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Current utilization of cardiac computed tomography in mainland China: the first national survey

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Highlights

1. This work is the first nationwide cardiac CT survey in China mainland, and probably the first analogous survey conducted by random sampling manner worldwide.
2. Authors managed an extensive investigation on each routine component of cardiac CT examination in terms of current CT apparatus, indications, imaging acquisition techniques, contrast media protocols, image reconstruction and interpretation, and clinical challenges. Thereby, an overall picture of current cardiac CT utilization in China was drawn.
3. This survey was sponsored by China International Regional Committees of Society of Cardiovascular CT (SCCT China IRC), which conformed to the duty of SCCT.

Background Surveys referring to the utilization of cardiac computed tomography (CT) were available in the United States, Germany and Taiwan, but not in mainland China.

Objectives To understand the clinical utilization of cardiac CT in mainland China.

Methods A 25-item questionnaire was designed by Society of Cardiovascular

Computed Tomography China International Regional Committee (SCCT China IRC)

Representatives. 240 hospitals were randomly chosen from all the level A & B

tertiary hospitals listed in an official report. Survey data were collected by interview,

and double checked by phone and email to providers.

Results 237 (98.8%) hospitals consented to this survey, but 85 were dropped due to

lack of advanced CT scanners or lack of volume. 152 (64.1%) questionnaires were

available for analysis. The most common indications for cardiac CT angiography at

each hospital was exclusion of coronary artery disease in patients with low-

intermediate pretest likelihood (100%), asymptomatic people with cardiovascular risk

factors (95.4%), and follow-up after coronary bypass grafting (66.4%). Each center

examined on median 1,037 patients (range 150-8,072) annually. Beta-blocker was

administered on a median heart rate threshold of >70 beats/min. Most (86.2%) used

sublingual nitroglycerin. Prospective ECG triggering acquisition was the predominant

technique in 44.1% of hospitals. Many (59.2%) providers adjusted the tube current to

the body mass but few (15.8%) adjusted the injection rate of contrast agents. The

mean examination and post-processing time per case were 14.2 min and 13.6 min,

respectively. Reporting took an average of 18.0 min per case.

Conclusions Cardiac CT has rapidly become established in clinical practice in mainland China, though needs to be more uniform in application and performance across the country.

Introduction

Computed tomography (CT) has been evolving since its birth 4 decades ago, and it is impossible to imagine current clinical practice without CT imaging. CT angiography is a relatively novel technique, with a history of ~20 years, which was born through a marriage of spiral CT and graphical volumetric image processing¹. Among organs or sites, coronary CT angiography (CCTA) is the most technically challenged, and is far more complicated than simply modifying the acquisition parameters and contrast infusion protocols for an anatomic region². Human hearts are in constant motion. A good CCTA acquisition requires a controlled heart rate, a regular heart rhythm, and carefully timed coronary enhancement during maximal arterial perfusion and minimal cardiac motion. After that, post-processing is conducted to optimize the evaluation of each coronary segment using multiple reconstruction techniques. Lastly, certificated cardiologists or radiologists interpret all the axial and reconstructed images and sign the reports^{3,4}. The same procedure happens everyday in China and the United States, but there are differences in the practice patterns for each component of CCTA examination among countries. Johnson and Maurer independently launched nationwide investigations in the United States and Germany years ago, but utilization and interpretation techniques were still not well delineated in China^{2,5}. China is the most populous nation on earth, and carries the heaviest burden of cardiovascular diseases⁶. According to an official report released by the National

Center of Cardiovascular Diseases (NCCD) during 2015 China Heart Congress held in Beijing, there were 270 million patients with cardiovascular disease in China⁷.

Chinese cardiovascular radiologists must do their part in this battle against cardiovascular diseases, but current utilization of cardiac CT scanners is not well known. The first 64-rows CT scanners in China (not including Taiwan, Hong Kong and Macao, similarly hereinafter) were installed in 2005, and now the estimated premium CT (64 rows or above) scanners number more than 3 thousand⁸. However, there is inadequate data, if not vacant, to demonstrate the amount of CCTA scans, indications, acquisition techniques, contrast media protocols, interpretation duration, and even radiation dose in China.

