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Factors Affecting which the Time Investment by the Operation Assistant to Identify the Instrument during the CTO-PCI Procedure

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Abstract:

Background: Chronic Total Occlusion（CTO）means occlusive (100%) stenosis with TIMI flow 0 for ＞3 months.More and more cardiovascular specialists are dedicated to the CTO-PCI opration because of the relatively fixed procedure on operative skill. The ultimate success of most CTO-PCI oprations need to combine the retrograde and antegrade technique. So it becoming a nececity that more quantity and variety of instruments might be used. While the oprator focuses on opration and to find the intrument and deliver it to oprator rely to assistants. Than, as a result, there needs lots of time investment to intruments idetification by the first assistant during CTO-PCI operation. Objective: To explore how to shorten the total time invested by evaluating which reletive factors that in instrument identification by CTO-PCI surgical assistants . Methods: Selected 32 CTO-PCI cases as experimetal group and 28 type A lesions cases as control group with randomly and double-blind. Analysis the correlation between instrument type counting (ITC) ，instrument type counting (ITC) , CTO-PCI total time invested（CPTTI）and asistant instrument identification total time invested （AITTI）. Conclusions: 1. The time spent by assistant in sorting and identifying surgical instruments during CTO-PCI was related to the number of guide wire used, the application of guide wire upgrading, the total types of instruments used, the varitise and quantity of microcatheters, and the total time of CTO-PCI；2. The more types of guide wire used, the more types and quantities of microcatheter used, the more applications of guide wire upgrading and degradation, the more types of instrument applications, the more types and quantities of microcatheter, and the longer the total time of CTO-PCI surgery, the more time the assistant would spending in identifying and sorting the guide wire.

Key words: *CTO lesion；instrument identification and sorting；Time investment*

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I. Introduction:

Chronic Total Coronary Occlusion (CTO) refers to coronary artery occlusive lesion with blood flow TIMI 0 and occlusion for more than 3 months[1]. Study datas showed that CTO recanalization could improved

the infarct-related scar of recurrent ventricular tachycardia，improve left ventricular remodeling and left ventricular function[2][3], alleviate angina pectoris, and improve quality of life[4] etc. During the operation of percutaneous coronary intervention (PCI)，that the instrument using，including guide wires are all the precision instrument and manufacturing process with very high technical requirements . The change of instruments used was determined according to the nature of the lesion. Those are different that the surgical procedure strategy and the instruments required at different stages of the operation.Excellent CTO-PCI operators have the situation well in hand such as the characteristics of the device and the timing of upgrade and downgrade. All these lead to a complex procedure for the surgical assistant to identify and sorting these instruments during CTO-PCI operation. Which the attention of the surgical assistant were kept on interrupting from understanding the procedure and surgical skills. Undoubtedly, the CTO-PCI learning curve were prolonged because the low efficiency of learning. In this study, the researchers will analysis the correlation between the CTO-PCI total time invested (CPTTI) by the same excellent , asistant instrument identification total time invested (AITTI), instrument type counting (ITC) and quatity of instruments (QI) used during CTO-PCI to explore how to make surgical assistants learn and progress efficiently during CTO-PCI.Training excellent CTO-PCI surgeons in less time and would benefit more patients.

II. Methods:

Consecutive cases of 60 that underwent successful PCI from June to December on 2023 prospectively, randomly and double-blind, 32 CTO lesions and 28 type A lesions. All cases were diagnosed by imaging. All CTO-PCI coronary artery would with occlusive lesion more than one blood vessels. The baseline clinical characteristics of the cases all are detailed in table 1.

TABLE 1 Baseline clinical characteristics of the case All (N = 60)

Patient-level variables All Age，in years	57.7±11.5
Male gender 45 (75%)	
Clinical presentation	unstable angina52 (87%) STEMI 8 (13%)
Cardiovascular risk factors	Hypertension 49 (82%)
High LDL-C 58 (97%)	
Diabetes mellitus 36 (60%)	
Current smoker 40 (67%)	
Cardiovascular history	Peripheral arterial disease (13%)
Prior PCI 25 （43%）	
CTO-PCI vessel	Vessel Right coronary artery 19 (59%)
Left anterior descending 7 (22%)	
Left circumflex artery 6 (19%)	

Timing method: Measured the total time invested that PCI assistant spent in sorting out and re-identifying the same instrument and delivering it to the PCI operator repetitive; Timing begins when the surgeon says the device needs to be used again until the surgical assistant finds the device and is ready to hand it to the surgeon; All the time instrument identification invested by assistants were added up is the assistant instrument identification total time invested (AITTI) ; Counting method of guide wire: counting would be repeated if the guide wire is damaged by hardness lesions during the operation due to re-used a new one.

