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KERUNIT
KNOWLEDGE AND EVALUATION RESEARCH

New Approach and New Context

--First Experience of SDM in China

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A clinic day in China hospital

Patient-Clinician Distrust

Poor knowledge

Public opinion

Status of disease

Clinician communication skill

Context

Education

Medical policy

Side effects and complications

Family burden

Short time of communication

Relationship between patients and clinicians

Type of insurance

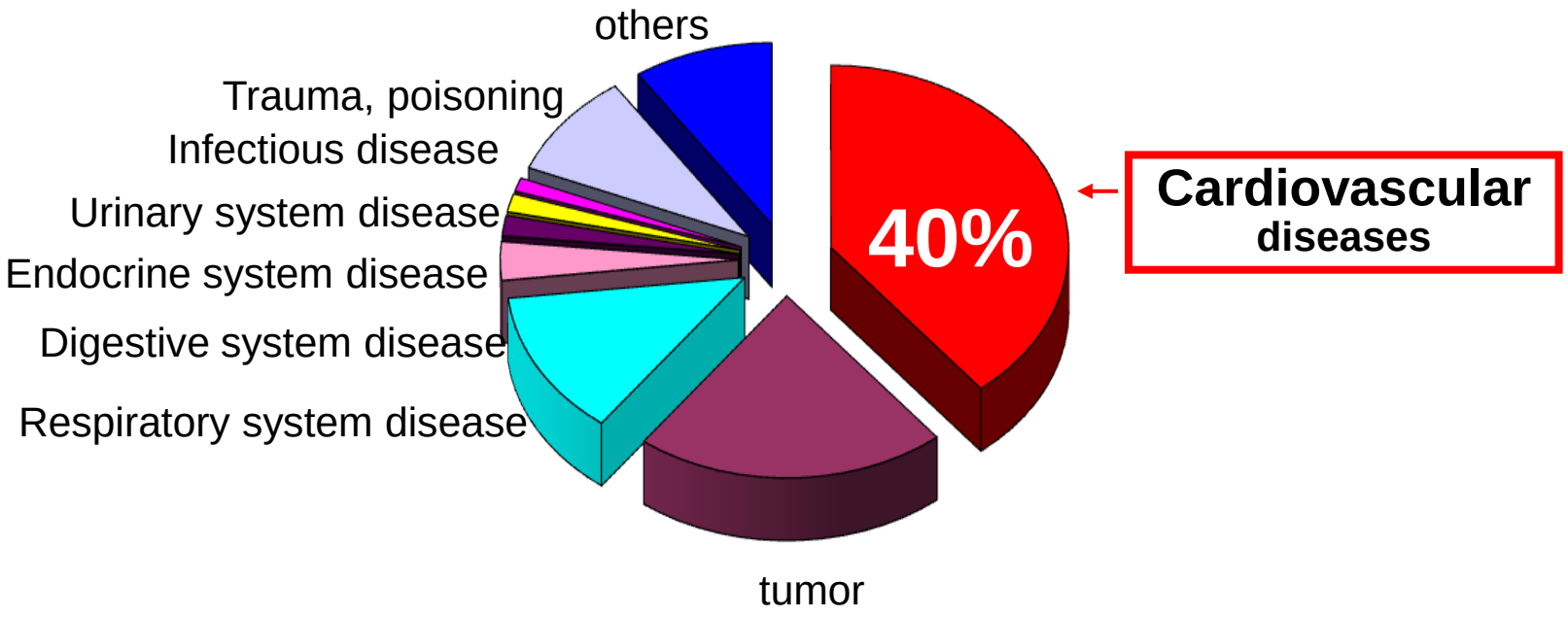
Costs

Clinical skill and knowledge

Regional disparity of hospitals and clinicians

Socioeconomic status

Cardiovascular diseases is of the major morbidity in China



Cardiovascular disease Reports in China 2016

Patient compliance and adherence to statin therapy in China

- The patients with coronary artery disease who hospitalized in our hospital stopped stain (36%, n=397) during five years follow-up.
- Statin adherence levels is related to prognosis (death, myocardial infarction, heart failure) in patients with unstable angina.

Huang, et al. Data unpublished

Patient compliance and adherence to statin therapy： a meta-analysis

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Jeppe N. Rasmussen 2007	-0.2231	0.0681	14.1%	0.80 [0.70, 0.91]
Li Wei 2008	-0.1863	0.1571	10.0%	0.83 [0.61, 1.13]
Luca Degli Esposti 2012	-0.7765	0.0975	12.8%	0.46 [0.38, 0.56]
P Michael Ho 2006	-0.4308	0.1876	8.6%	0.65 [0.45, 0.94]
P. Michael Ho 2006	-0.47	0.1454	10.5%	0.63 [0.47, 0.83]
P.Michael Ho 2007	-0.5978	0.0589	14.5%	0.55 [0.49, 0.62]
Sylvie Perreault 2008	-0.2107	0.0672	14.2%	0.81 [0.71, 0.92]
Sylvie Perreault 2009	-0.1985	0.0321	15.3%	0.82 [0.77, 0.87]
Total (95% CI)			**100.0%**	**0.68 [0.58, 0.80]**

Heterogeneity: $Tau^2 = 0.04$; $Chi^2 = 64.83$, df = 7 ($P < 0.00001$); $I^2 = 89\%$

Test for overall effect: $Z = 4.64$ ($P < 0.00001$)

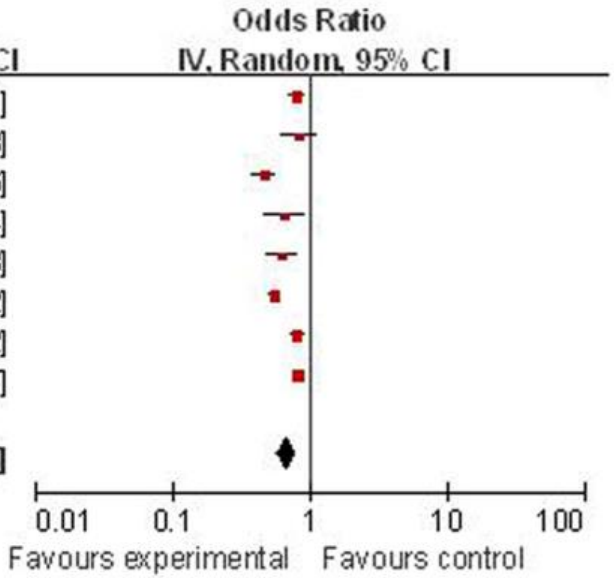


图2　高、低他汀类药物依从性患者间心血管不良事件OR值及95%CI比较森林图

注：高依从性（PDC≥80%），低依从性（定义为PDC＜80%、＜40%、＜20%）

Li ST, et al. Zhong Hua Xin Xue Guan Bing Za Zhi , 2016; 44(8): 684-690

Factors associated with Chinese patients' adherence

- Patient variables
- Trust between physicians and patients
- Knowledge about CHD, statin, et al
- progress of medical decision
- Hospital teaching status
- Socioeconomic status

.....

- **The results from the *Statin Choice* trial give us a clue that decision aids may increase trust through improvement in the decision-making process.**

- **Delivery of decision aids by clinicians during the visit improves knowledge and shows a trend toward better acceptability and less decisional conflict.**

Shared Decision-Making (SDM)

- Taking an active role and participating in investigating the options, one's preferences, and values as they relate to important healthcare decisions
- Actively working with provider to assure the communication flows both ways

"No fateful decisions in the face of avoidable ignorance."

"The care patients need and no less, the care they want and no more."

– Al Mulley, MD

Shared Decision-Making (SDM)
– When is it appropriate?

