Results of a retrospective mono-centric registry

From Standard Coronary Angiography to Double Rotational Angiography

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Introduction

The coronary CT scan is used, in recent times, for morphological diagnostics of coronary arterial tree pathologies. Its advantage, in relation to the standard coronary angiography (SCA), is of it being non-invasive and being able to be performed on a strict outpatient basis. However this examination delivers radiation and requires non negligible doses of contrast medium. If its negative predictive value is excellent[1], its indications in the diagnostic decision tree are still limited[2].

The invasive coronary angiogram is therefore still kept as the gold standard. This is, currently, a procedure with a low risk of complications but at the same time provides radiation to the patient, to the operator and to the paramedical team and of course requires the use of contrast medium.

In order to advance the SCA, the concept of a dynamic approach, based on rotation of the c-arm during the selective injection of contrast medium, was introduced in 1998 in the evaluation of coronary disease[3]. Recently, the introduction of the flat panel detector, "mechanical" progress of catheterisation tables and progress in terms of IT have allowed for the development of rotational coronary angiography (RCA). Two principle aims have been obtained using this technique: a reduction in radiation dose and a reduction in the quantity of contrast medium.

The aim of this study has been to assess these aims through the use of a new system marketed by Toshiba Medical Systems. In the first year of the system's operation, with technological innovations being progressively installed, we have been able to compare the SCA, the "simple" RCA and the double rotational coronary angiography (DRCA). Variations between operators have also been studied.

Patient selection

Various parameters have been recorded during and after each procedure for 250 patients, such as: Dose Area Product (DAP), fluoroscopy time, the number of images produced, the quantity of contrast medium used, the body mass index, date of birth, and the name of the operator, as well as the associated radiolographic protocols. All of the patients have been listed in a non-selective manner and without exclusion criteria from January 2009 to May 2009. The procedures are therefore sometimes composed of ventriculography, but also of additional examinations such as renal, abdominal, iliac or sigmoid angiography as well as bypass follow-ups.

Retrospectively, all of the additional sequences to coronary angiography, such as those described above, have been subtracted from the totals for the DAP, fluoroscopy time and number of images mentioned above. Only the quantity of contrast medium has not been subtracted, because it has not been registered for each sequence independently.

All of this data has been integrated in to management software of anonymous patient records (UNIMED), and then extracted by means of a request module which has allowed preliminary analysis of this data.

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	DAP (Gy.cm²)		Fluoroscopy duration (min)		Number of frames (n)	
	Average	Min-Max.	Average	Min-Max.	Average	Min-Max.
SCA (n=100)	39.3	4.7-210.65	8.4	0.8-38	575	175-1427
RCA (n=50)	33.64	4.95-85.6	2.8	1.1-26	503	314-836
DRCA (n=100)	24.26	5.74-51.1	3.9	1.3-14	272	127-429

Table I: Doses received by the patient in diagnostic coronary angiography

Techniques

All of the procedures have been performed on the Toshiba Infinix™ CF-i system, installed in April 2008 comprising a single plane floor mounted c-arm, a digital fluoroscopy system pulsed during cardiology applications at 10 images per second, and two acquisition modes (10 and 15 images per second), a four-field flat panel detector (20 x 20, 17 x 17, 15 x 15, 12 x 12 cm), a "Live Zoom" electronic enlargement system for dose reduction, a double collimation/filtration system without the need to emit X-rays (semi-transparent mobile filters and lateral filters), an efficient 100 kW generator interfaced with an X-ray tube consisting of three foci, one of which is of higher energy for obese patients.

100 patients have undergone diagnostics in SCA mode (static acquisitions; 4 projections for the left coronary artery and 3 projections for the right coronary artery), 50 patients in RCA mode (right anterior oblique/left anterior oblique, then craniocaudal) and 100 patients in DRCA mode (right anterior oblique/left anterior oblique combined with craniocaudal).

These procedures have been performed by four operators (3 experienced, 1 junior), and in 100% of cases by femoral access.

The imaging techniques used are variable according to the acquisition method.