Inclusion/exclusion criteria: Inclusion/exclusion criteria for time counting methods: Flushing catheter or guide wire are not counted as timing; For taking the wrong catheter or guide wire, wash it by mistaken and than change it to correct, the whole process were counted as timing; Inclusion/exclusion criteria for instrument counting methods: The same instrument is used when the guide wire or catheter is opened again due to damaging during use. That is the same instrument is re-opened after being abandoned and recorded as two instruments (because it takes the assistant's recognition time) . The device count does not include drug-coated balloons (DCB) or drug eluting stents (DES) . Inclusion/exclusion criteria for cases: Patients with a case history of CABG surgery were excluded. Cases in which coronary rotational atherectomy was that excluded ; Cases of CTO-PCI failure were eliminated. Patients with acute myocardial infarction（ AMI ） are not counted as type A lesions. Inclusion/exclusion criteria for instrument counting methods: Because this study focuses on the time investment of CTO-PCI assistants in the identification of instruments during the operation, instruments such as guide catheters, which are rarely replaced, and which need assistants to identify hardly, are not included in the category of instruments.

Features of included cases: Among the 32 CTO cases, 5 cases undergoing CTO lesion successfully by antegrade manipulation , but were performed by retrograde injection angiogram guidance. 27 CTO-PCI success cases were combined forward and reverse channel. ADR technology was applied in 10 CTO-PCI cases.

All CTO-PCI operations follow the CTO Globa Crossing Algorithm[5] . The J-CTO score of 32 CTO-PCI cases was 3±0.84. The CTO-PCI total time invested (CPTTI) was 178.2±6.1 minutes. The time input of surgical assistants to identify instruments during operation (AITTI) was 22.3±5.3 minutes. Percentage of AITTI in CPTTI is 15.5%±1.0 ; Ages for Study group : 57.5±3.3 years old,and for control group: 57.8±9.1 years old (P<0.01) . LDL-C in CTO-PCI group: 3.1±0.8; The LDL-C of the control group was 2.3±0.6; The instrument type counting (ITC) was 18.9±3.1. That the PCI total time invested in control group (PTTIC) was 56.6 ± 8.1. The asistant instrument identification total time invested in control group (AITTIC) was 16.2±1.6 second.

Statistical analysis: Statistical analyses were carried out using IBM SPSS Statistics 22. The continuous variables were calculated by mean±standard and the categorical variables were calculated by percentage (%) . Sensitivity analysis was performed for the measurement of the reliability of the combined results. Categorical variables are presented as counts and percentages and were compared by the X^2 test .

III. Results:

1. It's represented by a radar map that the factors related to the assistant instrument identification total time invested (AITTI) as Fig.1 . The feature of radar map manifestation was the comparison of CTO-PCI cases within a group . And the radar map combined scatter plots which pairwise comparisons showed that the longer the CPTTI, the longer the AITTI, and the more ITC .

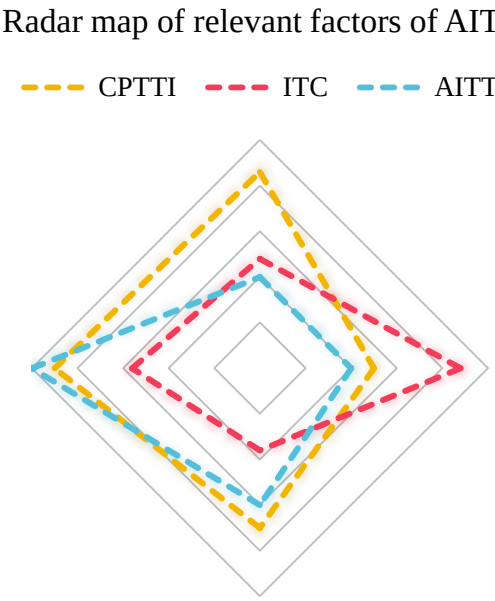

Fig 1. The radar map showed that the longer the CPTTI, the longer the AITTI, and the more ITC .