Risk

Benefit

Our experience

Statin Choice in China

(No. ChiCTR-OCS-1400464)

Huang R. et al. Patient Preference and Adherence. 2016; 10: 2341-2350
RC Huang, et al. Clin Transl Degener Dis, 2016;1:166-175
Yang X, et al. summit to Circulation Cardiovascular Quality and Outcoms
Huang R. et al. summit to Patient Education and Conceling

Intervention

- The intervention will consist of the use of a decision aid (Statin Choice) by patients and their physicians during the clinic encounter (http://kercards.e-bm.info) (Chinese version) http://statindecisionaid.mayoclinic.org.

DA cards and website(Chinese Version)

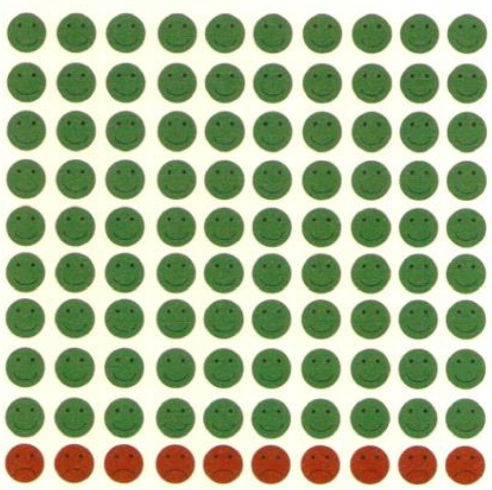
我应该服用他汀类药物吗？

一个决策工具

平均风险<15%

1. 在未来 10 年内我发生心血管事件的风险是多少？

在 100 位和您一样**未服用**他汀类药物的人中发生心血管事件的风险



未服用他汀类药物：

90 人未发生心血管事件（绿色）

10 人发生心血管事件（红色）

Training of physicians

- A two-day meeting in person discussion to show how to use the decision aid before it began

- A sample video of Chinese version for guiding physician and patients how to perform SDM in their practices

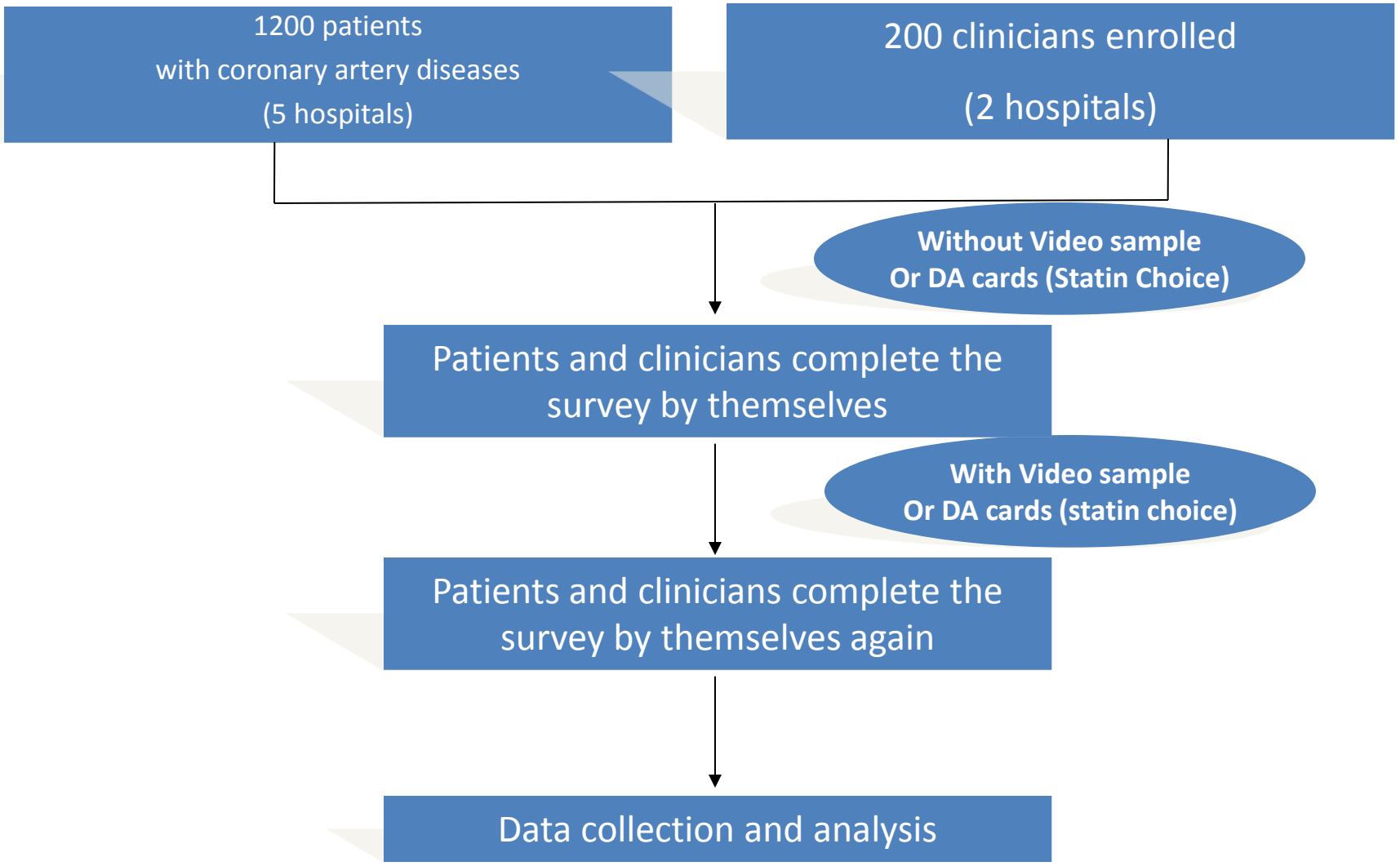
Training of physicians

Q1

Are Chinese physicians and patients are ready for SDM in their future experience ?

(data unpublished)

Survey Flow Chart



Clinician Questions selected to cover the following topics

- Clinician demographics
- Information Sharing Style
- Satisfaction with DA style
- Post DA satisfaction with tool

The basic characteristics of Chinese clinicians and questionnaire answers on SDM

Characteristics		Without DA (n=200)		With DA (n=193)	
		DMU（n=100)	CMU(n=100)	DMU(n=93)	CMU(n=100)
Male, n(%)		35 (35)	40 (40)	34(37)	40 (40)
Age, years, means(SD)		25.8 (1.6)	25.1 (2.3)	25.8 (1.6)	25.1 (2.3)
Study time, years, means(SD)		6.9 (0.8)	6.2 (1.5)	6.9 (0.8)	6.2 (1.5)
Q1 the type of decision making	1, n(%)	1(1)	3(3)	1(1)	2(2)
	2, n(%)	39(39)	38(38)	26(28)	38(38)
	3, n(%)	26(26)	39(39)	54(58)	39(39)
	4, n(%)	24(24)	16(16)	11(12)	21(21)
	5, n(%)	0(0)	4(4)	1(1)	0(0)
Q2 factors related to decision making	1, n(%)	51(51)	47(47)	50(54)	47(47)
	2, n(%)	29(29)	28(28)	25(27)	26(26)
	3, n(%)	10(10)	21(21)	13(14)	17(17)
	4, n(%)	10(10)	4(4)	5(5)	10(10)
Q3 preference in SDM	1, n(%)	45(45)	33(33)	49(53)	44(44)
	2, n(%)	48(48)	67(67)	43(46)	56(56)
	3, n(%)	7(7)	0(0)	1(1)	0(0)
Q4 preference in using DA	yes, n(%)	69 (69)	49 (49)	75(81)	58(58)
Q5 attitude on DA	1, n(%)	11(11)	8(8)	11(12)	7(7)
	2,n(%)	56(56)	31(31)	50(54)	35(35)
	3, n(%)	2(2)	10(10)	14(15)	16(16)
	4, n(%)	31(31)	51(51)	18(19)	42(42)

DMU means Dalian Medical University, CMU means Capital Medical University, SDM means shared decision making.