In the case of SCAs, the fluoroscopy was performed at a pulse rate of 10 images per second, in a 1024^2 matrix, with a low dose protocol thereby producing a reduction in dose of approximately 30%. In both cases, (fluoroscopy and acquisition), the "Live Zoom" mode was used with a 1.2 factor thereby allowing the largest field (20 cm) to be maintained with the lowest combined dose, whilst having electronic image enlargement equivalent to a field of 17 cm. Additional copper-based filtration (Eq = 0.3 mm) was used in the collimator.

The image acquisitions were also performed at 10 images per second in a 1024^2 matrix.

For RCAs, the fluoroscopy was performed at a rate of 10 images per second, in a 1024^2 matrix, with a low dose protocol thereby allowing a reduction in dose of approximately 30%.

Finally, for DRCAs, the image acquisitions were performed at 15 images per second in a 1024^2 matrix, combined with a rotational speed of the c-arm of 20 degrees per second in the combined axes.

Recorded parameters

The parameters recorded in this study are;

1) the patient's body mass index (BMI);

2) the patient's age; 3) the quantity of contrast medium used; 4) the fluoroscopy time in minutes; 5) the number of radiographic images acquired; 6) the DAP reading in $Gy.cm^2$, recorded by an ionisation chamber located at the exit of the X-ray tube. It must be remembered that the DAP, facilitating the routine measurement, is proportional to the equivalent dose (ED) received by the patient. The commonly used formula is:

ED (in mSv) = 0.2 x DAP (in $Gy.cm^2$).

All of these parameters have been recorded at the end of each procedure in the UNIMED software since the start of the new service in April 2008. Extraction of this data has been carried out thanks to a request application which is integral to the software.

Results

The three examination types studied are:

- 100 patients in SCA: average age 67 years [37-89], 69% men, average BMI 28.5 kg/m^2 [16-40] with 29% presenting with obesity defined by a BMI ≥ 30 kg/m^2.
- 50 patients in RCA: average age 64 years [28-81], 58% men, average BMI 27 kg/m^2 [18-36], of which 40% had a BMI ≥ 30 kg/m^2.
- 100 patients in DRCA: average age 64 years [34-85], 59% men, average BMI 29 kg/m^2 [17-41] of which 33% had a BMI ≥ 30 kg/m^2.

Fig. 1

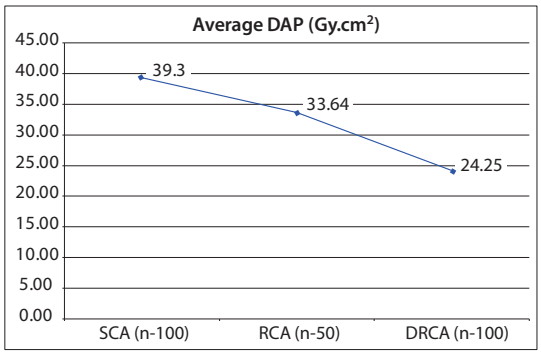


Fig. 2

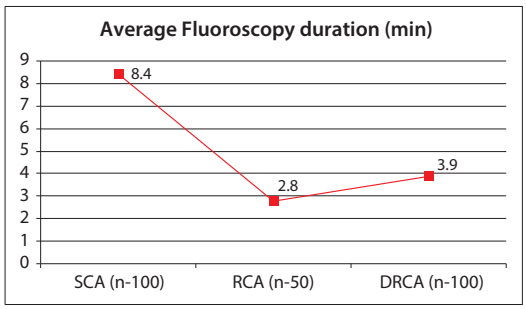
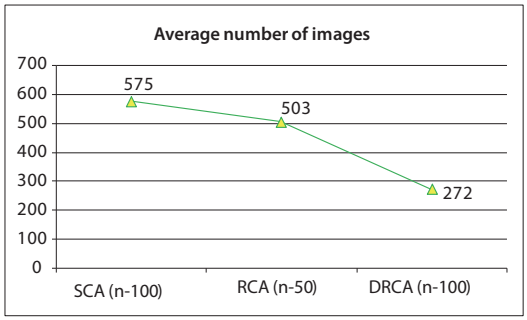


Fig. 3



The exposure data (DAP, time and number of images) for all of the examinations of the three techniques performed between January 2009 and May 2009 are shown in table (I) and figures[1-3].

