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A comparison of angina symptoms reported by clinicians and patients, pre and post revascularisation: Insights from the Stent or Surgery Trial☆

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ABSTRACT

Background: There are limited data comparing the consistency of angina reporting by patients and clinicians.
Methods: We performed a retrospective analysis of data from the randomised Stent or Surgery (SoS) trial. The trial required reporting of angina using the Canadian Cardiovascular Society (CCS) classification by both patients and clinicians at baseline and twelve months. We compared paired observations to describe the magnitude and direction of differences in clinician and patient reporting. The difference in CCS grade was expressed as the clinician minus patient value. We also examined the proportion of trial subjects reported as being free from angina (CCS = 0) in clinician and patient reporting.
Results: Paired CCS data was available for 912 and 887 cases at baseline and 12 months respectively. At baseline, clinicians reported freedom from angina in a single case (1/912 = 0.1%) compared to 70/912 (7.7%) patients (Delta 7.6% 95% CI 5.8 to 9.3, P ≤0.001). At 12 months, the position was reversed, with clinicians reporting 639/887 (72%) angina free compared to 449/887 (50.6%) for patients (Delta −21.4 95% CI −17.1 to −25.8 P ≤ 0.001). For the reported CCS grade at follow-up, the weighted linear kappa for overall agreement was 0.312. Discordant reporting involved the clinician suggesting less angina rather than more (36% v 8% of cases).
Conclusions: These findings have implications for our perception of previous research which has, in the main, focussed on clinician reporting. This emphasises the importance of patient reporting and a need to better understand reasons for discordance.

1. Introduction

Primary outcomes in studies examining revascularisation for coronary artery disease usually report the rates of occurrence of subsequent adverse events. These include mortality, subsequent myocardial infarction and the need for additional unplanned revascularisation.

There has been increasing recognition of the value of Patient Reported Outcome Measures (PROMs) in the evaluation of treatment effect, symptom burden and quality of life [1–4]. There is limited work comparing the reporting of functional improvement by patients and clinicians following coronary revacularisation.

Revascularisation procedures aim to restore or improve blood flow to the heart muscle and include coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI). Revascularisation can have a prognostic benefit in certain patterns of more advanced disease or when performed in the setting of an acute coronary syndrome. Most procedures, however, are performed to reduce angina symptoms [5,6].

Following an extensive literature search, we found only two studies that compared clinician and patient reporting of angina symptoms [7,8]. Neither of these examined the reporting of CCS classification, a measure that is commonly used in clinical practice and trial reporting.

2. Methods

The Stent or Surgery Trial was a prospective randomised controlled trial conducted in fifty-three centres in eleven countries in Europe and Canada. The design paper was published in 1999 [9] and the main results in the Lancet in 2002 [10]. Informed consent was obtained from each patient prior to randomisation. The SoS protocol conforms to the 1975 Declaration of Helsinki. The trial randomised 988 patients over the period 1996–1999. Patients were included if they were believed to have angina and had multi-vessel coronary artery disease at angiography. Patients were excluded if they had a previous thoracotomy or coronary revascularisation procedure. Patients were randomised to either PCI or CABG and were followed for a minimum of twelve months.

The primary outcome measure of the SoS trial was a comparison of the rate of subsequent additional revascularisation between CABG and PCI. Secondary outcomes were the composite of death or Q wave myocardial infarction and all-cause mortality.

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Angina symptoms were reported in terms of CCS class, by clinicians, at baseline and again at 6- and 12-months follow-up (see Table 1b). Angina rating was performed in the context of a face to face visit, by clinical staff trained for this role as part of their trial responsibilities. The descriptors of the CCS scale were presented in the trial CRF as explanatory notes – presented on the facing page of relevant section of the document. Patients - at the same time-points - completed a number of PROM instruments including the Cardiac Health Profile (CHP) which includes the CCS question [11]. The CHP form also included the same descriptors of the CCS scale, but translated into the local language.

This affords a unique opportunity to compare patient and clinician reporting of angina both before and after revascularisation.

2.1. Statistical analysis

This paper is a post-hoc analysis of data from the SoS trial. All analyses were performed using SPSS v 24, except for the weighted linear kappa tests which were performed using the tool at Vasser statistics site [12]. Continuous data have been reported as means and standard deviations or medians and inter-quartile range as appropriate. Comparative tests were two-sided and a p value of ≤0.05 was assumed to indicate significance. All analyses have been performed on an intention to treat basis.

The proportion of trial subjects reported as anginal free by clinicians and patients were compared with McNemar's test. We calculated the 95% confidence interval for the magnitude of the difference both at baseline and at follow up.