Patient Questions selected to cover the following topics

- Information Sharing Style
- Satisfaction with DA style
- Knowledge about Risks
- Knowledge about Benefits
- Decisional Conflict
- Trust

Chinese patient preferences in decision-making on stain choice

Type of decision making	DMU(n=282)		CIU (n=103)		TPH(n=144)		SJH(n=30)		CMU(n=200)		Total (n=759)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1, n(%)	3(1.1)	4(1.4)	1(1.0)	1(1.0)	2(1.4)	5(3.5)	1(3.3)	0	3(1.5)	1(0.5)	11(1.4)	11(1.4)
2, n(%)	33(11.7)	33(11.7)	15(14.5)	12(11.6)	24(16.7)	21(14.5)	1(3.3)	0	26(13.0)	28(14.0)	99(13.0)	94(12.4)
3, n(%)	**101 (35.8)**	**102 (36.2)**	**28 (27.2)**	**28 (27.2)**	**32 (22.2)**	**35 (24.3)**	**7 (23.3)**	**8 (26.7)**	**87 (43.5)**	**87 (43.5)**	**255 (33.6)**	**260 (34.3)**
4, n(%)	57(20.2)	55(19.5)	30(29.1)	29(28.2)	42(29.2)	44(30.6)	2(6.7)	3(10.0)	41(20.5)	41(20.5)	**172 (22.7)**	**172 (22.7)**
5, n(%)	88(31.2)	88(31.2)	29(28.2)	33(32.0)	44(30.5)	39(27.1)	19(63.3)	19(63.3)	43(21.5)	43(21.5)	223(29.3)	222(29.2)

1 Decision made by patient themselves, 2 Decision made by patient themselves after considering clinician's option, 3 Shared decision-making, 4 Clinician made the decision after considering patient's options, 5 Clinician made the decision;

DMU: The First Affiliated Hospital of Dalian Medical University, CJH: China-Japan Union Hospital of Jilin University, TPH: The Third People's Hospital of Dalian, SJH: Shengjing Hospital of China Medical University, CMU: Beijing Anzhen Hospital, Capital Medical University

Change in physician-patient trust before and after shared decision-making process on statin choice

Change of scores	Q3(n,%)	Q12(n,%)	Q13(n,%)
-2	16(2.1)	6(0.8)	10(1.3)
-1	80(10.5)	62(8.2)	53(7.0)
0	627(82.6)	648(85.4)	644(84.9)
1	28(3.7)	39(5.1)	44(5.7)
2	8(1.1)	4(0.5)	6(0.8)
3	0	0	2(0.3)

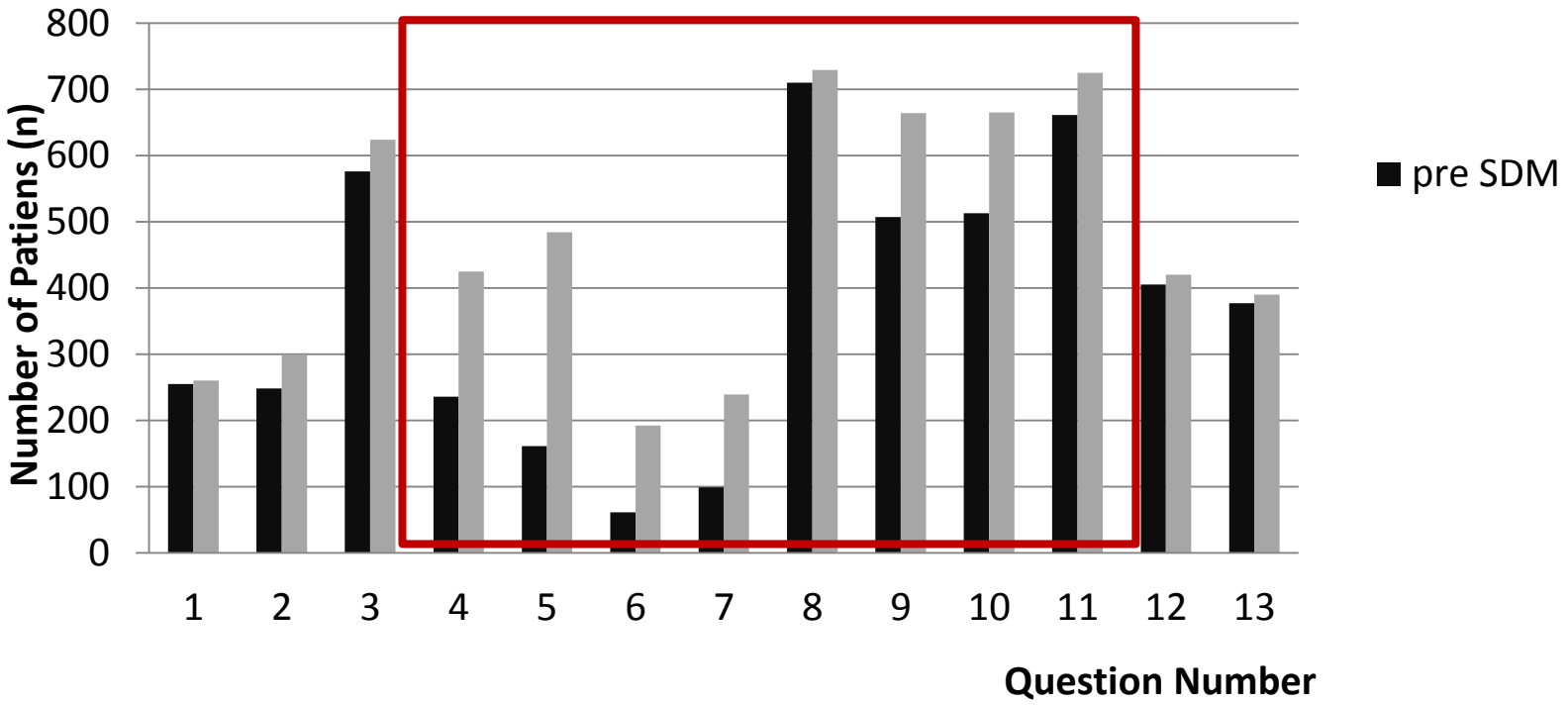
Q3, the extent of preference for shared decision-making in further visits; Q12, the extent of physician telling patients the truth about disease; Q13, the degree of physicians understanding patient concerns

Relationship between the basic characteristics of patients and change in physician-patient trust

P value	Change of Q3	Change of Q12	Change of Q13
Age	0.628	0.780	0.541
Gender	0.576	0.587	0.592
Cardiovascular events risk scores	0.315	0.891	0.880

Q3, the extent of preference for shared decision-making in further visits; Q12, the extent of physician telling patients the truth about disease; Q13, the degree of physicians understanding patient concerns

The change in patient population preferring shared decision-making (SDM) and giving the answer “yes” to the questions on statin choice before and after SDM



1: Patients who chose SDM, 2: Patients who want to present information about statins to other patients, 3: Patients who want to know information about other treatment choices through SDM, **4–5: Patients who know the adverse effects of statins, 6–7: Patients who know their cardiovascular risk with or without statins, 8–11: Patients who are sure of the clinical decision,** 12–13: Patients who think the physician can completely tell them the truth and understand their concerns.

