–	4.5
Van Mieghem, 2006 [24]	64	Siemens	70	70	83	61 (11)	57 (7)	70	0
Rixe, 2006 [25]	64	Siemens	64	102	64	58 (10)	60 (5)	–	42
Rist, 2006 [26]	64	Siemens	25	46	92	59 (12)	62 (8)	56	2.2
Ehara, 2007 [27]	64	Siemens	81	125	78	67 (10)	72 (13)	25	12
Oncel, 2007 [28]	64	Siemens	30	39	90	58 (10)	–	–	0

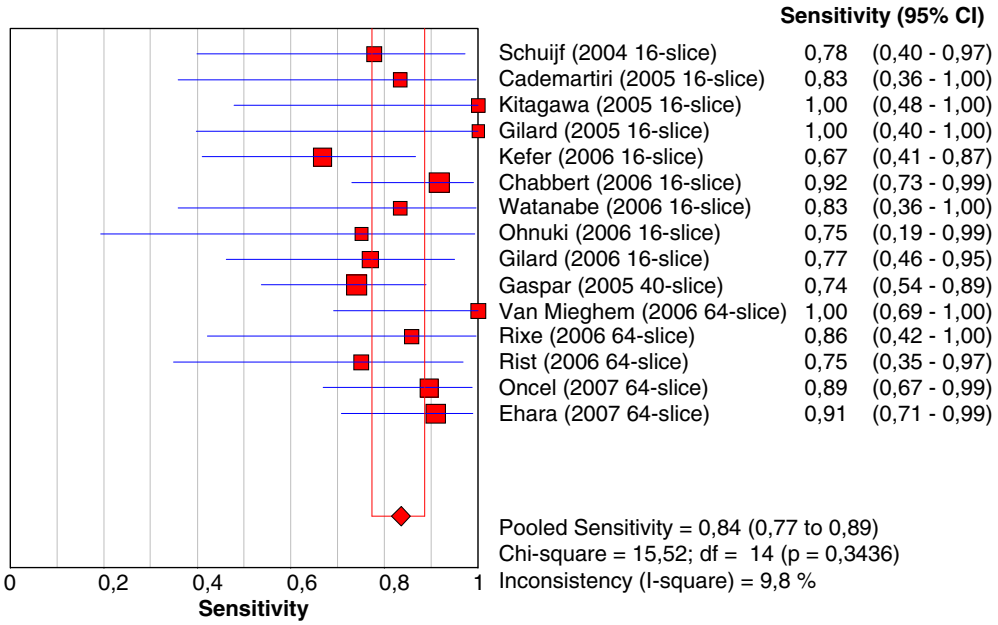

Fig. 2 Plot and table of in-stent restenosis detection sensitivity of MSCT-CA in comparison to CA

likelihood ratio, and a 67.7 (95% CI 21.2–215.8) diagnostic odds ratio.

Finally, we performed meta-regression analyses exploring the impact of sample size and publication year on the diagnostic performance of MSCT. While the latter did not disclose significant results, we found a significant interaction between changes in sample size and diagnostic odds ratios in the individual studies ($P<0.04$).

Pooled summary estimates are given in Table 2. Quality assessment for all included studies is shown in Table 3.

Discussion

In the present study, we focused on the diagnostic performance of the newest generation of MSCT (≥16 slices) for the detection of in-stent restenosis. First of all, the rate of scanned stents judged unassessable by the investigators was very high 13% (ranging from 0% to 45.6%) and constitutes a major limitation of these analyses, which is important to keep in mind while interpreting the relatively high specificity (91%) and sensitivity (84%) of