The magnitude and direction of any difference between individual pairs of observations was quantified by subtracting the patient score from the clinician score. Descriptive statistics are presented as frequency histograms and the calculation of the mean score and standard error of the mean. The values were compared using a Wilcoxon signed-rank test.

We examined the rates of additional revascularisation in the year after symptom reporting - calculating the confidence intervals with the method of Clopper and Pearson, and comparing the rate between groups using Fishers exact text.

3. Results

The main results of the SoS trial have been published [10] Table 1a reproduces the baseline characteristics of the population, typical for revascularisation studies. There is a predominance of males and the mean age is just over 60 years. There were no important differences between the randomised groups. Table 1a also details both concordant and discordant agreement of CCS between clinician and patient for each demographic category. This aspect if further broken down between baseline and twelve-months. Concordance only relates to paired data.

Fig. 1 describes the trial conduct and patient numbers at baseline and follow-up. We present specific information on the number of individual CCS observations made by the clinician, by patients and the resulting number of paired observations at each time point and for the trial groups created at randomisation. There were 912, 886 and 887 sets of paired observations at baseline, 6 months and 12 months respectively.

Table 1b shows the number and proportion of subjects, at each time point, reported as manifesting each of the 5 possible CCS grades, with results for all recorded observations; for cases with paired clinician and patient information at that time point and, for these paired data, the information for the randomised treatment groups. From these data we can make some key observations. Clinician reporting is more complete than patient reporting. Our use of paired data does not result in substantial data loss, excluding about 6.5% and 7.6% of the clinician reported population at baseline and 12 months respectively. The CCS group proportions are consistent between the individual clinician or patient reported and paired data sets, suggesting that the paired data information is representative of the whole study population.

Similarly, for all groups, a near identical distribution of proportions is seen at the 6- and 12-month follow-up points. Analyses at follow up were performed with the 12-month data but numerical results and conclusions would be representative of the findings at the earlier time point.

The proportion of subjects reported as being free from angina are summarised at Fig. 2. The p-values are derived from McNemar's test. Physicians were reluctant to report freedom from angina at baseline, declaring CCS 0 in a single patient (1/912 = 0.01%). In contrast 70/912 = 7.7% of patients reported this status - Difference (95% CI) = 7.6% (5.8–9.3); p ≤ 0.001. At follow-up the reverse was true with clinicians declaring 639/887 = 70.1% to be free of angina compared to 449/887 = 50.6% of patients - Difference (95% CI) = −21.4% (−17.1 - -25.8); p ≤ 0.001. Fig. 2 also shows the separation of the confidence intervals for the differences and confirms a substantial and significant change in the pattern of reporting from baseline to follow-up.

3.1. Differences between clinician and patient gradings

Fig. 3a shows frequency histograms for the difference in paired scores (clinician minus patient). At baseline there is agreement in just over a third of cases (36%). The linear weighted kappa statistic for overall

Table 1a
Baseline characteristics of patients randomised in the Stent or Surgery Trial [10].

Category	Allocation		Baseline[a]			Twelve months[a]		
	PCI	CABG	Clinician reports LESS angina than patient	Clinician reports MORE angina than patient	Concordant reporting of angina between patient/Clinician	Clinician reports LESS angina than patient	Clinician reports MORE angina than patient	Concordant reporting of angina between patient/clinician
n =	488	500	236	345	330	317	71	499
Men	390 (80%)	392 (78%)	188 (71%)	286 (83%)	250 (76%)	258 (81%)	61 (86%)	395 (79%)
Age (mean, SD years)	61 (9.2)	62(9.5)	60 (8.8)	60 (9.1)	61 (9.5)	61 (9.2)	62 (8.6)	61 (9.4)
Previous myocardial infarction	214 (44%)	234 (47%)	99 (42%)	169 (49%)	140 42%)	160 (50%)	32 (45%)	213 (43%)
Previous cerebrovascular accident	5 (1%)	14 (3%)	6 (3%)	5 (1%)	6 (2%)	5 (2%)	1 (1%)	11 (2%)
Previous transient ischaemic attack	7 (1%)	11 (2%)	7 (3%)	7 (2%)	3 (1%)	3 (1%)	2 (3%)	12 (2%)
Previous peripherical vascular disease	31 (6%)	35 (7%)	9 (4%)	27 (8%)	26 (8%)	22 (7%)	7 (10%)	32 (6%)
Type I diabetes	19 (4%)	9 (2%)	8 (3%)	10 (3%)	7 (2%)	7 (2%)	3 (4%)	11 (2%)
Type II non-insulin dependent diabetes	49 (10%)	65 (13%)	26 (11%)	43 (12%)	38 (12%)	48 (15%)	3 (4%)	56 (11%)
Hypertension	212 (43%)	235 (47%)	102 (43%)	144 (42%)	161 (49%)	131 (41%)	37 (52%)	238 (48%)
Hyperlipidaemia	258 (53%)	251 (50%)	129 (55%)	164 (48%)	178 (54%)	182 (57%)	27 (38%)	252 (51%)
Current smoker	77 (16%)	72 (14%)	29 (12%)	64 (19%)	40 (12%)	47 (15%)	6 (8%)	78 (16%)
Ex-smoker	259 (53%)	286 (57%)	132 (56%)	179 (52%)	196 (59%)	187 (59%)	42 (59%)	268 (54%)