The following immediate conclusions were seen.

A reduction of the DAP (-14%) according to the difference in technique between SCA and RCA, associated with a reduction in the fluoroscopy time (-67%), the number of images acquired (-13%) and the quantity of contrast medium (-38%).

When using the DRCA, an even more significant reduction of the DAP (-38%), the number of images acquired (-53%) and the fluoroscopy time (-54%) has been shown, whereas the reduction in quantity of contrast medium is shown to a lesser extent (-29%).

This less significant reduction than in the RCA has since been analysed, and the conclusion is that the DRCA requires a more accurate initial adjustment to the isocentre than in RCA. Consequently the fluoroscopy time is slightly increased in relation to the latter (+39%).

The quantities of contrast medium are not able to be determined. Nevertheless, when retrospectively analysing a sample from a patient who has only undergone a SCA, without any other additional procedures, it has been shown that 41% of patients who have undergone a coronary angiography in DRCA have received an average quantity of contrast medium of 53 ml [24-110].

A second analysis has been carried out on the irradiation of patients according to the user, comparing only the SCA and DRCA techniques.

The exposure data (DAP, fluoroscopy time and number of images) for all of the examinations of the two techniques are shown in tables (II) and (III).

	SCA				
	Examination	BMI (kg/m²)	No. Images	DAP (Gy.cm²)	Fluoroscopy time (min)
Operator 1	25	32.01	622	36.87	5.65
Operator 2	30	29.81	502	34.88	6.29
Operator 3	23	32.41	787	61.12	6.37
Operator 4	22	29.13	473	41.87	6.40

Table II: Doses received by the patient in standard diagnostic coronary angiography per operator

DRCA					
	Examination	BMI (kg/m²)	No. Images	DAP (Gy.cm²)	Fluoroscopy time (min)
Operator 1	24	30.52	282.00	23.90	3.26
Operator 2	34	30.44	279.00	21.49	4.61
Operator 3	21	29.17	287.00	25.87	4.59
Operator 4	21	31.78	313.00	25.87	4.82

Table III: Doses received by the patient in double rotational diagnostic coronary angiography per operator

SCA versus DRCA				
	No. Images	DAP (Gy.cm²)	Fluoroscopy time (min)	Contrast (ml)
Operator 1	-340 -54.7 %	-12.97 -35.2 %	-2.39 -42.3%	-41 -31.3%
Operator 2	-223 -44.4 %	-13.39 -38.4 %	-1.68 -26.7%	-21 -22.3%
Operator 3	-500 -63.5 %	-35 -57.7 %	-1.78 -27.9%	-18 -12.7%
Operator 4	-160 -33.8 %	-16 -38.2 %	-1.58 -24.7 %	4 3.6 %

Table IV: Comparison of the doses received by the patient per operator

The number of procedures and the patient data were homogeneous for the four operators. The senior users are numbers 1 to 3 and the junior user is number 4.

The comparative results of the exposure data (DAP, fluoroscopy time and number of images) for all of the examinations of the two techniques are shown in table IV. Taken as a whole, for the four operators, the DAPs shown are clearly, significantly reduced.

The average values show a reduction in the number of images acquired (-54.7%) for operator no. 1 (experienced), associated with a reduction of the DAP (-35.2%) and of the fluoroscopy time (-42.3%). Operator no. 2 (experienced) records a reduction of the number of images to a lesser extent (-44.4%), the DAP (-38.4%) and also of the fluoroscopy time (-26.7%). This lower reduction is explainable by the fact that this operator had already been using the minimum values during the SCA, and therefore the decrease values are lower than those shown for the other operators. Operator no. 3 (experienced), has reduced by a very significant extent the number of images acquired (-63.5%) as well as the DAP (-57.7%), and the fluoroscopy time (-27.9%). Operator no. 4 (junior) has also reduced the number of images acquired (-33.8%), the DAP (-38.2%) and the fluoroscopy time (-24.7%).

Although the data collected shows that there is a reduction in the quantity of contrast medium in DRCA, it turns out that for operator no. 4, this value has increased very slightly (+3.6%) without having been able to determine the cause.