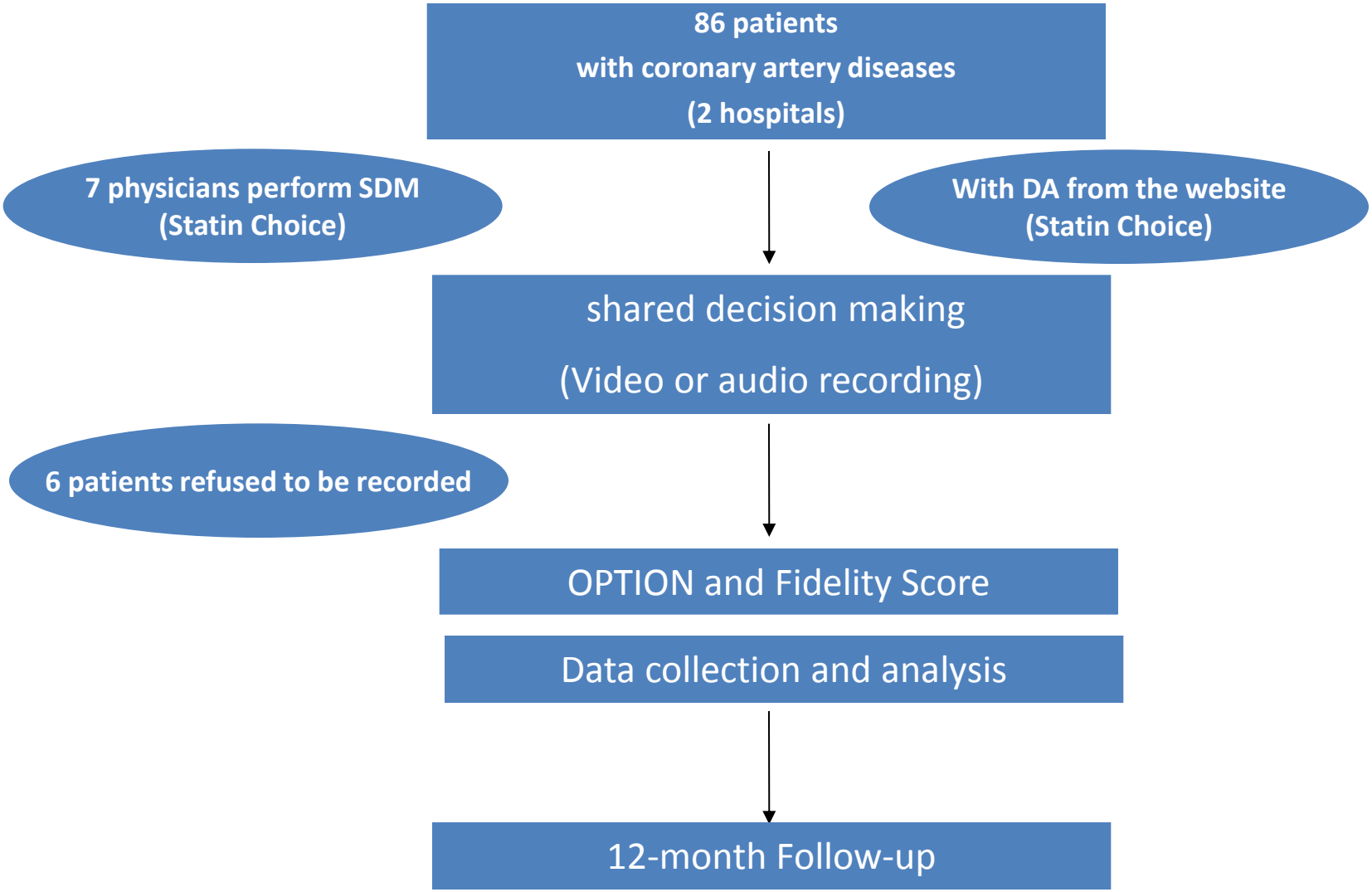
Conclusions-1

- Most young Chinese clinicians want to participate in shared-decision making.
- Approximately one-third of Chinese patients prefer SDM.
- The implementation of SDM interviews and use of decision aids improve the patient's cognitive level of the disease and treatment, and reduces decision-making conflicts.
- The main barriers for both of physicians and patients in China to perform SDM are lack of experience, and time.

Q2

Is it feasible for Chinese physicians perform SDM in China?

Flow Chart


86 patients
with coronary artery diseases
(2 hospitals)
7 physicians perform SDM
(Statin Choice)
With DA from the website
(Statin Choice)
shared decision making
(Video or audio recording)
6 patients refused to be recorded
OPTION and Fidelity Score
Data collection and analysis
12-month Follow-up