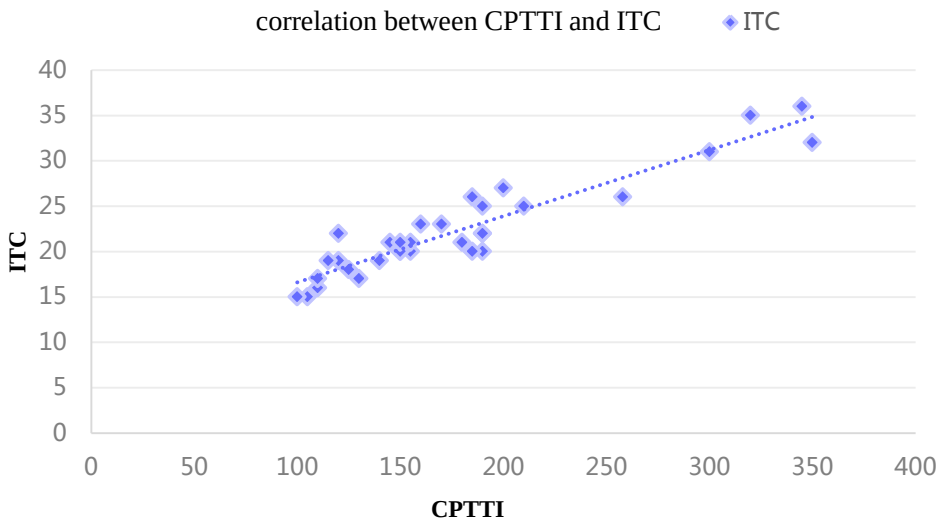

Fig 2. Pearson product-moment correlation coefficient 0.73,P<0.01

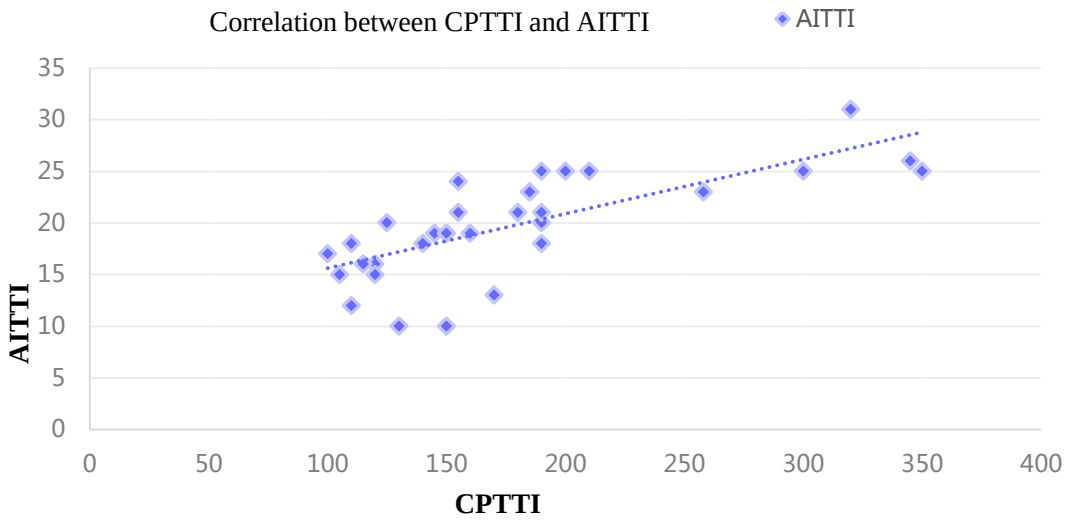

Fig 3. Pearson product-moment correlation coefficient 0.94, P<0.01

2. The Fig4. showed that AITTI percentage in CPTTI.

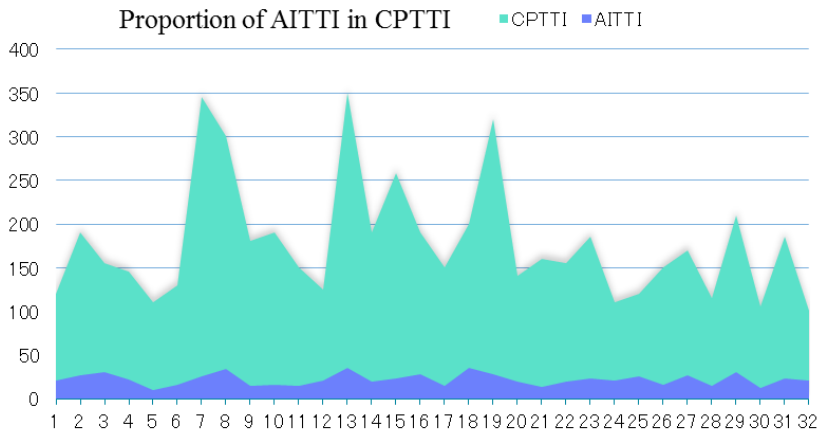

Fig 4. Percentage of AITTI in CPTTI is 15.5%±1.0

3. Successful CTO-PCI cases of 32 of Which Conquest Pro12, Gaia3 and PILOT200 accounted for a relatively high proportion in the use of CTO guide wires . The proportion of microcatheter use ranked Corsair, Finecross, Zhishuang, etc. The proportion of counting devices in this study is shown in Fig. 5.

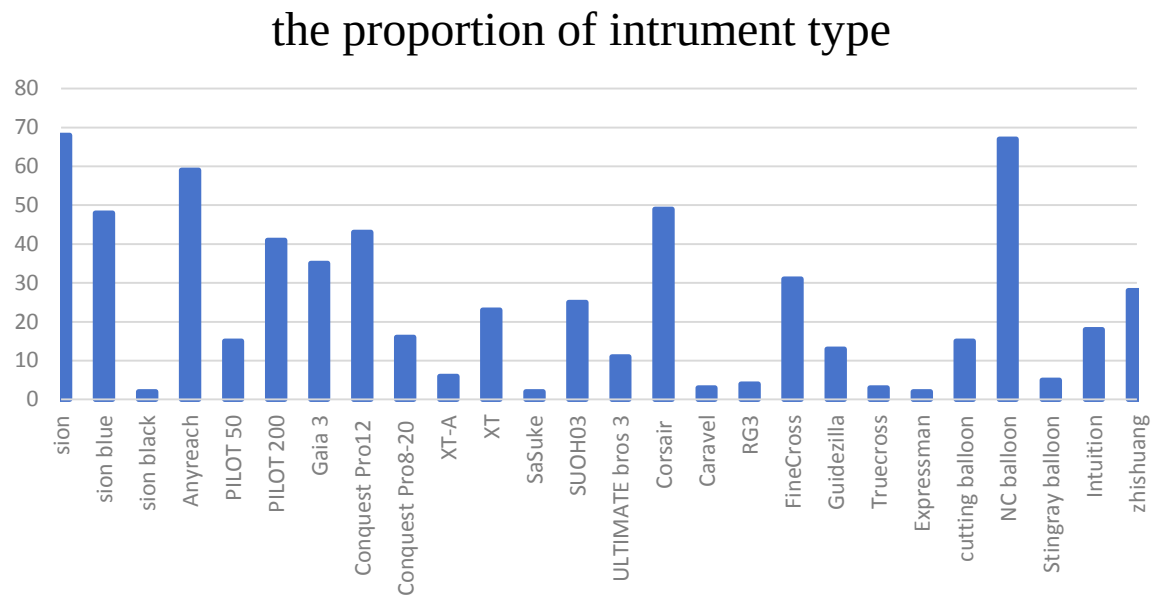

Fig 5. The proportion structure all instrument used among 32 CTO-PCI manipulation cases

4. Successful CTO-PCI cases of 32 of Which Conquest Pro12, Gaia3 and PILOT200 accounted for a relatively high proportion in the use of CTO guide wires . The proportion of microcatheter use ranked Corsair, Finecross, Zhishuang, etc. The proportion of counting devices in this study is shown in Fig. 5.
5. CTO-PCI assistants need constant interruptions to organize and identify instruments.
6. The comparison of PCI manipulation total time invested in the experimental group and the control group and the assistant instrument identification total time invested is shown in Fig. 6.