Discussion

The results obtained by comparing the two techniques (SCA and DRCA) shows a very clear significant reduction of the fluoroscopy time (-54%) and the number of images acquired (-53%). We would have thought that the DAP values would be reduced in similar proportions, but this reduction is less (-38%); this is primarily linked to the fact that the source-detector distance is increased in order to allow consistent and reproducible rotation around the patient with respect to the isocentre and with no risk of collision. In coronary angiography it is not so much the impact of the fluoroscopy time rather the impact of the acquisition time (number of frames) which shall determine the impact on the DAP. It is useful to remember that the

dose per image is eight to ten times greater in acquisition mode compared to fluoroscopy mode. Consequently we can assume that a reduction of the DAP is associated, on average, to the same reduction factor only in acquisition for similar protocols. This is observed in the technique of RCA where the reduction of the number of images acquired (-14%) in relation to the SCA, is directly linked to a reduction of the DAP (-13%) whereas the fluoroscopy time is reduced drastically (-67%).

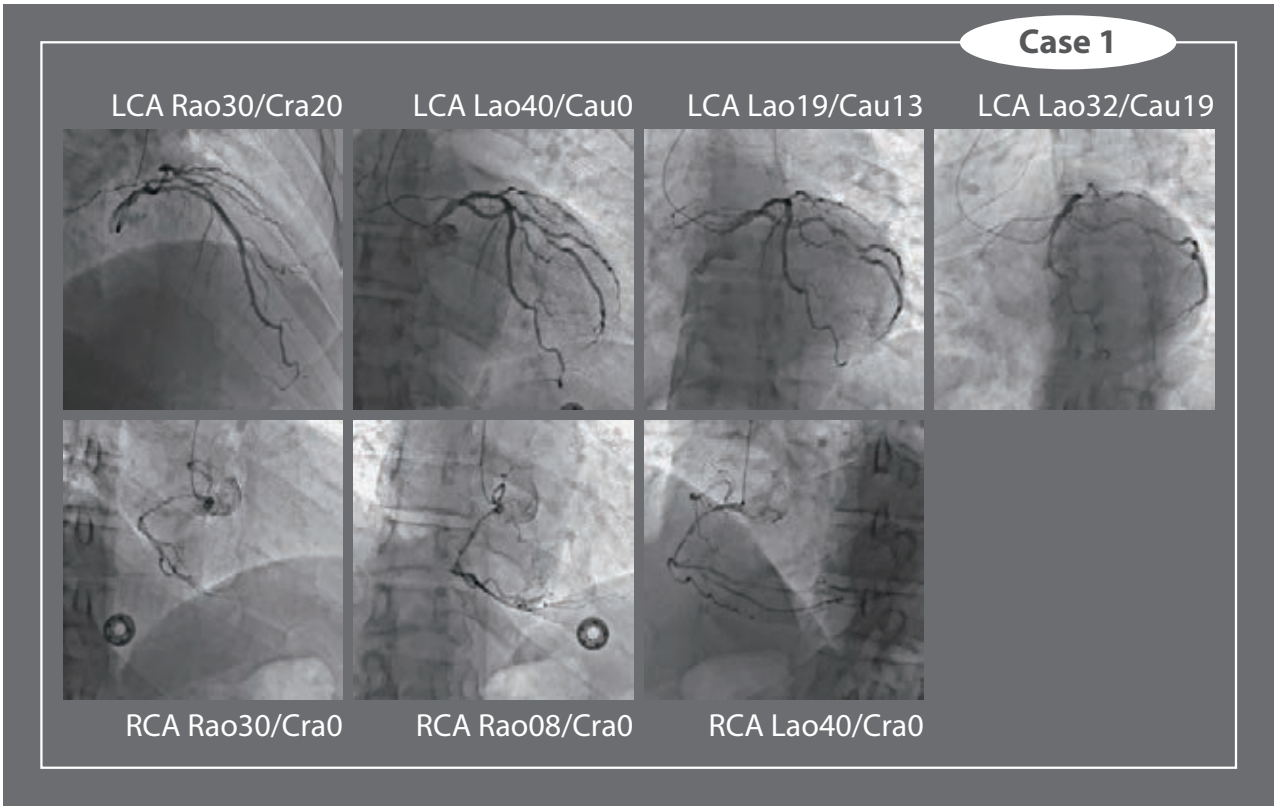
In SCA it is well known that the total dose of the procedure is linked to a certain number of factors including the duration of radiation exposure (fluoroscopy and acquisition), number of images, type of projections, magnification factor and use of collimation / filtration. The introduction to the market of flat panel detectors, in relation to the classic image intensifier, should certainly not mean that these inescapable principles of radiation protection are forgotten. With regard to the staff performing the procedure the same principles are still current, therefore they must combine, in terms of radiation protection, the use of combined classic systems, if possible, with the new injection systems (ACIST or MEDRAD) which allow the operator to be at a safe distance in relation to the X-ray tube.