[a] Both baseline and twelve-month data are paired. Therefore, the sum of concordant and discordant will not equal the sum of CABG and PCI cases.

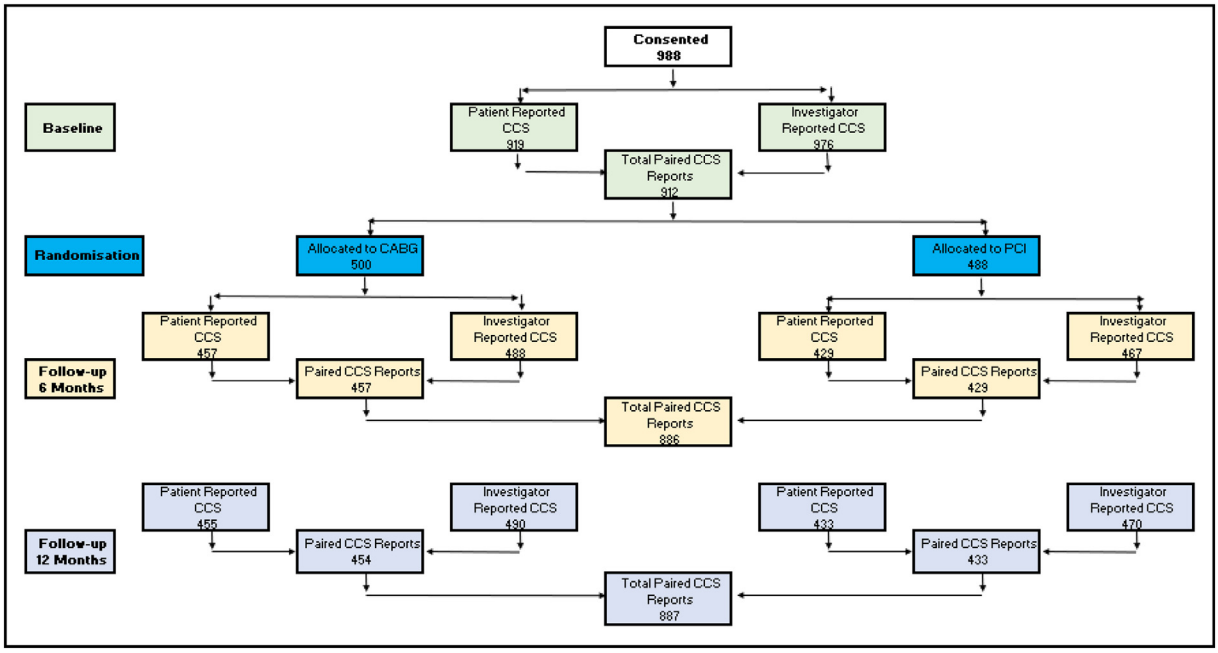


Fig. 1. Patient flow diagram for comparison of CCS score by patient and clinician.

agreement is 0.185. The distribution of the observed differences is near normal suggesting a tendency of the clinicians to report more angina (38% of cases) rather than less (26% of cases).

At follow-up the distribution is very different. There is a greater proportion of paired values declaring the same grade (56% of cases). The weighted kappa for overall agreement is 0.312. The majority with discordant reporting now involves the clinician suggesting less angina rather than more (36% v 8% of cases).

We compared the distribution of the individual differences in the paired value reporting at baseline and 12 months using Wilcoxon Sign Rank test and found this difference to be significant p ≤0.001.