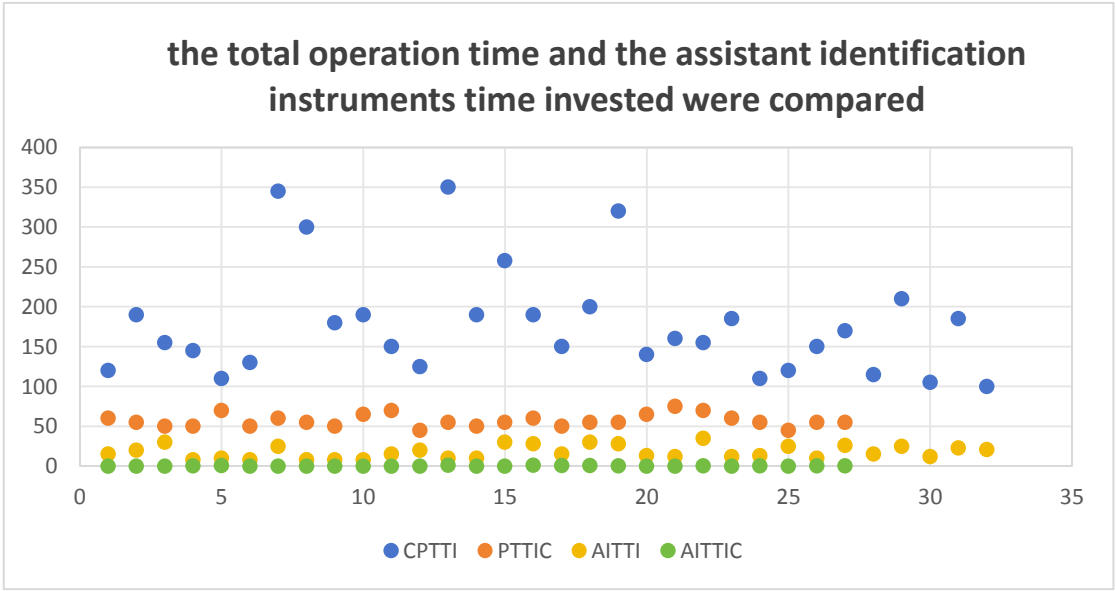

Fig 6. the CTO-PCI total time invested (CPTTI) ; asistant instrument identification total time invested (AITTI) ; The PCI total time invested in control group (PTTIC) ; The asistant instrument identification total time invested in control group (AITTIC) .

IV. Conclusions:

1. The time spent by assistant in sorting and identifying surgical instruments during CTO-PCI was related to the number of guide wire used, the application of guide wire upgrading, the total types of instruments used, the varitise and quantity of microcatheters, and the total time of CTO-PCI; 2. The more types of guide wire used, the more types and quantities of microcatheter used, the more applications of guide wire upgrading and degradation, the more types of instrument applications, the more types and quantities of microcatheter, and the longer the total time of CTO-PCI manipulation investment , the more time the assistant would spending in identifying and sorting the instruments .

V. Discussion:

There is a Chinese proverb, "a handy tool makes a handyman". Structural characteristics of vascular lesion of each complex CTO-PCI opration is a blind box preoperation. To successfully complete a complex CTO-PCI , in addition to the PCI manipulation experience of the cardiovascular specialists is very important, the types of instruments that the Cardiac Catheterization Room can proived, the upgrading and degrading techniques of the instruments using during PCI , and the replacement of different instruments are the keys point to the success of CTO-PCI.

The existing instruments are placed on the operating table disorderly, which reduces the speed of cooperation of the assistant. Especially, when the operation is complicated and the operation time is long, the surgical assistant is changed during the operation, and it is difficult for the assistant that replaced to recognize the position of the instrument placed by the previous assistant, which further prolongates the time investment of the assistant , and has a negative impact on the treatment. Moreover, even if the surgical assistant is not replaced, for the too long operation duration time, the memory of the assistant is tired, and the assistant will forget the position of the instrument, but also increase the time investment in instrument identification. In addition, assistants spend more time on instrument identification, so they cannot focus on the learning of surgical procedures and methods, which will reduce the learning efficiency of surgical assistants for CTO-PCI technique .