As shown we can observe, on average, a very clear reduction of the DAP going from SCA to RCA and finally to DRCA. Furthermore the level of contrast medium used between SCA and DRCA is also significantly reduced.

If we look at the results per operator, operator no. 3 gives significantly more exposures in SCA than the other three; as the technical characteristics of the procedure are the same, this is only linked to the number of projections preferred by this operator for their diagnostic interpretation.

In DRCA, we see a consistency of the DAP between the various operators but this result is a little "artificial" given they use the same protocol of two double rotational acquisitions on the left coronary artery and the double rotational acquisition on the right coronary artery.

If we refer to the "PDS GACI 2006" survey on dosimetry in interventional cardiology carried out by Bar and Maccia, the average value of the DAP in SCA is 56 Gy.cm^2 (5-291 Gy.cm^2). The diagnostic reference level in Europe is 57 Gy.cm^2. We can record that in our centre, the average DAP, whether this is in SCA, RCA or DRCA, is very much lower than this reference value and the average value of the GACI survey; this difference is going to, of course, be more significant when going from SCA to DRCA (cf. table I). Our centre had participated in the GACI 2006 survey; the same operators worked, at that time, in a room with an image intensifier. In 2006 the average DAP, with the same operators, was 54.6 Gy.cm^2 in SCA. We therefore observe a very significant reduction of the average DAP in SCA between the use of the catheterisation room in 2006 and that mentioned in this register (54.6 Gy.cm^2 versus 39.3 Gy.cm^2). Without mentioning the dynamic possibilities of the rotational coronary angiography, this very clear reduction is linked to the technological possibilities that are currently available and to the optimised use of these features during