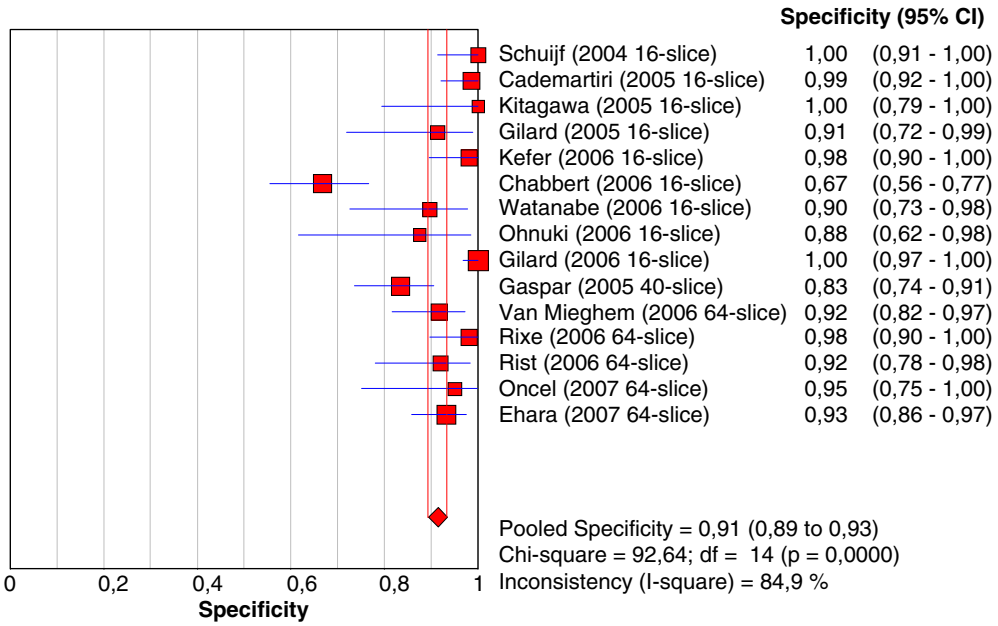

Fig. 3 Plot and table of in-stent restenosis detection specificity of MSCT-CA in comparison to CA

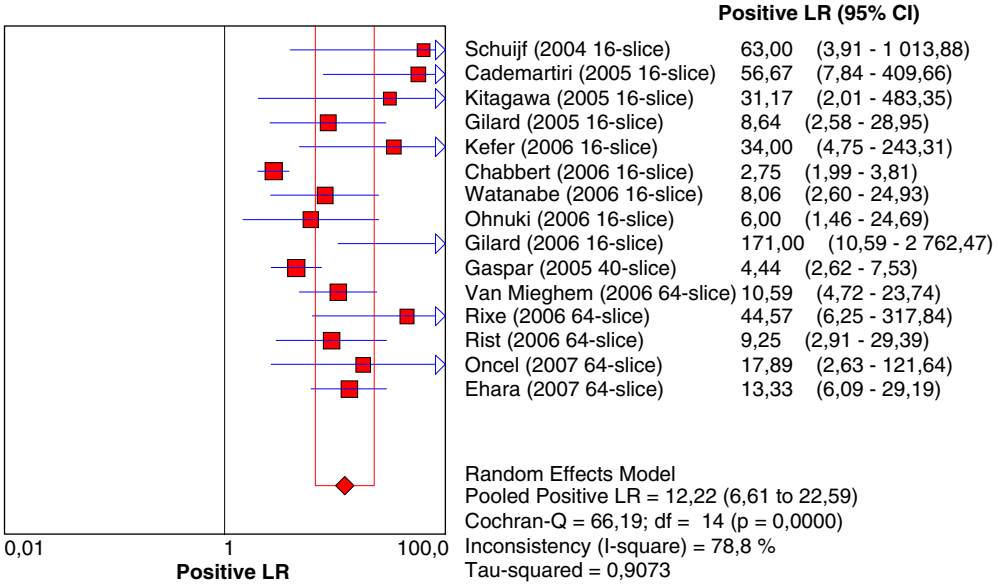

Fig. 4 Plot and table of in-stent restenosis detection positive likelihood ratio of MSCT-CA in comparison to CA

MSCT for in-stent restenosis detection presented in our pooled estimates. Furthermore, these figures were provided in highly selected patients, favoring again the positive perception of MSCT as a valuable diagnostic tool. These results are in keeping with recent recommendations that patients with previous coronary stenting should not routinely undergo CT coronary angiography, to avoid unjustified radiation exposure [29].