3.2. Subgroup analyses: Impact of randomised treatment type, patient sex and age

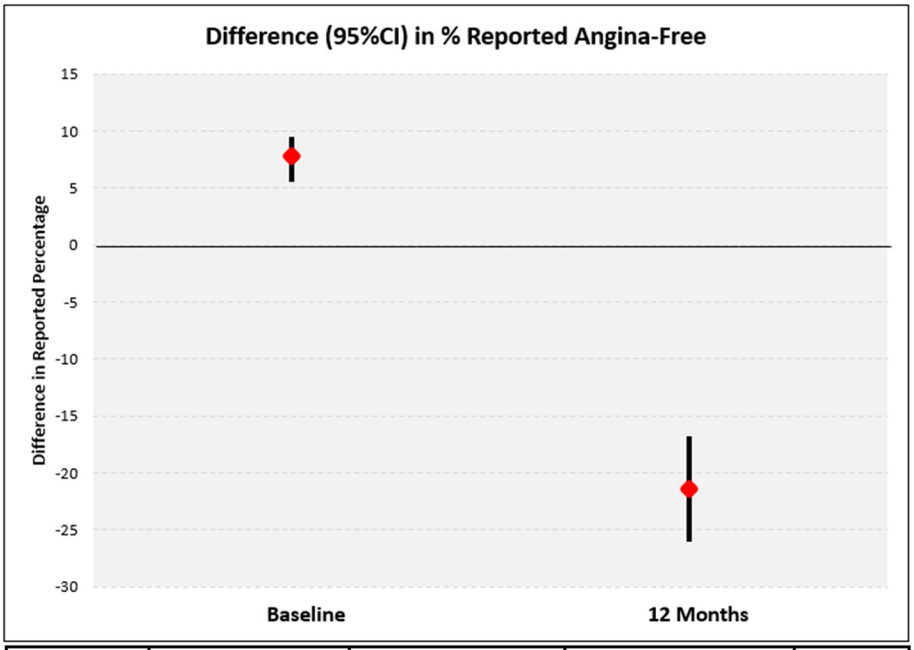
Fig. 3b, c and d show histograms relating to subgroup analyses for the treatment allocated at randomisation, patient sex and age, dichotomised at 65 years. The nature and magnitude of the differences between clinician and patient reporting is consistent across these subgroups.

3.3. The impact of discordant symptom reporting on clinical outcome

We were interested if discordant reporting of angina at 12 months affected mortality and repeat revascularisation over the subsequent 12 months. Table 1c summarises the results. There are too few deaths to compare mortality between the groups. There were more additional revascularisation events, but the absolute numbers are modest and the associated confidence intervals are wide. We note however that, when clinicians report more angina at 12 months, the rate of revascularisation over the subsequent 12 months is higher than for trial subjects with concordant reporting: 7.04% versus 2%; p = 0.036.

Table 1b
Proportion of subjects for each CCS grade as reported by patients and clinicians at baseline and follow-up.

Baseline																
CCS	ALL DATA (unpaired)				ALL DATA (paired)				CABG (paired)				PCI (paired)			
	Patient	%	Clinician	%	Patient	%	Clinician	%	Patient	%	Clinician	%	Patient	%	Clinician	%
	n = 919		n = 976		n = 912		n = 912		n = 451		n = 451		n = 461		n = 461	
0	72	7.8%	1	0.1%	70	7.7%	1	0.1%	29	6.4%	1	0.2%	41	8.9%	0	0.0%
1	187	20.3%	125	12.8%	184	20.2%	118	12.9%	92	20.4%	55	12.2%	92	20.0%	63	13.7%
2	285	31.0%	400	41.0%	284	31.1%	378	41.4%	141	31.3%	177	39.2%	143	31.0%	201	43.6%
3	215	23.4%	248	25.4%	214	23.5%	232	25.4%	107	23.7%	122	27.1%	107	23.2%	110	23.9%
4	160	17.4%	202	20.7%	160	17.5%	183	20.1%	82	18.2%	96	21.3%	78	16.9%	87	18.9%
Twelve months																
CCS	ALL DATA (unpaired)				ALL DATA (paired)				CABG (paired)				PCI (paired)			
	Patient	%	Clinician	%	Patient	%	Clinician	%	Patient	%	Clinician	%	Patient	%	Clinician	%
	n = 888		n = 960		n = 887		n = 887		n = 454		n = 454		n = 433		n = 433	
0	449	50.6%	694	72.3%	449	50.6%	639	72.0%	261	57.5%	358	78.9%	188	43.4%	281	64.9%
1	209	23.5%	178	18.5%	209	23.6%	165	18.6%	92	20.3%	66	14.5%	117	27.0%	99	22.9%
2	160	18.0%	70	7.3%	159	17.9%	66	7.4%	71	15.6%	23	5.1%	88	20.3%	43	9.9%
3	42	4.7%	15	1.6%	42	4.7%	14	1.6%	18	4.0%	6	1.3%	24	5.5%	8	1.8%
4	28	3.2%	3	0.3%	28	3.2%	3	0.3%	12	2.6%	1	0.2%	16	3.7%	2	0.5%



Time-point	Clinician Reported n/d = p%	Patient Reported n/d = p%	Delta (95% CI)	P value
Baseline	1/912 (0.1%)	70/912(7.7%)	7.6% (5.8 – 9.3)	.001*
12 Months	639/887 (72%)	449/887 (50.6%)	-21.4% (-17.1 - -25.8)	< .001*

* McNemar's test

Fig. 2. Difference and associated 95% CI for trial subjects reported as angina-free by clinicians and patients at baseline and at 12 months. Clinicians attribute angina-free status to fewer patients at baseline and more patients at follow-up.