Based on the above considerations, it was necessary to launch a national survey concerning the utilization of cardiac CT in China, of which the China International Regional Committees (IRC) of Society of Cardiovascular CT (SCCT) was the eligible organizer. SCCT China IRC was established in February 2013, which was set up to promote cardiovascular CT and the objectives of SCCT in our region⁹. As it was the first nationwide survey, we attempted to buildup China's CCTA information database including the level of methodology behind each scan, and compared with the previous reports in other countries^{2,5}.

Methods

This investigation was deemed exempt by the institutional review board of our hospital. A 25-item questionnaire was designed by SCCT China IRC Representatives (Table 1). A preset question (No. 0) was authentication information, including the respondent's name, position, contact, and hospital. The first question was whether there was at least one premium CT scanner in the hospital: if no, the survey was

ended as premium CT scanners are a pre-requisite for CCTA. Questions No. 2 was whether the CCTA procedures were over 100 in the last 12 months: if no, the survey was not continued as the hospital was assume to be less experienced. The remaining questions pertained to the facility the radiologists work in (teaching or non-teaching hospital), the indications for cardiac CT, patient preparation (e.g., administration of sublingual nitroglycerin or beta-blocker, breath-hold test), and technical aspects of the “double low” (radiation and iodine) protocols (e.g., gland shield, prospective triggering, tube current adjustment, contrast agent administration). The last 7 questions (No. 19-25) referred to the storage and interpretation of cardiac CT data sets (e.g., overall duration), and the future needs for cardiac CT.

Hospitals in China are organized according to a 3-tier system designated as primary, secondary or tertiary institutions that recognize a hospital's ability to provide medical care, medical education, and conduct medical research. Based on the level of service, size, medical technology, medical equipment, the 3 tiers are further subdivided into 3 subsidiary levels: A, B and C, resulting in a total of 9 levels¹⁰. The procedure for choosing our sample size as well as the list for hospitals to be surveyed started from analyzing a list of all the tertiary hospitals in China, because the survey mainly focused on CCTA scans, primary and secondary hospitals would not be applicable. Therefore it was determined that the most likely group of hospitals to meet the requirements were the level A & B tertiary hospitals (designated as *LABEL* hospitals) from this list of hospitals gathered by the National Health and

Family Planning Commission (NHFPC) of China, making the population size of the experiment 1,442¹¹. It was determined that a sub-sampling of the population is needed in order to make the study practice with limited resource. For a finite population, the sample size, s , can be calculated based on the following equation: $s = s'N/(s' + N - 1)$ with $s' = Z^2 p(1-p)/c^2$, where $N=1,442$ as the population size, Z was the Z-Score, p was the standard deviation, and c stood for the margin of error. The desired confidence level for this study was selected to be 90% which meant $Z=1.645$. Since no prior knowledge was available, a p value of 0.5 was selected which was a conservative estimation to ensure the sample size was sufficient. c was willing to undergo 5%. Based on the above assumption, the required sample size was determined to be 228. Given the varying economic and population levels in China's provinces, the sample size needed to be split evenly among the different provinces based upon the number of *LABEL* hospitals located in, guaranteeing that each province had at least one representative hospital. The final sample size ended up being 240 due to a buffer (5%) being added in case of absent response to the survey from a hospital, which was believed to adequate to make our results universal and convincing. At last, a notarized random sampling was taken.

Under directions of SCCT China IRC, this survey was done during December 2014 to February 2015. Our respondents were either the directors of CT departments or their deputies with authentication. The numbers of CCTA procedure amount were obtained exactly from Picture Archiving and Communication System (PACS) if available or from an estimated value which was confirmed by another senior

radiologist (>10 years experience) if PACS was not available, with a maximum expected error of 50 scans/year. As an incentive for completing the questionnaire, 10 copies of an educational book *Coronary CT Angiography Manual* (Chinese version translated by authors, original English version by Robert Pelberg and Wojciech Mazur, Springer 2007) were offered as gifts to all respondents. Questionnaires were collected by either the marketing team of GE Healthcare China (83.5%) or SCCT China IRC representatives (16.5%), but 30% (60/198) forms provided by GE were randomly picked and checked by SCCT China IRC representatives via telephone, email or Wechat (Tencent Inc., Shenzhen, China) to clear the suspicions of commercial bias.