Overall subtle in-stent hyperplasia quantification remains impossible and only qualitative assessment of coronary stents is feasible [6, 19]. It has been suggested that MSCT could reduce the need for invasive diagnostic procedures by non-invasively excluding in-stent restenosis [14–28]. The present meta-analysis identifies that this optimistic view could be envisioned only in highly selected patients and mainly in patients with proximal and large stents, as frequently commented on in the individual studies [22, 23]. Indeed small stent diameter has been identified by several groups as a major factor for failure of in-stent restenosis assessment, with a consensus that only stents with diameter >3 mm are routinely interpretable [6, 14–28]. However, in routine clinical settings, many patients are treated with relatively small stents, having diameters of 2.5 mm or 3.0 mm. Therefore, further improvement in

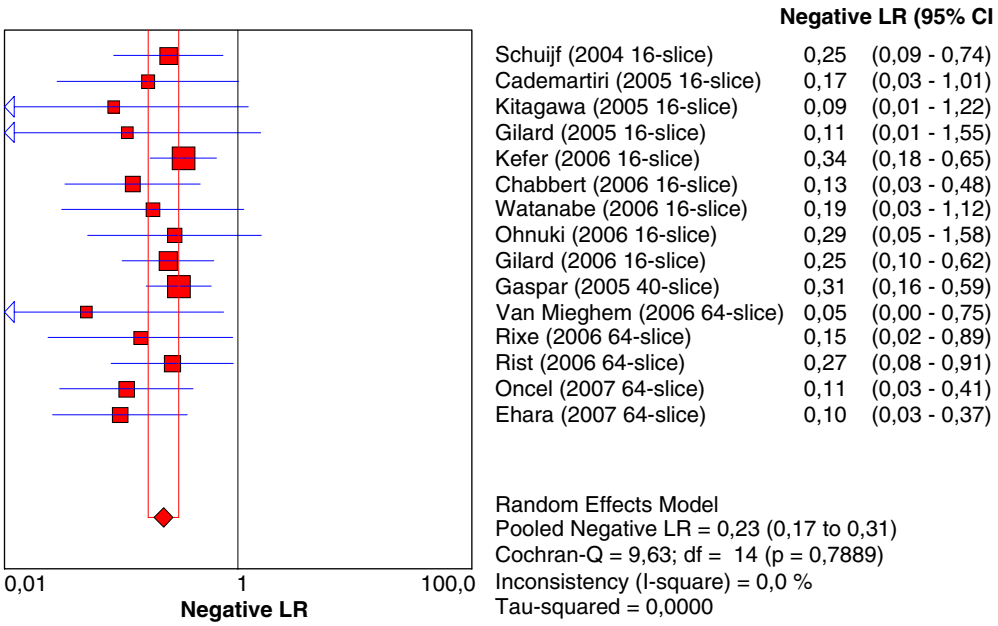

Fig. 5 Plot and table of in-stent restenosis detection negative likelihood ratio of MSCT-CA in comparison to CA

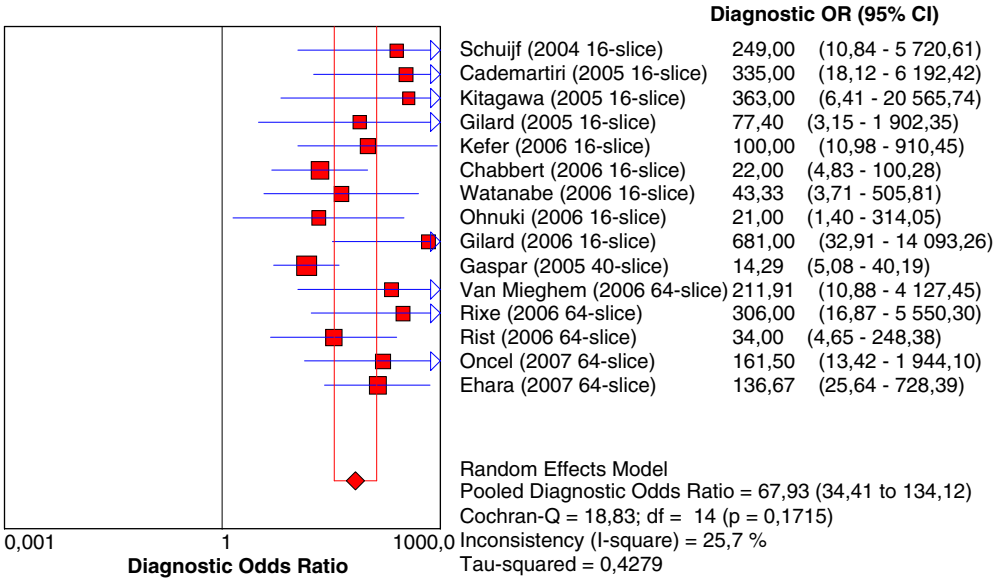

Fig. 6 Plot and table of in-stent restenosis detection diagnostic odds ratio of MSCT-CA in comparison to CA

spatial resolution and temporal resolution is required for MSCT to become a realistic routine diagnostic procedure for the evaluation of in-stent restenosis [30].