In order to reduce the time invested by the assistant in the instruments sorting and the identification for re-using, the measures taken as follows: 1) Using easily identifiable instruments as far as possible , for example, the SION as workhorse guide wire have the same tail to Gaia, but the intuition with 1cm gold mark at the end if be selected would easly to identification from the Gaia. It would be helpful for the subsequent PCI assistant to identify and distinguish the guide wire when it be re-used and without affecting the operation speed of the PCI maniputation and can reduce unnecessary time investment of assistants; 2) Try not to change the surgical assistant during the CTO-PCI manipulation ; 3) When the operation is complex and needs to use different performance of the guide wire, the first measure can not be fully realized. The time spent by CTO-PCI assistant in sorting out and identifying PCI instruments is related to the complexity of CTO lesion . When the CTO-PCI lesions are complex, the operation time is prolonged and it is difficult to do without changing the PCI assistant. To this point, we propose an instrument arrangement device for the PCI manipulantion table. The instrument arrangement device is conducive to faster and more accurate cooperation of the assistant in the operation, because the instrument arrangement device has a fixed and uniform logo, and the replacement of the PCI assistant does not affect the total time investment of instrument identification.

The author's team of this article designed an instrument sorting device for PCI operating [6] , and Chinese intellectual property granted for utility model patent (patent authorization announcement number: CN219022068U). Its design drawing is decribled Fig 7 as follows:

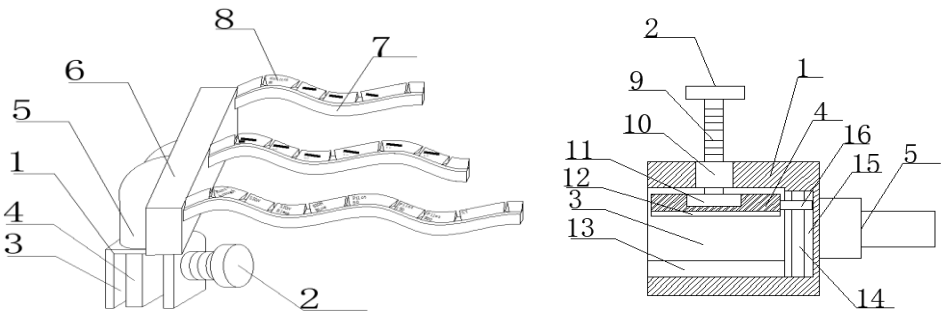

Fig 7. 1.fixing clamp; 2. Turn the handle; 3.clamping groove; 4.clamping plate; 5.damping shaft; 6.fixed plate; 7. card slot frame; 8. Name identification plate; 9. screw rod; 10.thread sleeve; 11.limit sleeve; 12. the protection pad; 13. Lower protection pad; 14. sliding rod; 15. side chute; 16. Sliding sleeve.

Specifically, as shown in the figure, a clamping slot 3 is provided inside the fixing clamp 1, the clamping plate 4 slides inside the clamping slot 3, the side of the fixing clamp 1 is provided with a rotating handle 2, the side of the rotating handle 2 facing the fixing clamp 1 is fixed with a threaded rod 9, the surface of the fixing clamp 1 is fixed with a threaded sleeve 10, and the surface of the fixing plate 4 is fixed with a limited bit sleeve 11. The end of the thread rod 9 is rotationally connected with the limit sleeve 11, and the thread rod 9 is threaded with the thread sleeve 10. When used, the finishing device can be fixed on the operating bed where the patient is lying or on the operating table. This finishing device is equipped with a name tag on the side of each card slot, so that different types of CTO-PCI instruments such as guide wire, microcatheter and balloon are placed separately, which is convenient for the identification of guide wire, microcatheter and balloon when rapid sorting and re-application, and improves the coordination speed of PCI assistance. It reduces the amount of time spent by the assistant on instrument identification during CTO-PCI, and improves the learning efficiency of the assistant on CTO-PCI procedure. The S-shaped card slot frame can save space. The device is simple and easy to operate, does not occupy a flat operating table, and is suitable for mass production. In addition to being applied to CTO-PCI surgery, it can also be used in ordinary PCI surgery.

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