Results

Hospitals and CCTA procedure volumes

Two hundred and forty hospitals were nominated through random drawing, but 3 were unwilling to cooperate. After the Question 1 & 2, 69 (29.1%) hospitals were dropped due to lack of premium CT and 16 (6.8%) because of inadequate CCTA volumes (<100 scans per year). Finally, 152 (64.1%) LABEL hospitals were surveyed (Figure 1). The median CCTA procedure volume of the valid hospitals was 1,037 (range 150-8,072), which was somehow linear distribution at the index of 2 if the independent variable was the order of the volumes (Figure 2A).

CCTA indications

With regard to the inpatient/outpatient proportion, CCTA examinations were performed mostly ($\geq 90\%$) for inpatient in 17.8% (27/152) hospitals, often (50%-89%) for inpatient in 36.2% (55/152) hospitals, sometimes (11%-49%) for inpatient in 37.5% (57/152) hospitals, and occasionally ($\leq 10\%$) for inpatient in 8.5% (13/152)

hospitals. Further, the proportions of inpatient decreased as hospital volumes increased.(Figure 2B).

The indications of CCTA were for the exclusion of coronary artery disease (CAD) in patients with a low to intermediate likelihood of disease by 100% of centers (152/152), for screening to rule out CAD in asymptomatic patients by 95.4% (145/152), for follow-up of patients with coronary bypasses by 66.4% (101/152), for the exclusion of coronary anomalies by 64.5% (98/152), for evaluation for pericardial disease by 38.8% (59/152), for follow-up of patients with coronary stents by 28.3% (43/152), for diagnosis of CAD in patients with a high pretest likelihood by 21.1% (32/152), and for triple rule-out by 18.4% (28/152, Table 2).

CT acquisition technique & radiation dose

Beta-blockers were routinely used by 30.3% (46/152) hospitals regardless of the heart rates before CCTA scanning, and administered based upon heart rate limits in the remaining, i.e., ~70bpm (65-74) by 37.5% (57/152) hospitals, ~80bpm (75-84) by 22.4% (34/152) hospitals, and ~90bpm (85-100) by 9.7% (15/152) hospitals (Figure 2C). Routinely administration of sublingual nitroglycerin prior to cardiac CT was reported by 86.2% (131/152) of respondents. In all the hospitals (100%), patient's breath-hold capacity was tested before the scan. The majority (63.2%, 96/152) of respondents stated that they did not perform cardiac CT in patients with atrial fibrillation at all, 23.0% (35/152) did conditionally, and 13.8% (21/152) stated they did as a routine (Figure 2D). The tube current was adjusted to the patient's body weight or body mass index by 59.2% (90/152, Figure 2E), while 80.9% (123/152) shielded thyroid or genitals with lead apron.

Prospective electrocardiogram (ECG) triggering acquisition was widely adopted ($\geq 90\%$) in the daily scanning by 13.2% (20/152) hospitals, often adopted (50%-89%) by 30.9% (47/152) hospitals, sometimes adopted (11%-49%) by 46.0% (70/152) hospitals, and occasionally adopted ($\leq 10\%$) by 9.9% (15/152) hospitals (Figure 2F). Three eighth (37.5%, 57/152) hospitals had experiences of novel CCTA techniques, viz. GE single shot snap, Siemens high-pitch, or Toshiba ^{SURE}Cardio Prospective, but only 15.1% (23/152) believed them to be practical. Regarding iterative reconstruction algorithms, it was encouraging that 82.2% (125/152) hospitals used these protocols, but it was only 30.3% (46/152) believed them to be useful. Radiation dose is an unavoidable issue for CCTA. In our survey, 15.8% (24/152) hospitals chose $>15\text{mSv}$ as the modal value of radiation dose, 42.1% (64/152) chose 10-15mSv, 31.6% (48/152) chose 6-9mSv, 10.5% (16/152) chose 3-5mSv, and no hospitals chose $<3\text{mSv}$ (Figure 2G). The median dose among all the *LABEL* hospitals was 10-15mSv, but after adjusting by CCTA volume, the median dose among Chinese patients was 6-9mSv (Figure 2H).

Contrast media

Contrast media suppliers in China can be divided into two categories, domestic manufacturers and foreign/joint ventures. The former included Beijing Beilu Pharmaceutical, Yangtze River Pharmaceutical, Jiangsu Hengrui Medicine, and so on; the latter were mainly represented by Bayer Schering Pharma, Bracco Sine Pharmaceutical, and GE Pharma. We investigated the market shares of domestic and foreign holding vendors, and found that 28.3% (43/152) hospitals used almost all

(≥90%) foreign products, 28.9% (44/152) used more than half (50%-89%), 21.1%

used less than half (11%-49%), and 21.7% used few (≤10%) foreign agents. Only about one sixth of centers (15.8%, 24/152) stated that they adjusted the

injection rate based upon the patient's body weight or body mass index. Over 97%

use biphasic or triphasic injection protocols for contrast injection. Principally biphasic

represented 74.4%, (113/152), followed by triphasic (23.0%, 35/152) and uniphasic

(2.6%, 4/152, Figure 2I)¹².