4. Discussion

Our results suggest important differences in the reporting of angina by clinicians and patients, particularly when considered in relation to the timing of the observation - before and after revascularisation. At baseline there is reasonable agreement with a modest over-statement of angina by clinicians. At follow-up this is reversed with clinicians declaring a greater treatment effect than their patients. These findings have clear and important implications for our perception of previous research in this field which has, in the main, focussed on clinician reporting.

The CCS was first described in the literature in 1976 [11] and is a classification of symptom burden and has been used to evaluate patients angina burden (Table 1d). CCS provides distinct grades, from one – the lowest - to four, describing the level of exertion that will induce angina. A grade zero is used to indicate no angina symptoms. CCS has been adopted worldwide [13].

We are not aware of any publications that compared clinicians' assessment of patients' angina burden with the patient's own assessment using the CCS instrument.

Shafiq et al. in 2016 [8] compared patient and physician discordance in reporting symptoms of angina frequency using the Seattle Angina Questionnaire (SAQ). The angina frequency domain of the SAQ was completed in an Outpatients department by patients in respect of the previous four weeks. Following their visit, cardiologists estimated the frequency of the patients' angina. Cohen's kappa was used to assess the degree of agreement. Kappa was 0.48, which was assessed as moderate agreement. This study only examined angina frequency. When patients reported no angina, their cardiologist agreed 93% of the time. In those patients who reported either daily or weekly angina, 26% of their cardiologists noted no angina.

The CADENCE study [14] examined angina frequency in patients attending Australian Primary Care physicians. Patients completed the SAQ detailing angina in five domains (frequency, recent change of symptoms, physical limitations, quality of life and satisfaction with current treatment). GPs completed the CCS and were asked if the patient's angina was 'optimally controlled'. The angina frequency domain of the SAQ was compared with GPs CCS. The primary end-point was prevalence of weekly angina. There was a discordance between GPs and patients' assessment of angina control. The study concluded that physicians often underestimated the extent of angina and its impact on patient's health status. Angina was declared as being optimally controlled even in subjects reporting frequent symptoms.

The Spanish ADVANCE registry [15] in 2012 examined stable angina. Patients completed the SAQ and a second instrument called SF-12, the Short Form Health Survey. Cardiologists reported subjective impressions of the disease and its limitations on patients. The key finding was that, irrespective of the patient reported angina burden, clinicians tended to report less significant symptoms.

In the SoS trial, one inclusion criterion demanded symptoms and hence clinicians would be reluctant to declare CCS 0 as this would be a protocol violation. It is also possible that patients with symptoms at screening had been prescribed additional medical therapy that had taken effect before functional status was reported.

At follow-up patients may report persisting chest discomfort or related symptoms (such as breathlessness) as angina even if the characteristics of the symptoms appear to have a non-cardiac cause when assessed by the clinician. This may suggest a role for more objective evaluation, with exercise testing for symptoms and imaging evaluation for ischaemia. A recent study used formal adjudication for symptom reporting and, interestingly reported anginal rates comparable to those noted in SoS [16].