Physicians Characteristics

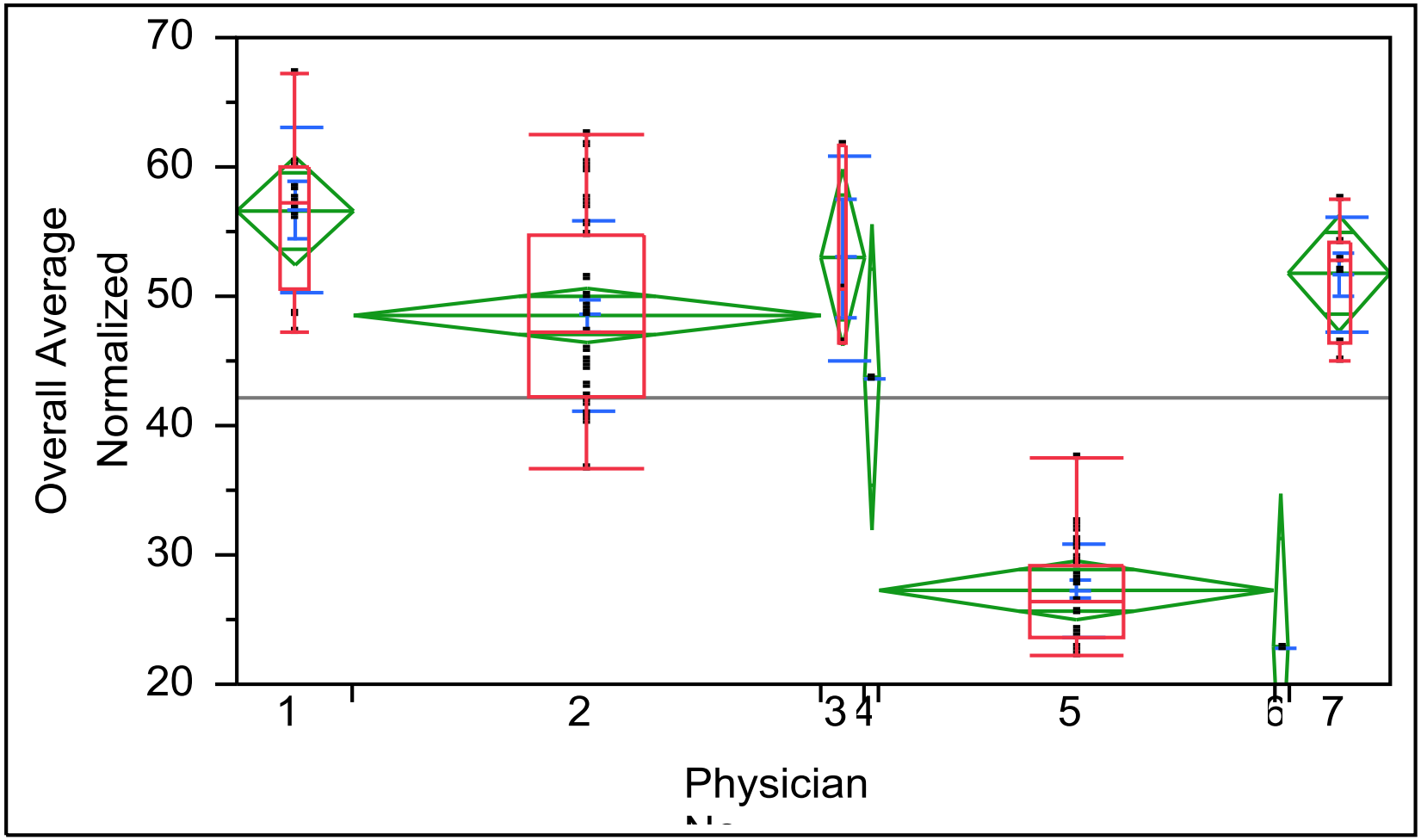
Table 1 Participants' characteristics

Characteristics	Hospital A				Hospital B			Total
	Clinician 1	Clinician 2	Clinician 3	Clinician 4	Clinician 5	Clinician 6	Clinician 7	All
Patients' characteristics								
Number of encounters	8	31	2	7	27	3	2	80
Sex, male, n (%)	7 (88)	17 (55)	2 (100)	6 (86)	23 (85)	1 (33)	0 (0)	56 (70)
Age (years), median (range)	63 (44, 76)	66 (44, 78)	76 (72, 79)	55 (45, 71)	61 (41, 77)	57 (44, 59)	55 (54, 56)	62 (41, 79)
Current smoker, n (%)	7 (88)	11 (36)	0 (0)	2 (29)	10 (37)	1 (33)	1 (50)	32 (40)
Atrial fibrillation, n (%)	1 (13)	1 (3)	0 (0)	0 (0)	2 (7)	1 (33)	0 (0)	5 (6)
Coronary heart diseases, n (%)	5 (63)	26 (84)	2 (100)	4 (57)	25 (93)	3 (100)	1 (50)	66 (83)
Previous myocardial infarction, n (%)	1 (13)	3 (10)	0 (0)	1 (14)	1 (4)	0 (0)	0 (0)	6 (8)
Hypertension, n (%)	7 (88)	27 (87)	1 (50)	5 (71)	15 (56)	2 (67)	0 (0)	57 (71)
Diabetes, n (%)	3 (38)	12 (39)	1 (50)	4 (57)	10 (37)	2 (67)	0 (0)	32 (40)
Taking aspirin before enrollment, n (%)	2 (25)	15 (48)[a]	1 (50)	1 (14)	27 (100)	0 (0)	1 (50)[b]	47 (59)[c]
Taking statin before enrollment, n (%)	1 (13)	6 (19)	0 (0)	1 (14)	26 (96)	0 (0)	1 (50)[b]	35 (44)[d]
Education ≥ high school, n (%)	4 (50)	10 (32)	0 (0)	4 (57)	15 (56)[e]	1 (33)	0 (0)	34 (43)[c]
Self-reported illiterate, n (%)	0 (0)	2 (7)	0 (0)	1 (14)	0 (0)	1 (33)	0 (0)	4 (5)[d]
Employed, n (%)	0 (0)	6 (19)	0 (0)	4 (57)	6 (22)	1 (33)	2 (100)	19 (24)
Retired, n (%)	5 (63)	15 (48)	1 (50)	3 (43)	15 (56)[f]	2 (67)	0 (0)	41 (51)[g]
With health insurance, n (%)	8 (100)	31 (100)	2 (100)	7 (100)	26 (96)	3 (100)	1 (50)	78 (98)
Living in rural area, n (%)	4 (50)	9 (29)	0 (0)	1 (14)	3 (11)	1 (33)	0 (0)	18 (23)
Received patient education before enrollment, n (%)	1 (13)	11 (36)	1 (50)	1 (14)	0 (0)	0 (0)	0 (0)	14 (18)
SDM time (minutes), median (range)	14 (12, 31)	13 (8, 30)	13 (9, 19)	20 (10, 22)	6 (3, 11)	14 (12, 15)	10 (6, 14)	12 (3, 31)
Total time (minutes), median (range)	18 (15, 38)	18 (9, 39)	20 (13, 28)	21 (15, 24)	9 (5, 19)	17 (13, 18)	13 (6, 20)	15 (5, 38)
Clinicians' characteristics								
Sex	Female	Male	Female	Male	Female	Male	Female	–
Age (years)	41	28	27	35	30	41	27	–
Medical education	MD	MS	MS	MD	MS	MD	MD	–
Years as a cardiologist	18	2	2	9	5	18	4	–

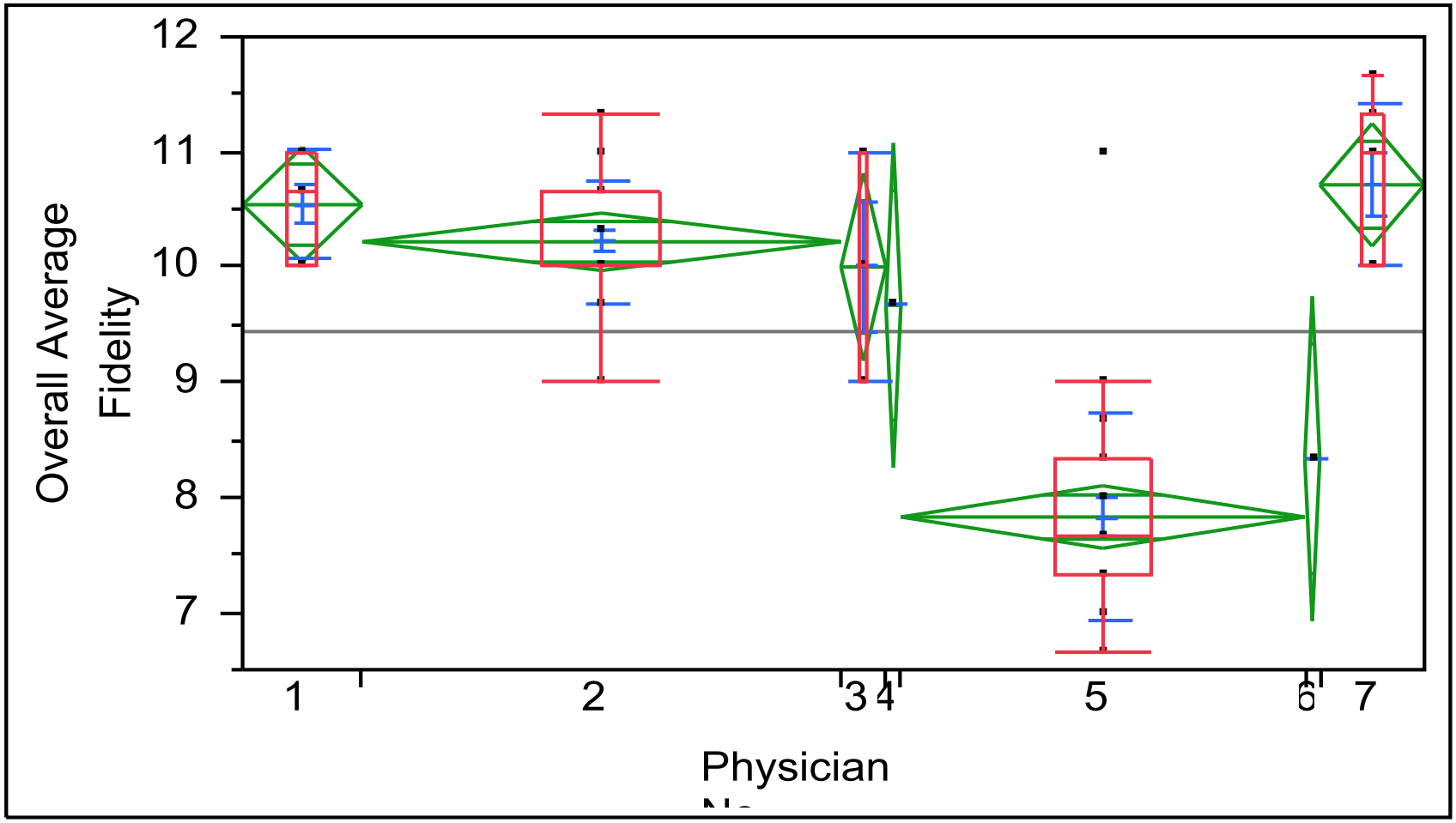
Notes: [a]Data on 30 of 31 (97%). [b]Data on 1 of 2 (50%). [c]Data on 78 of 80 (98%). [d]Data on 79 of 80 (99%). [e]Data on 25 of 27 (93%). [f]Data on 23 of 27 (85%). [g]Data on 76 of 80 (95%).

