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CBSMD 专访

ULTIMATE 研究者张俊杰
谈 IVUS 之过去、现在和未来

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CBSMD: 作为一名精通各种冠状动脉影像学的介入医生，您如何评冠脉造影、IVUS 和 OCT?

张俊杰: 冠脉造影曾是冠心病诊断的“金标准”，具有鉴别冠状动脉是否闭塞以及闭塞的严重程度的能力，目前其局限性已广为介入医生所知，如 Gary S. Mintz 所介绍的“相对于 IVUS 或 OCT 是对冠状动脉的断层或横断面的成像，冠脉造影呈现的管腔影像不是对病变血管本身的成像，而仅是将对比剂注射后的管腔按透视法缩小后，呈现出的伴有阴影的平面投影”¹。从实际操作来看，冠脉造影所提供的冠脉闭塞程度不一定精确，术者需要参照临近血管节段才能加以判断，且根据造影数据无法获知动脉的真实数据。若参照物同样是有病变的血管，所作出的判断的出入就更大了。冠脉造影常低估冠状动脉临界病变的严重程度。冠脉造影会受到影像缩短效应的影响，难以准确指导支架尺寸及长度的选择。

血管内超声（Intravascular Ultrasound, IVUS）的原理是将超声探头放入血管腔，从血管内部 360° 观察血管壁的情况，因为 IVUS 采用的是声波反射，所以观察过程不受血流动力学的影响，同时利用虚拟组织学（virtual histology, VH）可对斑块内纤维、纤维脂质混合、坏死核和钙化等四种组织进行辅助判断。

光学相干断层成像术（OCT）采用的是红外线扫描，分辨率高，但组织穿透

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力不如 IVUS。因红外线易受血流影响，目前正在研发在最短时间内获取扫描病变部位的血管壁图像。

所有影像技术应用的目的是为了优化支架的置入效果，从对现有临床研究证据的掌握以及对各影像学检查手段的优缺点来看，IVUS 或 OCT 的介入用途已从最初判断支架膨胀是否良好拓展到了是否能有效改善患者预后，冠脉造影必将被 IVUS 或 OCT 等腔内影像学取代。

CBSMD: PCI 40 年历程中经历了怎样的技术变迁，IVUS 对冠心病患者带来了怎样的临床获益？

张俊杰： IVUS 的应用贯穿在冠心病的诊断及介入治疗的发展进程中。在 PCI 前冠心病的诊断阶段，积累的研究已证明腔内影像学与功能学指标血流储备分数（fractional flow reserve, FFR）在综合考虑病变部位、病变血管的直径、供血血管的大小、心肌范围的大小等因素的前提下，可以为疾病诊断或术前策略制定提供相对客观的标准来评价病变是否会引发缺血性证据及其介入风险，比如对 ACS 易损斑块、回声衰减、大脂核等斑块高危衰减斑块可能引发的无复流等并发症。

在 PCI 过程中要依靠 IVUS 对病变性质、程度和累及范围以及参考血管的精确判断，帮助术者选择治疗策略和方法，指导并优化介入治疗过程、评价介入效果，同时监测相关并发症。从 IVUS 指导优化介入治疗过程来看，无论是裸支架

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到药物支架时代，从降低再狭窄率到“The bigger, the better”理念，还是“high-pressure final balloon dilatation”²，相较于造影，IVUS除了可呈现更多的冠脉解剖结构相关信息以更好地选择支架外，还可指导术者在介入中通过即刻具体参数，比如对膨胀指数以避免支架膨胀不良、最小管腔面积，严重的组织脱垂预测近期远端心肌灌注不良、支架边缘夹层 ≥ 3 mm 等数据的掌握可评价支架置入效果，降低近、中、远期支架内再狭窄率，靶病变血运重建率，更重要的是支架内血栓率的发生风险。

支架的研发进程一直是在探索中前行的。Andreas Grüntzig 于 1977 年首次施行球囊成形术 (balloon angioplasty) 的两个主要缺陷表现在支架内血栓和会在 5-10% 的患者中引发因弹性回缩 (vascular elastic recoil) 导致的急性闭塞 (acute occlusion)，在接近 30% 的患者中导致术后 6 个月内新生内膜增生伴再狭窄。为了克服这一技术上的短板，Sigwart 等在 1987 年研发并在球囊成形术后置入了首个自膨式金属支架。而经美国 FDA 批准入市的一代金属支架也有它的不足，即支架内血栓 (stent thrombosis) 和支架内再狭窄 (in-stent Restenosis, ISR)。从上世纪 90 年代起，有大量的研究致力于从分子机制解释血栓及再狭窄的机制。在明确当将西罗莫司和紫杉醇等药物包裹在金属支架外层对新生内膜增生具有抑制效果后，Edwardo Sousa 于 1999 年置入了首例西罗莫司洗脱支架 (sirolimus-eluting stent, SES)。历经了数个 RCT 研究证实 SES 在降低 ISR 和 TLR 方面优于 BMS 之后，2003 年西罗莫司洗脱支架在美国