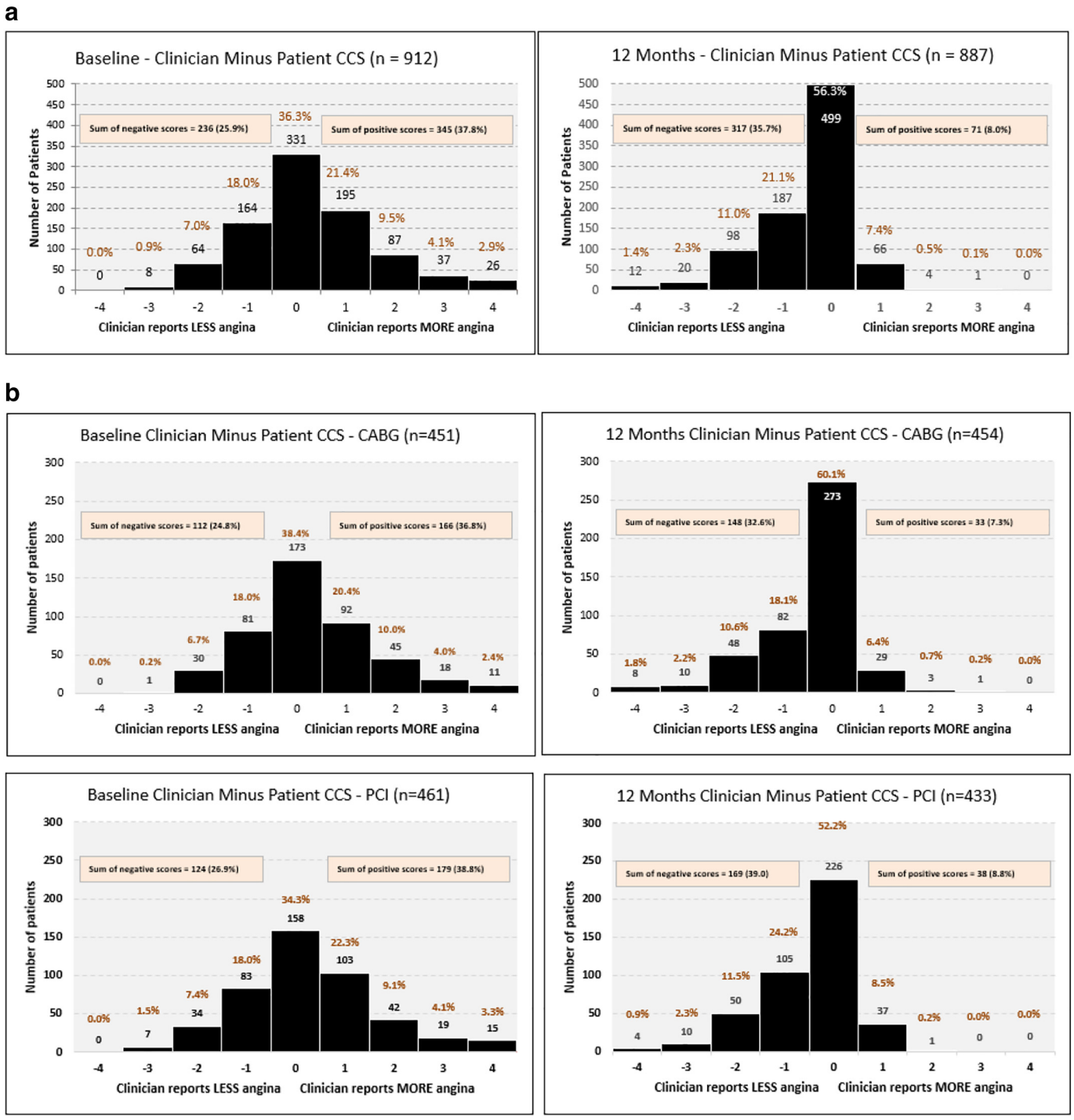


Fig. 3. a: Baseline and 12 months clinician minus patient CCS score, paired data. b: Baseline and 12 months clinician minus patient CCS - split between CABG and PCI randomisation, paired data. c: Baseline and 12 months clinician minus patient CCS, split by patient sex, paired data. d: Baseline and 12 months clinician minus patient CCS, split by age dichotomised at 65 years, paired data.

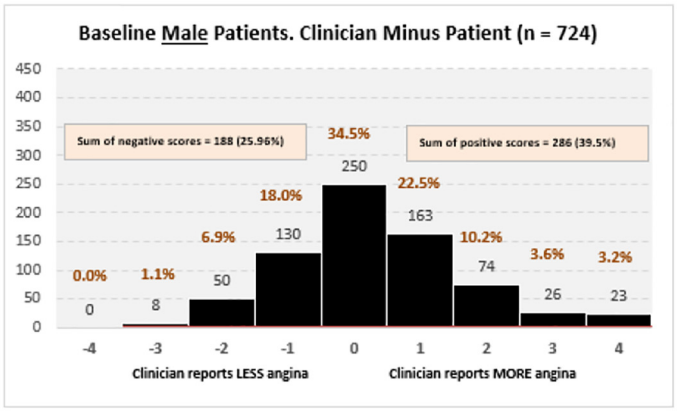
Clinicians may wish to be positive about the results of revascularisation and this may influence their reporting of angina symptoms resulting in a subconscious minimisation of the true symptom burden.