Abbreviations: SDM, shared decision making; MD, Doctor of Medicine; MS, Master of Medicine.

Overall Average Normalized OPTION Scale By Physician No (patients' preference)



Overall Average Fidelity By Physician No (physicians' preference)



12-month Follow-up

Table 4 Clinical outcomes at 12-month follow-up (n=73)

Clinical outcomes	Statin PDC <80% (n=4)	Statin PDC ≥80% (n=69)
Side effects of statin		
Muscle aches or myalgia (n, %)	1, 25	0
Elevated levels of CPK (n, %)	1, 25	2, 2.9
MACEs		
All-cause mortality (n, %)	0	1, 1.4
Cardiac death (n, %)	0	0
Acute myocardial infarction (n, %)	1, 25	0
Angina (n, %)	1, 25	2, 2.9
Coronary revascularization (n, %)	1, 25	2, 2.9
Heart failure (n, %)	0	0

Abbreviations: CPK, creatine phosphokinase; MACEs, major adverse cardiac events; PDC, percentage of days covered.

Conclusions-2

- Using an encounter decision aid developed in the US, it was feasible to implement SDM in a referral cardiology practice in Mainland China.

- Further work to ensure that the encounter aid is pertinent to the Chinese population and that SDM is tested in at-risk patients could contribute to the implementation of SDM across Mainland China.

Barriers to practicing SDM

- Clinicians
  - Challenge to physician autonomy
  - Don't recognize preference sensitive decisions
  - Evidence difficult to extract, interpret, communicate
  - **Communication skills**
- Practice
  - Logistics
  - **Lack of time**
  - Lack of reimbursement
- Patients
  - "Patients don't want to participate"
  - Variation in role preference
  - Literacy, Numeracy
  - **Lack of basic science on medicine**
- Decision aids

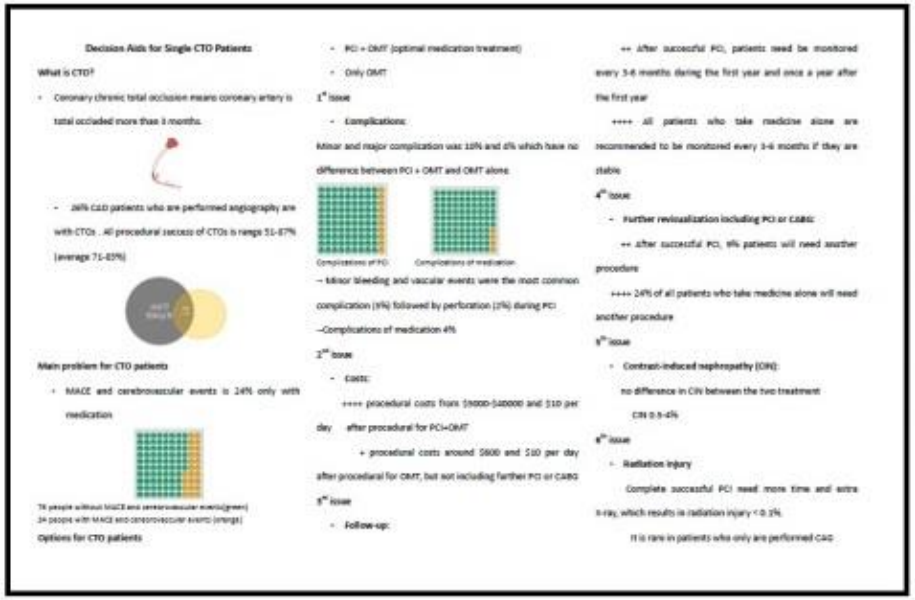
Implement SDM in China

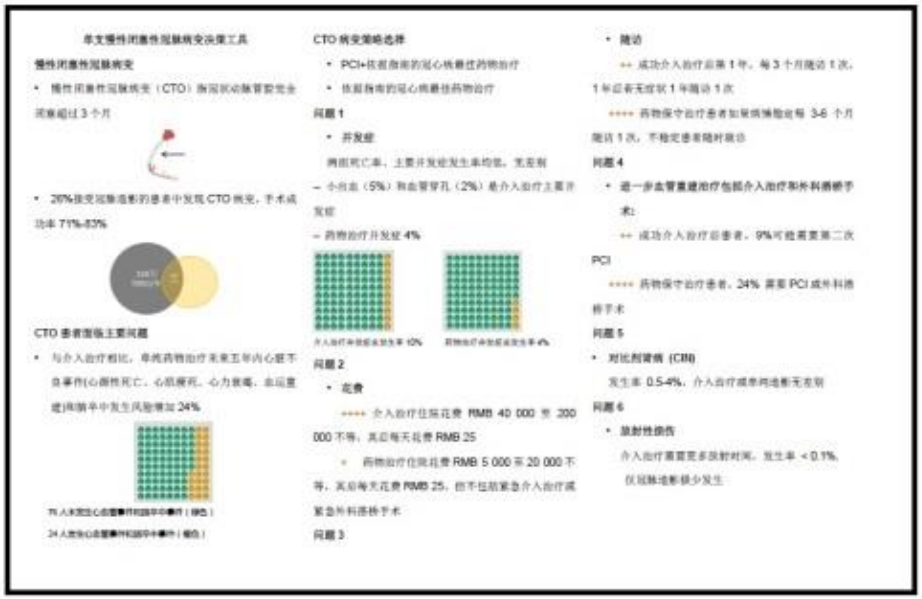
Group Education before and after SDM

Group SDM process

Modify DAs for Chinese patients

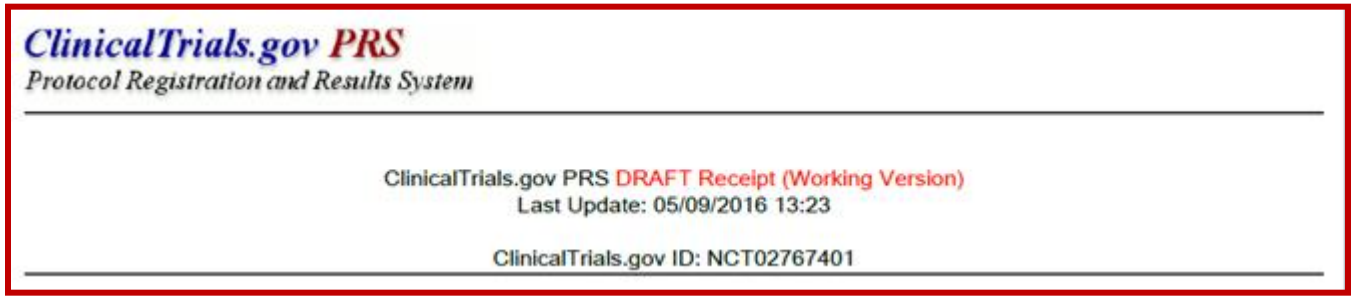
CTO Decision Aids for patients with single chronic total artery occlusion