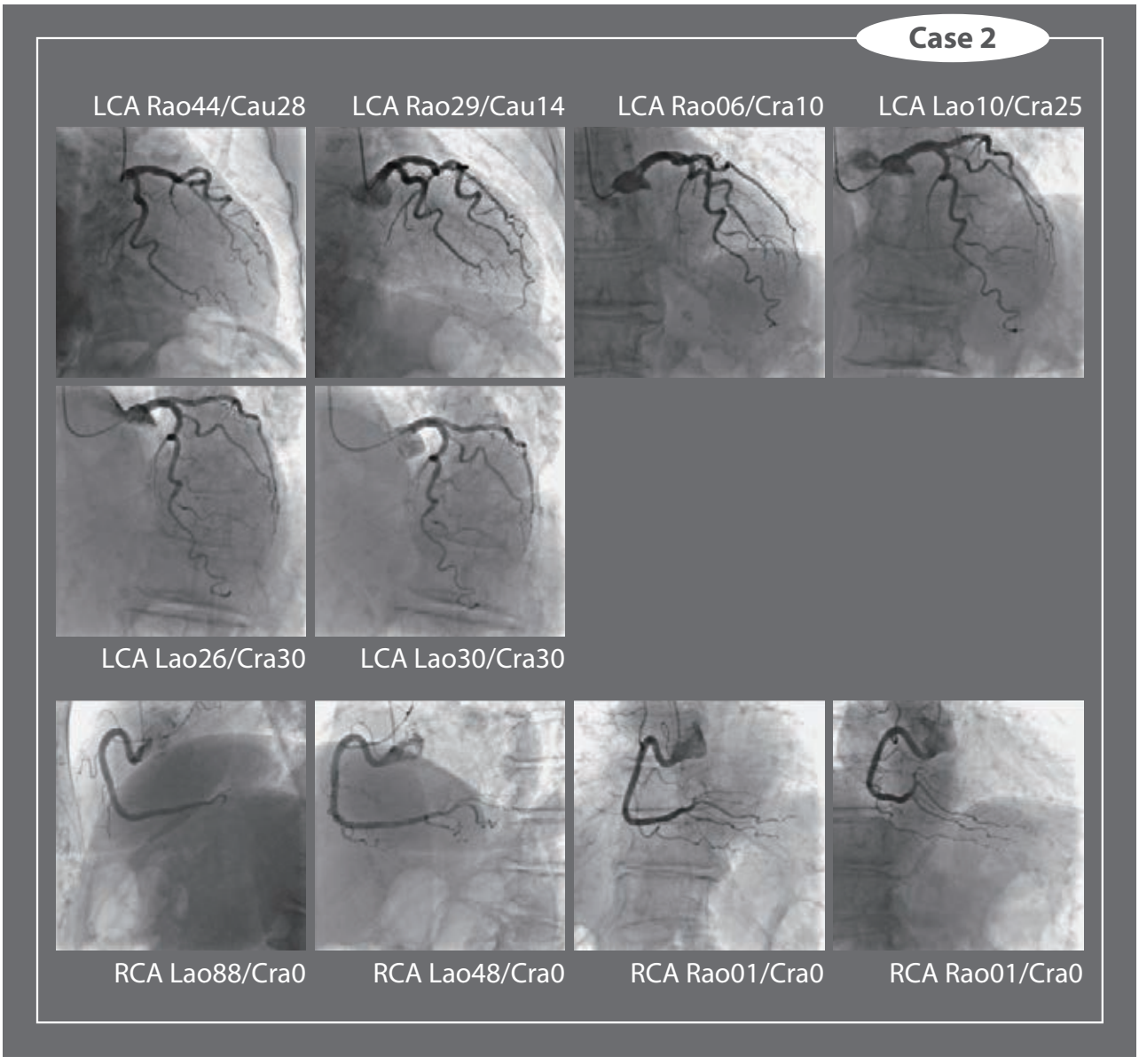


procedures. It is important to remember that for every new catheterization room, and regardless of the staff involved, the initial parameters are "factory-set" and require adapting, on site, according to the usual departmental working directives, imaging preferences of the operators, type of patients, and any other local criteria.

All of the procedures have been performed using femoral access. We see that for certain authors[4] radial access would constitute giving more radiation exposure.

However the data from the literature corroborates the results previously described. A randomised trial[5] SCA versus RCA concluded in a reduction of contrast medium by 33% (52.8 versus 35.6 ml) and a reduction of the DAP by 28% (53.9 versus 39 Gy.cm^2). Another randomised trial of the same type[6] finds a reduction of 36% of the DAP and of 33% of the total dose of contrast medium in favour of the RCA. A third randomised trial[7] shows a reduction of 40% for the contrast medium but the lack of a difference in terms of the DAP; this is explained by the authors as being linked to a drastic optimisation of the SCA prior to the use of the RCA.

Another limit of our study is the absence of a quantifiable comparison of the lesions between SCA and DRCA but this would of course have required that a double procedure be performed for each patient (SCA and DRCA). This has been performed in a trial[8] which shows very good comparability in terms of finding evidence of coronary lesions and in terms of quantification of these; moreover we again find the same evidence in a trial which has previously been cited[6]



Conclusion

The use of the technological possibilities of the current catheterisation rooms allows a reduction, which is significant, concerning the exposure dose to the patient in SCA mode. In an even more significant manner, this reduction in exposure dose and the reduction of contrast medium are more pronounced in DRCA mode if this can be used exclusively. It remains to be determined what type of patients can benefit from a DRCA exclusively as a replacement to the SCA and / or to supplement this SCA. The dynamic rotational coronary angiography is evidently a new advanced technology but, the arrival of real time three-dimensional coronary angiography has not yet arrived.

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