Images storage, interpretation and reporting

95.4% (145/152) of respondents stored image data in PACS, and the other 4.6%

(7/152) stored on compact disks. The estimated average duration of a CCTA

examination was 14.2 minutes (median 15 min; range 5–30 min, Figure 2J). The

average post-processing time was 13.6 minutes (median 15 min; range 5–25 min,

Figure 2K), and the duration required for interpretation and reporting was 18.0

minutes (median 20 min; range 8–30 min, Figure 2L). Only 30.3% (46/152) of the

centers reported that they also evaluated pulmonary structures and other non-

cardiac structures, and the remainder stated that CCTA was scanned using a large

field of view but did not include a lung sequence. In most (80.9%, 123/152) hospitals,

the coronary artery calcium scores, Agatston scores were not calculated, instead the

degrees of calcification, i.e., mild, moderate, and severe, were reported.

Clinical challenge

The last question was open, referring to the current challenges of performing CCTA.

The most frequent answer (92.8%, 141/152) was “less sophisticated scanner and/or

software”, followed by “time consuming” (67.8%, 103/152), “indifference and/or

mistrust of physicians” (55.9%, 85/152), “less patients” (48.7%, 74/152) , “inadequate

and/or uncertain diagnostic information” (44.7%, 68/152), “high radiation dose”

(29.6%, 45/152), “less training” (25.7%, 39/152), and “high price” (19.1%, 29/152).

One third (51/152) of respondents talked about the unbalanced development among hospitals, which meant economic developed regions and provincial capital cities utilized more medical resources, either by more advanced scanners or experienced radiologists.

Discussion

To our knowledge, this work is the first nationwide cardiac CT survey in China mainland, and probably the first analogous survey conducted by random sampling worldwide. Developed by SCCT China IRC, the authors managed an extensive investigation on each routine component of cardiac CT examination in terms of current CT apparatus, indications, imaging acquisition techniques, contrast media protocols, image reconstruction and interpretation, and clinical challenges. This study establishes an overall picture of current cardiac CT utilization in China. China is a government-dominated country with a vast territory, so it is difficult to conduct a nationwide survey without administrative directives. Chinese Society of Radiology (CSR) is one of the primary branches of Chinese Medical Association, the biggest and most orthodox academic organization with official background, and ideally should act as the originator of this survey. However, it was deemed to be too costly to have CSR administer this survey, as the optimal way in China to get convincing data is face-to-face interview, and the travelling expenses alone will be cost prohibitive. Moreover, cardiac CT is still a niche specialty in China. At this point, SCCT China IRC offered to take the responsibility, took advantage of his their members, and achieved the initial aim at a very low expense.

SCCT released the appropriate use criteria for cardiac CT in 2010, and two guidelines for the interpretation and reporting of CCTA in 2009 and 2014^{3,4,13}.

Authors, members of CSR cardiothoracic group, published a Chinese CCTA guideline in January 2011 in the form of expert consensus. These files played a significant role in promoting the normative development of cardiac CT in China.

Nevertheless, the survey results suggested that the utilization of cardiac CT was still limited in China mainland.

First, cardiac CT scanners were not uniformly available. Although our target

hospitals were of the highest level in China, one third of candidate hospitals did not own one premium CT scanner. The *LABEL* hospitals were all public, thus to obtain

such an expensive scanner via government procurement was less likely. Besides,

part of the *LABEL* hospitals were cancer hospitals, children hospitals, maternity

hospitals, mental hospitals and traditional Chinese medicine hospitals, and as such,

cardiovascular diseases were not their major concern.

Second, several of the CCTA indications used by these hospitals were considered

generally inappropriate by guidelines. For example, 95.4% of respondents stated

that they performed CCTA in clinically healthy people, which was conflict to the latest

criteria¹³⁻¹⁸. The common view of appropriateness criteria for cardiac CT is to detect

asymptomatic coronary artery disease with intermediate pretest likelihood and

suspected coronary anomalies, though few experts deemed that CCTA could be

used as a screening test^{19, 20, 21}.