Q4

CTO Choice in Chinese Stable Angina Patients



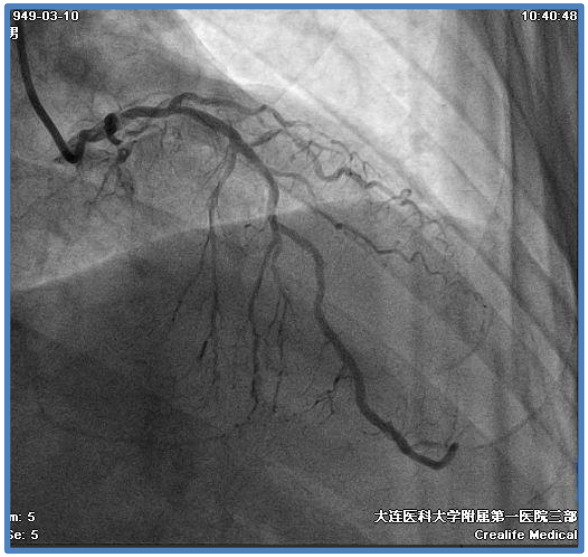
ClinicalTrials.gov PRS
Protocol Registration and Results System

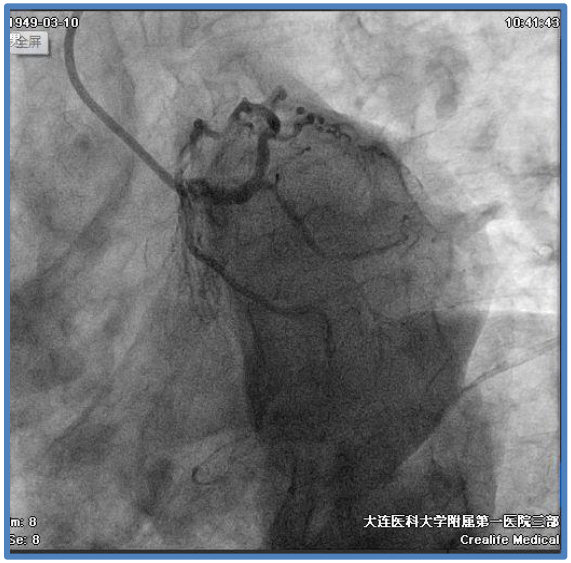
ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 05/09/2016 13:23