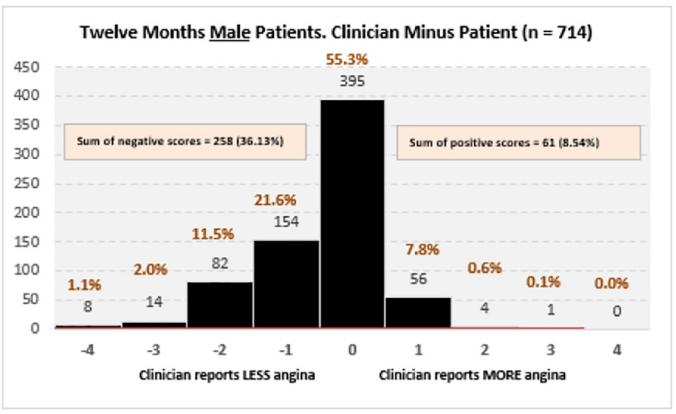
The nature of the consultation process may be suboptimal in terms of setting, time available or in the communication process such that the clinicians do not acquire an accurate perception of the true symptom state.

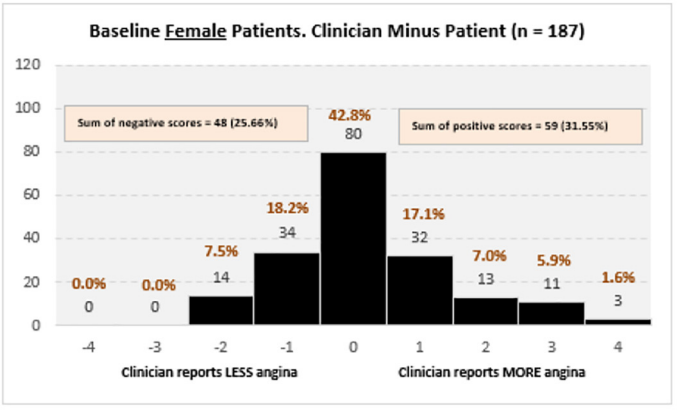
5. Limitations

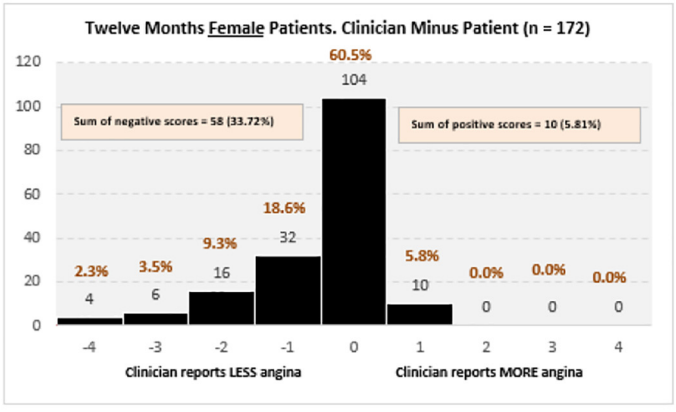
These data are derived from a study conducted about 20 years ago and we cannot be sure that the results would translate to contemporary practice. The specific setting of a clinical trial may have affected reporting as, for example, clinicians - keen to recruit for the study - may have been inclined to report symptoms as this was an inclusion criterion.

c









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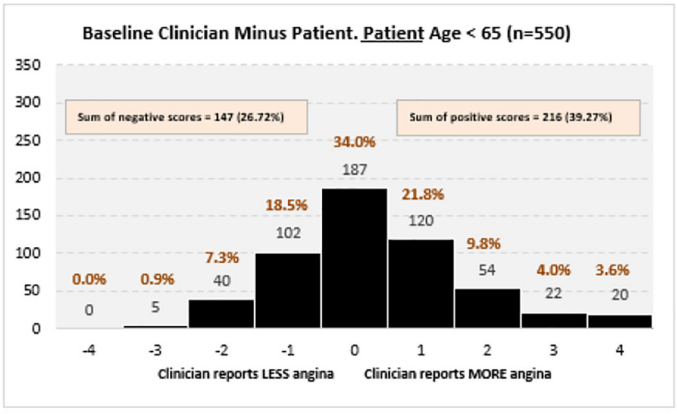