Third, the radiation dose was still high. Hausleiter *et al* reported the dose reports

from the PROTECTION I study, and showed that the estimated radiation dose of

CCTA on a global scale was ~12mSv in 2007, and that of east Asia was ~15mSv²².

In the past eight years, dozens of effective strategies to reduce radiation dose have become available, even a submillisievert CCTA scan has become feasible²³⁻²⁶. In our survey, the median dose among hospitals was 10-15mSv, and the median dose among patients was 6-9mSv, which is demonstrating improvement as compared to 2007. Nevertheless, median doses differed significantly among sites. Some essential strategies, as prospective ECG triggering acquisition, tube current adjustment, iterative reconstruction algorithms, were not frequently used in China²². The dose reduction is largely dependent on the innovations of CT scanners' hardware and operating systems, and Chinese radiological technicians need a user-friendly operating interface, only by which low dose scanning would become routine practice, rather than a passive acceptance ordered by their bosses. Fourth, the maturity of cardiac CT varied, e.g. CCTA procedure volumes varied from 150 to over 8,000 per year; radiation dose varied from 3-5mSv to >15mSv; cumulative time comprising scanning, reprocessing and reporting varied from 18min to 85min. Too many factors caused the inequality, but one action can attenuate this diversity, this was continuing education²⁷. SCCT China IRC started education and training programs from its inception, duplicating the SCCT training programs and the Core Cardiovascular Training of American College of Cardiology^{28,29}. Over 500 hundred radiologists have attended the programs, and plans are in place to train more. Compared to the previous questionnaires, the current had features specific to China. First, we did not ascertain the apportioning roles of radiologists and cardiologists, because Chinese cardiologists just ordered CCTA exams and hardly participated in the data acquisition and reporting, which is different from practices in

the United States, Germany, and Taiwan^{2,5,20,30}. Second, CCTA charge was excluded as it is fixed by provincial governments. Third, we omitted some details, for example, route of beta-blocker administration and dose, the exact flow rate (ml/s) of the contrast agent, how to initiate the scan (test bolus or others), the reconstructed slice thickness (mm), images set using for interpretation (transverse source images, volume rendering, maximum intensity projection, or curved planar reconstruction), which we felt may be inaccurate if chief radiologists and not technicians answered them. Fourth, we created an open question (No. 25), letting our respondents explain their dissatisfactions and point out their expectations.

Our study does have some limitations. It was conjectured the interviews of different people were not uniform across the country, and this bias may be region dependent due to GE's organization form. Other biases might have resulted from the recall of the respondents. To avoid inaccuracies as fully as possible, we designed the questionnaire to be confidential and promised our respondents that the results would be published in an unidentified pattern. The authentication information (No. 0) was strictly confidential, only used for subsequent data checking by the organizer. Some of the largest centers were not included, such as Fuwai hospital, the biggest cardiovascular center in China. Fuwai radiologists performed over 22 thousands CCTA annually, that was over 100 scans per workday. The estimated dose per scan was ~3mSv or less, and <1mSv in selected patients²⁴. Some centers were not included due to random sampling.

Conclusion

We believe that our data provides a comprehensive overview of the current practice of cardiac CT in China mainland, and provides interesting insights into the different

practical aspects of its routine use. The results of our survey show that cardiac CT via 64+ row scanners has become an established radiological modality in China after nearly ten years' of evolution, though there are continued needs to be more sophisticated and develop with nationwide balance. Being the first study of its kind, the study will serve as a baseline for future studies to judge changes in CCTA scanning as well as other related procedures in China.

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Figure Legends

Figure 1: Flowchart of valid hospital selection

Figure 2: Practice characteristics for each component of CCTA examination in China

with the ascending order of CCTA amounts as the horizontal axis: A) CCTA amounts;

B) frequency of inpatient scanning; C) upper heart rate limit of beta-blocker

administration; D) whether to perform CT in case of atrial fibrillation; E) whether to adjust tube current to body mass; F) proportion of perspective ECG triggering acquisition; G) estimated radiation dose among hospitals; H) estimated radiation dose among patients; I) contrast injection protocols; J) estimated average duration of CCTA acquisition; K) estimated average duration of post-processing; L) estimated average duration of interpretation and reporting.