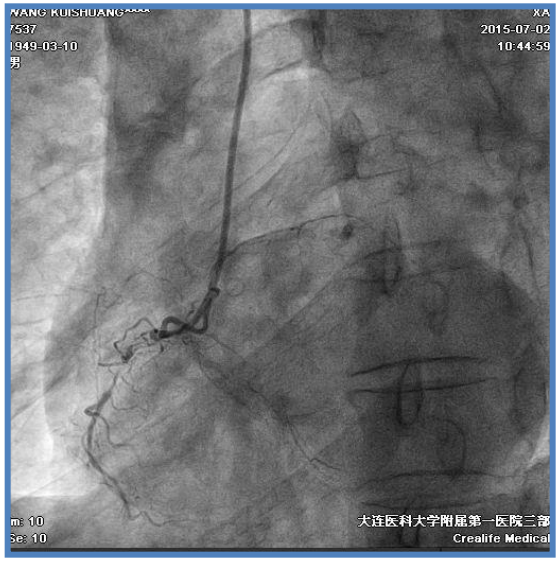
ClinicalTrials.gov ID: NCT02767401

Ongoing trial

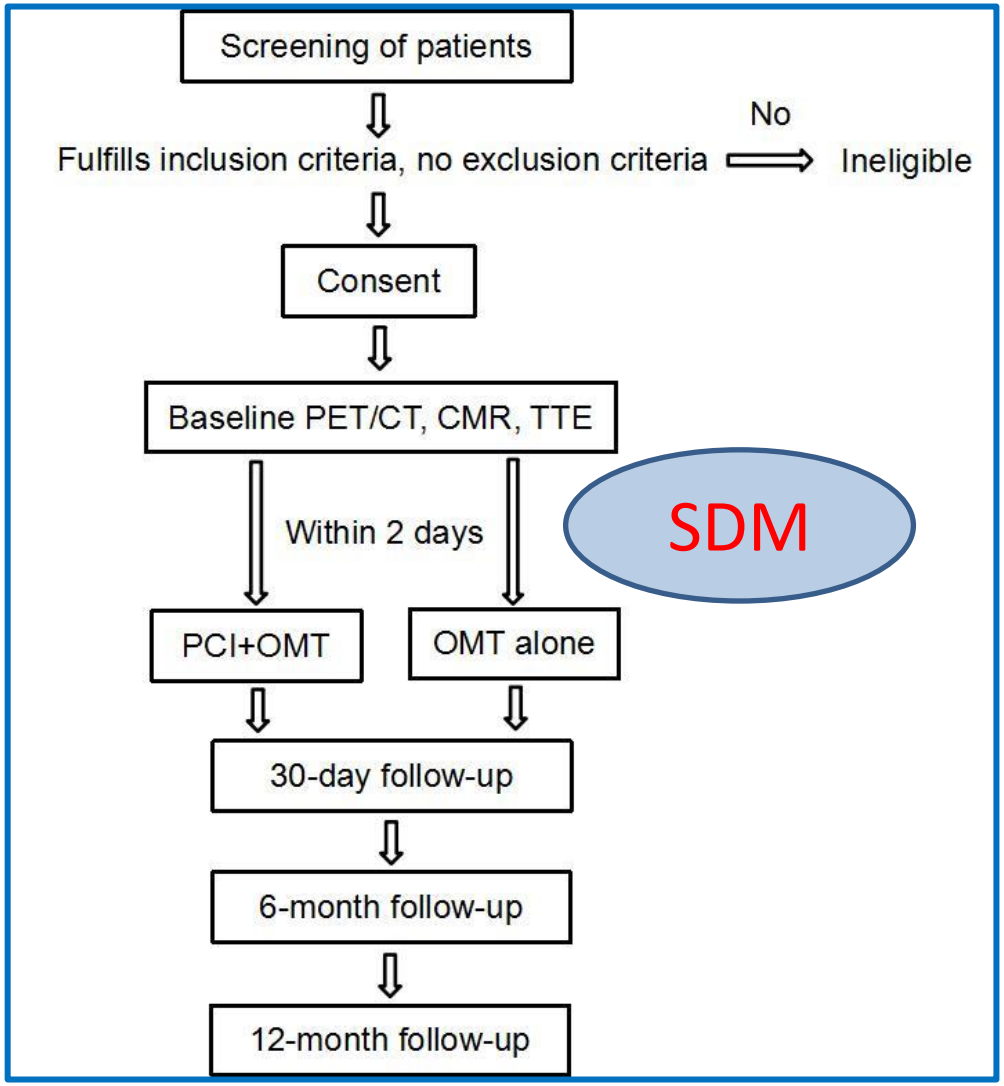
Coronary Angiogram



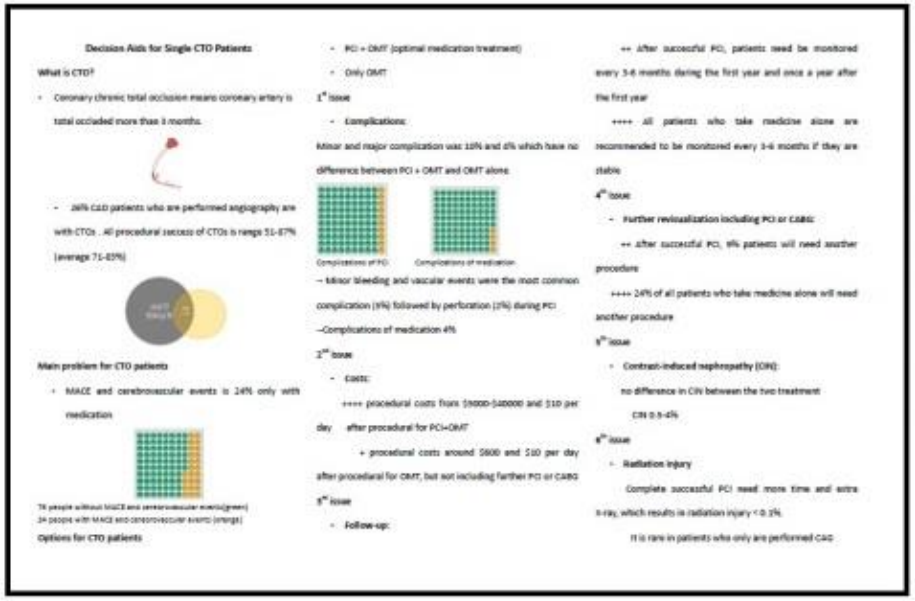




Flow Chart


Screening of patients
Fulfills inclusion criteria, no exclusion criteria
No
Ineligible
Consent
Baseline PET/CT, CMR, TTE
Within 2 days
SDM
PCI+OMT
OMT alone
30-day follow-up
6-month follow-up
12-month follow-up

Open CTO or not- CTO DA



Decision Aids for Single CTO Patients

What is CTO?

- Coronary chronic total occlusion means coronary artery is total occluded more than 3 months.

- 26% CAD patients who are performed angiography are with CTOs . All procedural success of CTOs is range 51-87% (average 71-83%)

Main problem for CTO patients

- MACE and cerebrovascular events is 24% only with medication

74 people without MACE and cerebrovascular events(green)
24 people with MACE and cerebrovascular events (orange)

Options for CTO patients

- PCI + OMT (optimal medication treatment)
- Only OMT

1st issue

- Complications:

Minor and major complication was 10% and 4% which have no difference between PCI + OMT and OMT alone.

Complications of PCI Complications of medication

-- Minor bleeding and vascular events were the most common complication (6%) followed by perforation (2%) during PCI

--Complications of medication 4%

2nd issue

- Costs:

++++ procedural costs from $6000-$40000 and $10 per day after procedural for PCI+OMT

+ procedural costs around $600 and $10 per day after procedural for OMT, but not including further PCI or CABG

3rd issue

- Follow-up:

++ After successful PCI, patients need be monitored every 3-6 months during the first year and once a year after the first year

++++ All patients who take medicine alone are recommended to be monitored every 3-6 months if they are stable

4th issue

- Further revisualization including PCI or CABG:

++ After successful PCI, 6% patients will need another procedure

++++ 24% of all patients who take medicine alone will need another procedure

5th issue

- Contrast-induced nephropathy (CIN):

no difference in CIN between the two treatment

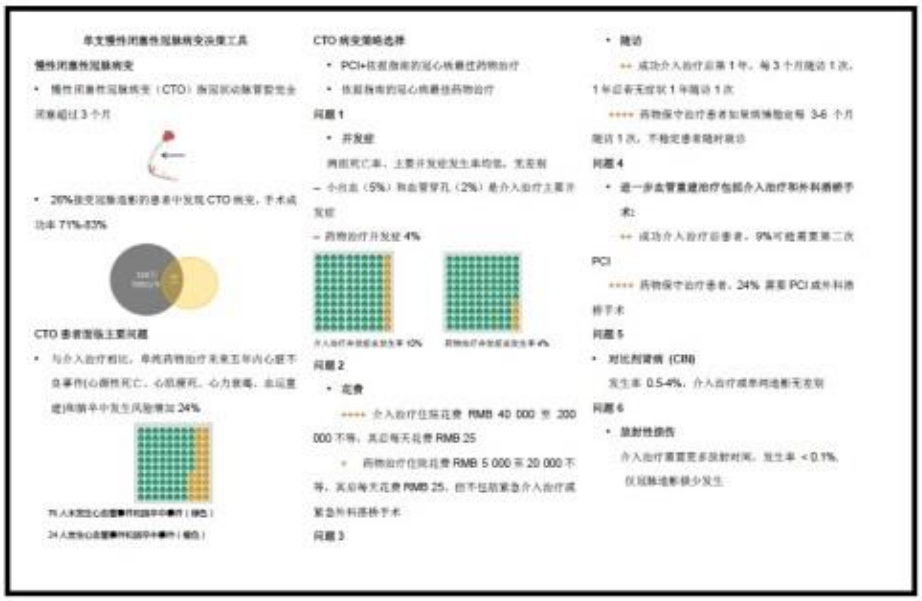
CIN 0.5-4%

6th issue

- Radiation injury

Complete successful PCI need more time and extra x-ray, which results in radiation injury < 0.1%

It is rare in patients who only are performed CAG



单支慢性闭塞性冠脉病变决策工具

慢性闭塞性冠脉病变

- 慢性闭塞性冠脉病变（CTO）指冠状动脉管腔完全闭塞超过 3 个月

- 26%接受冠脉造影的患者中发现 CTO 病变，手术成功率 71%-83%

CTO 患者面临主要问题

- 与介入治疗相比，单纯药物治疗未来五年内心脏不良事件(心源性死亡、心肌梗死、心力衰竭、血运重建)风险中发生风险增加 24%

74 人未发生心血管事件和脑卒中事件（绿色）
24 人发生心血管事件和脑卒中事件（橙色）

CTO 病变策略选择

- PCI+优质指南的冠心病最佳药物治疗
- 仅指南的冠心病最佳药物治疗

问题 1

- 并发症

两组死亡率，主要并发症发生率均低，无差别

- 小出血（5%）和血管穿孔（2%）是介入治疗主要并发症

– 药物治疗并发症 4%

介入治疗并发症发生率 10% 药物治疗并发症发生率 4%

问题 2

- 花费

++++ 介入治疗住院花费 RMB 40 000 至 200 000 不等，其后每天花费 RMB 25

+ 药物治疗住院花费 RMB 5 000 至 20 000 不等，其后每天花费 RMB 25，但不包括紧急介入治疗或紧急外科搭桥手术

问题 3

- 随访

++ 成功介入治疗后第 1 年，每 3 个月随访 1 次，1 年后若无症状 1 年随访 1 次

++++ 药物保守治疗患者如果病情稳定每 3-6 个月随访 1 次，不稳定患者随时就诊

问题 4

- 进一步血管重建治疗包括介入治疗和外科搭桥手术：

++ 成功介入治疗后患者，9%可能需要第二次 PCI

++++ 药物保守治疗患者，24% 需要 PCI 或外科治疗手术

问题 5

- 对比剂肾病 (CIN)

发生率 0.5-4%，介入治疗或单纯造影无差别

问题 6

- 放射性损伤

介入治疗需要更多放射时间，发生率 < 0.1%，仅冠脉造影极少发生

Ongoing data

- Of all 240 patients, 112 patients completed one-year follow-up.

- CTO patients were all satisfied with the process of SDM. DA is helpful to improve the knowledge of CTO and decrease the conflict of making decision.

Take home messages

- In China context, SDM is acceptable for both physicians and patients. They could perform SDM in their practice after patient education and modifying decision aids.

- It is feasible to implement SDM in China with new SDM model and DA.

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Thank you for your comments