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FDA 批准下正式入市。尽管如此，前路依然险阻，后续随访发现，DES 的晚期临床事件比如心梗（MI）、晚期支架内血栓（late ST）的发生率较 BMS 高，主要与置入 DES 后干扰血管壁再内皮化有关。至此以预防晚期临床事件发生的双抗治疗加入历史舞台。而二代 DES 则采用钴铬（CoCr）或铂铬（PtCr）材料以减少支架厚度，依维莫司类洗脱支架（CoCr-EES，PtCr-EES）、和佐他莫斯洗脱支架（CoCr-ZES）进一步降低了靶病变血运重建和支架内血栓。2015 年证实入市的三代 DES 采用生物可降解 DES 针对性地解决了永久性药物涂层所致的过敏反应的问题。现在我国有团队正在继续四代生物可吸收支架的研究。随着支架改良所带来的技术性进步，术者要为每一例病患平衡靶病变血运重建、支架内血栓和出血事件之间的关系。

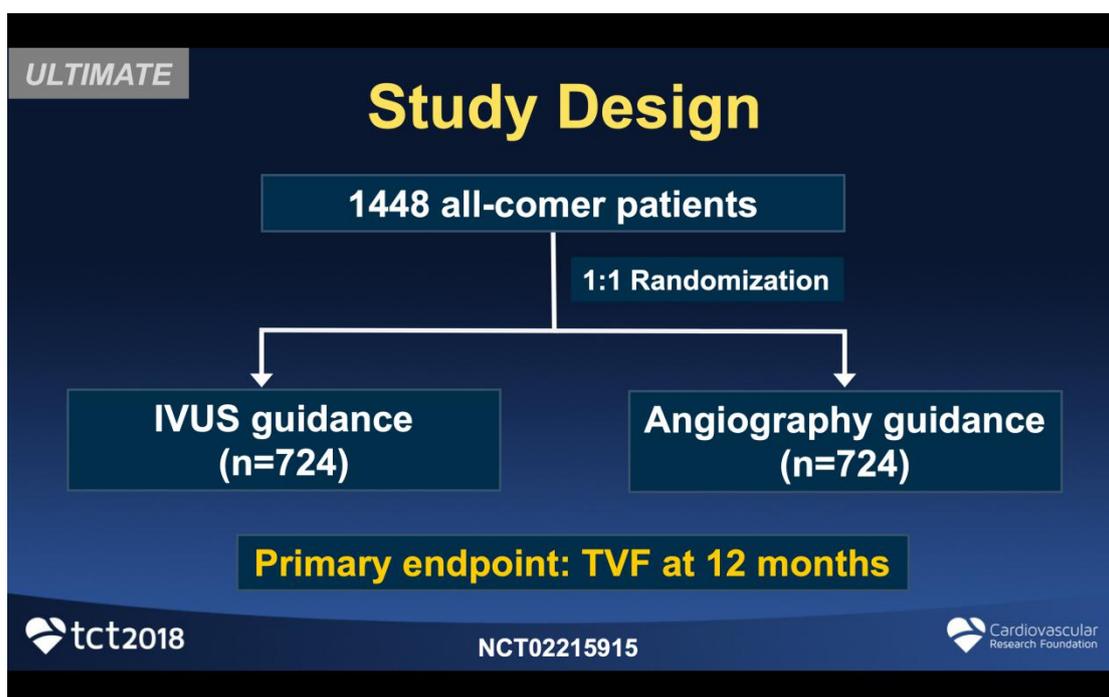
在 PCI 后从 IVUS 指导改善不同支架介入治疗效果来看，既往 7 项 RCT 研究都试图去证实 IVUS 的有效性，单独考虑单项检验力不足的 RCT 研究结果均不能充分体现出 IVUS 的全面价值，IVUS 指导所带来的获益主要体现在对血运重建风险的改善上。但是整合了 7 项 RCT 研究³⁻⁹（各 RCT 研究详见表一）和 24 项前瞻性注册研究的荟萃分析的结果却是一目了然，在 DES 时代，IVUS 指导经皮冠脉介入治疗（PCI）优于造影指导 PCI，可降低平均 15 个月随访期间的 MACE 风险，主要通过降低缺血驱动的靶病灶血运重建；既往所有研究显示 IVUS 可以改善复杂病变介入的临床预后。最近我代表各分中心及陈绍良教授在 TCT 2018 上汇报的最新临床研究 ULTIMATE 研究¹¹在全冠脉患者（其中包含 65% 的复杂病变患者）

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中观察临床终点事件靶血管失败 (target vessel failure, TVF)，从此项优效性检验的结果推断，IVUS 不仅改善复杂病变 PCI 患者的预后，也可以改善简单病变 PCI 患者的预后，也就是说 ULTIMATE 研究从根本上定义了 IVUS 指导 PCI 的适应证（前期研究适应证详见表一）。



CBSMD：ULTIMATE 研究中全患者群的疾病构成是怎样的？

张俊杰：根据研究方案设计，ULTIMATE 研究入选的患者是经诊断为无症状缺血、稳定或不稳定心绞痛或 >24 小时因胸痛入院的心肌梗死（包含 STEMI 和 NSTEMI）的符合药物洗脱支架置入条件的患者。参与研究的 8 家中国介入中心的、符合入选条件的 1448 名患者按照 ACC/AHA 建议进行病变分组 Type A, Type B1, Type B/C（IVUS 组 66.1% vs. 冠脉组 67.7%）。78.5% 的患者第一诊断为 ACS，有 8 例造影组的患者因复杂病变治疗需要最终接受的是 IVUS 指导 PCI。IVUS 指导组

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和造影指导组在病变长度、部位、类型及程度上均无统计学差异。

CBSMD : ULTIMATE 研究的结果显示, 相对于对照组而言, 即相对于造影指导 PCI, 对靶血管再狭窄的改善有多大?