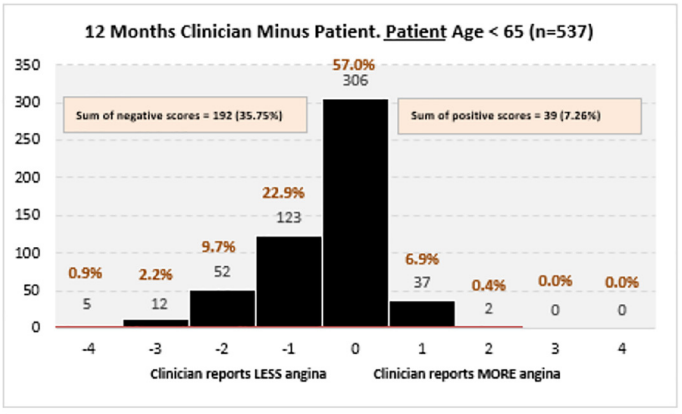

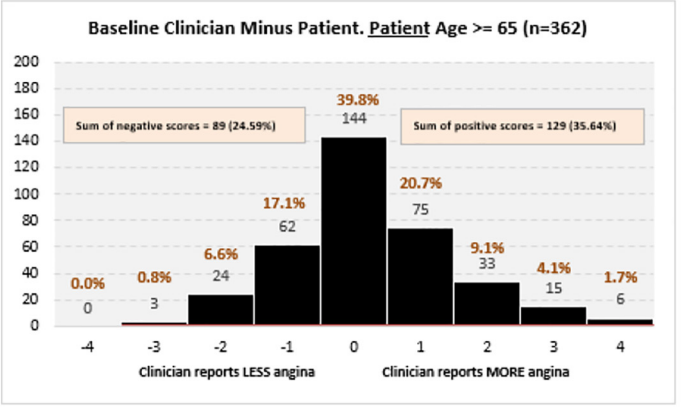

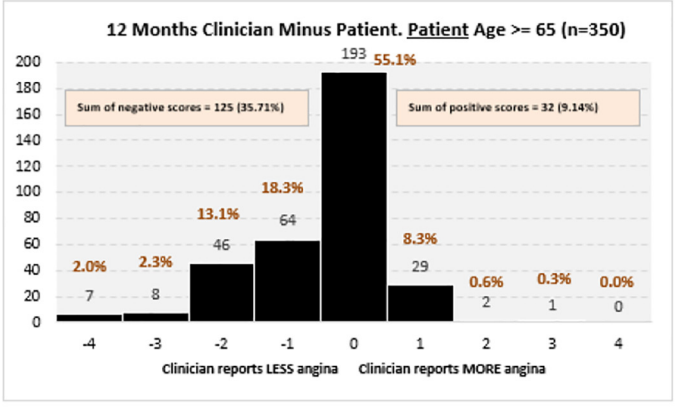

Fig. 3 (*continued*).

Table 1c
Clinical events between 12 and 24 months in patients with concordant and discordant reporting of angina by clinicians and patients.

Angina reporting at 12 months		Mortality	Revascularisation		
Angina reporting group	n	n (%)	n (%)	% (95% CI)	P value
Agreement between clinician and patient	499	5 (1%)	10 (2%)	2% (0.097–3.65)	
Clinician reports more angina	71	0 (0%)	5 (7.04%)	7.04% (2.33–15.67)	0.036
Patient reports more angina	317	2 (0.63%)	10 (3.15%)	3.15% (1.52–5.72)	0.36

The 95% CI has been calculated by the exact method of Clopper and Pearson.
The P values are from Fishers exact test comparing each of the groups with discordant reporting, with the concordant group.

The SoS trial did not involve any protocol directed, symptom-limited exercise testing or other objective tests for ischaemia. This makes it difficult to identify the aetiology of chest discomfort reported at follow-up.

The analyses are restricted to trial subjects with angina reporting by both clinicians and patient, resulting in the exclusion of some of the randomised population. It is reassuring however that the requirement for pairing excluded only about 7% of the original population and that the distribution of reported CCS grades are very similar in the original and study datasets. Patient retention over the 12-month follow-up period was good with 16 patients dying and a further 16 lost to follow-up.

This study uses the CCS classification and limitations of this system have been identified in the literature [17,18]. There are only 4 grades for the description of symptoms and a single grade may describe different types of limitation with an assumption of equivalence. There is only a weak relationship between the scale and anatomic disease or prognosis. We are not aware of any studies that have validated the use of the CCS grading system by patients and we cannot be sure that there will have been a consistent understanding of the explanatory text used in the presentation.

6. Conclusions

The SOS trial was one of the first to report angina status reported in the same terms, by clinicians and patients, both before and after coronary revascularisation. Our results suggest that, when compared to patient reporting, clinicians may declare a modest overstatement of angina at baseline. In contrast, at follow-up, clinicians report a greater proportion of patients to be angina-free and tend to minimise the extent of symptoms in other subjects. It is possible that studies reporting outcomes declared by clinicians may exaggerate the therapeutic effect as perceived by patients. This study emphasises the importance of including patient reported outcomes in evaluating the treatment of coronary artery disease.

Table 1d
Canadian cardiovascular society grading of angina pectoris.

Grade	Description
I	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with prolonged exertion at work or recreation.
II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only in the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Marked limitation of ordinary physical activity. Walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.
IV	Inability to carry on any physical activity without discomfort, anginal syndrome may be present at rest.

Declaration of Competing Interest

None.

Acknowledgements

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