Imaging coronary stents using CT is a technically more demanding task than imaging native coronary arteries. The degree of metal artifacts of stents, including partial volume effects is related to stent material, the size of the diameter, the thickness and strut design [6, 31–34]. The metal artifact of tantalum is so severe in comparison with other materials that it is considered to be impossible to assess the lumens of the stents made of tantalum by MSCT. The gold markers of some stents also cause severe artifacts, making the lumen at the edges of these stents difficult to evaluate. Other patient factors that might limit proper assessment of stent lumen as

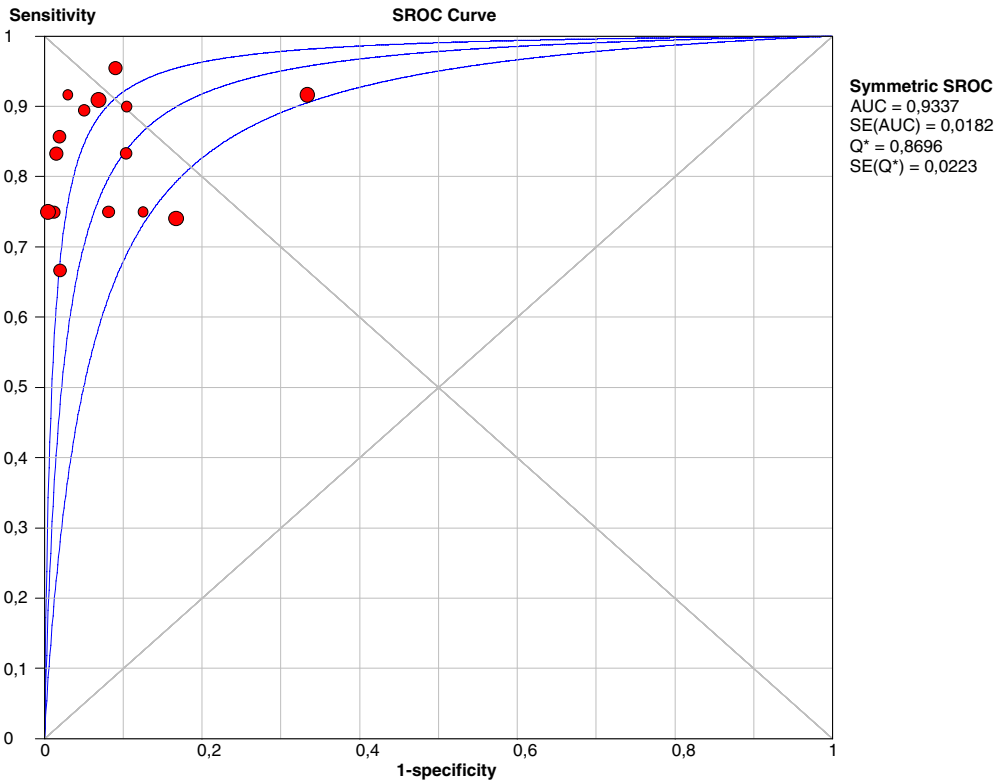

Fig. 7 Plot of symmetric summary receiver operator characteristic of MSCT-CA in comparison with CA for in-stent restenosis detection. The receiver operator characteristic curve provides a graphical display of diagnostic accuracy, by plotting 1-specificity on the horizontal axis and sensitivity on the vertical axis. The pertinent area under the curve (AUC) and Q* statistic (the point where sensitivity and specificity are maximal), both with standard errors (SE), are also included

Table 2 Summary of pooled estimates in different subgroups (*LR+* positive likelihood ratio, *LR-* negative likelihood ratio, *DOR* diagnostic odds ratio)

	Sensitivity (95% CI)	Specificity (95% CI)	LR+ (95% CI)	LR– (95% CI)	DOR (95% CI)
All studies	0.84 (0.77–0.89)	0.91 (0.89–0.93)	12.2 (6.6–22.6)	0.23 (0.17–0.31)	67.9 (34.4–134.1)
Left main	1.0 (0.77–1.0)	0.92 (0.83–0.97)	9.9 (5.1–19.5)	0.07 (0.01–0.50)	133.1 (15.1–1173.4)
16-slice	0.82 (0.72–0.89)	0.92 (0.88–0.94)	16.1 (5.1–50.6)	0.24 (0.16–0.37)	69.9 (30.3–161.3)
>16-slice	0.85 (0.76–0.92)	0.91 (0.88–0.94)	10.0 (5.5–18.2)	0.20 (0.11–0.33)	67.7 (21.2–215.8)

well as the native coronary artery lumen include cardiac motion artifacts, more frequent in the second segment of RCA, and severe coronary calcification [5, 9].

In-stent restenosis remains a limitation for the long-term efficacy of coronary stenting in complex lesions like bifurcation or left main stenting. In case of left main restenosis patient outcome is threatened. Because in-stent restenosis is often asymptomatic, its detection with non-invasive technology, especially when a large amount of myocardium is concerned, is critical and clinically relevant. Proximal or left main in-stent restenosis is easier to assess given the larger diameter of the stents implanted in these coronary segments. Recently, dedicated MSCT studies for in-stent restenosis assessment have suggested that, using the latest generation MSCT, these patients may be suitable for non-invasive angiographic follow-up [26].

Table 3 Quality assessment (QUADAS)

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14
Schuijf, 2004 [14]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cademartiri, 2005 [15]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Kitagawa, 2005 [16]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes
Gilard, 2005 [17]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Kefer, 2006 [18]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Chabbert, 2006 [19]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Watanabe, 2006 [20]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ohnuki, 2005 [21]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Gilard, 2006 [22]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gaspar, 2005 [23]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Van Mieghem, 2006 [24]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rixe, 2006 [25]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rist, 2006 [26]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ehara, 2007 [27]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Oncel, 2007 [28]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Item 1: was the spectrum of patients representative of the patients who will receive the test in practice?
Item 2: were selection criteria clearly described?
Item 3: is the reference standard likely to correctly classify the target condition?
Item 4: is the time period between reference and standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?
Item 5: did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?
Item 6: did patients receive the same reference standard regardless of the index test results?
Item 7: was the reference standard independent of the index test (i.e., the index test did not form part of the reference standard)?
Item 8: was the execution of the index test described in the sufficient detail to permit replication of the test?
Item 9: was the execution of the reference standard described in the sufficient detail to permit its replication?
Item 10: were the index test results interpreted without knowledge of the results of the reference standard?
Item 11: were the reference standard results interpreted without knowledge of the results of the index test?
Item 12: were the same clinical data available when test results were interpreted as would be available when the test is used in practice?
Item 13: were uninterpretable/intermediate test results reported?
Item 14: were withdrawals from the study explained?

Study limitations

As mentioned previously, substantial statistical heterogeneity has been documented, casting caution on the results and interpretation of the estimates of comprehensive, pooled effects, although the use of the random-effects model should still provide relatively robust results. The well-known tendency towards publication bias favoring studies with positive and encouraging results also complicates comprehensive evaluation. In this meta-analysis, data abstraction and quality assessment were done by independent reviewers and, in the case of any divergences, resolution was made by consensus. Thus, the inter-operator agreement could not be quantitatively assessed. We should also acknowledge that not all reports provided details regarding technically important issues like kernel convolution filter use, which has been shown to substantially enhance the stent lumen depiction [6, 31, 34].

Conclusions

In highly selected patients with proximal large stents, the use of the newest MSCT with 64 slices provide adequate diagnostic performance. However, the use of MSCT for the detection of in-stent restenosis has shortcomings difficult to overcome in daily practice and the diagnostic accuracy remains moderate. In the future, the detection of in-stent restenosis might be possible with clinically useful accuracy, but the currently high rate of unevaluable stents does not permit the recommendation of MSCT for stent assessment in unselected patients.

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