张俊杰: ULTIMATE 研究最核心的成果是报道了全冠心病人群经 IVUS 指导的 DES 置入一年血管失败率为 2.9%, 显著低于经造影指导后的靶病变发生率 5.4%。需要强调的是, ULTIMATE 研究中术者对照组的处理已经达到了很高的水准, 接近 95% 的后扩压力达到了 19 a. t. m, 参与本研究的术者也是根据各指南所推荐的高年资、手术量超过 200 例的经验丰富、介入技术娴熟的术者。

CBSMD: 既往研究及 ULTIMATE 研究均提到了药物洗脱支架置入的 IVUS 标准, ULTIMATE 研究也提到了只有达到此标准, 介入才能被定义为成功的治疗。请您再详细的解读一下理想的 IVUS 标准? 您对达到这一标准有什么建议?

张俊杰: ULTIMATE 研究设计中加入了理想的药物洗脱支架置入的 IVUS 标准, 即 1) DES 植入后支架段最小管腔面积 $>5.0\text{mm}^2$, 或大于 90% 的远端参考血管的最小管腔面积; 2) 支架近端或远端 5mm 内的最大斑块负荷 $<50\%$; 3) 无深达中层且存在长度超过 3mm 的夹层。当以上三项标准均达标时, 对于全冠心病患者的介入质量就有了客观指标的保证, “三分天注定, 七分靠打拼” 中的 “人为” 的环节就做到了。手术达标是介入质控的核心, 这有赖于对医生和技师的持续培训。

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高质量的介入效果能有效降低卫生经济学成本，我们建议各中心权衡 IVUS 设备的投入、患者卫生经济学负担与长期随访观察下所带来健康获益之间的关系。目前普遍的共识是，哪怕是介入技术已经很高的资深医生，腔内影像学也能进一步优化其手术质量，发挥“介入医生第三只眼”的作用。

CBSMD: 在 ULTIMATE 研究之后，IVUS 与 OCT 之间，您会按照什么样的标准加以选择？

张俊杰: ESC 2018 版心肌梗死血运重建指南汇总就基于两种影像学的特性对临床质控给出了明确的建议：IVUS 和 OCT 均可准确评估因过多新生内膜增生导致的支架内再狭窄、晚期获得性贴壁不良、支架膨胀不全、支架挤压和边缘夹层等 5 类评估支架置入成败等指标；OCT 更多地被用来评价新生动脉粥样硬化和支架外翻。

CBSMD: 从一个成熟术者的角度，在您经历了看山是山（感觉 IVUS 会带来获益）、到看山不是山（IVUS 的获益尚未经大样本 RCT 研究证实），到看山还是山（亲历 ULTIMATE 研究证实了 IVUS 指导 PCI 可带来预后获益的时候），您对 IVUS 未来的技术性改善有什么期许？

张俊杰: 从技术角度看，现在国内普遍应用的是 40-MHZ 的 IVUS，国外已将 IVUS 分辨率提高到 60-MHZ，期望在不久的就得将来，国内也能用上高分辨率的 IVUS，

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进一步提高对病变的解读能力。从改善临床终点的角度来分析，尚未观察到 IVUS 对死亡率有任何的改善，目前所获得的改善性研究结论均是基于联合终点的比较研究，对临床硬终点的改善会是我们坚定不移的目标。

CBSMD：未来您对于 ULTIMATE 研究有什么计划？

张俊杰：ULTIMATE 研究是我们基于既往研究成果、从临床观察出发验证 IVUS 具有改善全冠心脏病患者介入预后的临床试验，现阶段在 TCT 大会上还仅是汇报了一年的随访结果，我们下一步会持续进行中期和远期的随访。在此基础上，希望 ULTIMATE 研究可以对推广 IVUS 在世界心血管介入的应用起到推波助澜的作用。

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RCTs	Design	Indication	N	Primary Outcome	Outcome
HOME DES IVUS ³	IVUS-guided superior to angiography guided DES implantation + 6 month dual antiplatelet therapy	complex coronary artery disease and high clinical risk profile with special attention to the development of late stent thrombosis (LST)	210	MACE = death, MI and reintervention at 18 month	Negative
AVOI trial ⁴ 2012	to evaluate the safety and efficacy of IVUS guided post-dilatation in increasing the final MLD, as compared with angiographic guided post-dilatation	complex lesions (bifurcations, long lesions, chronic total occlusions or small vessels)	284	Primary end point: post-procedure in lesion minimal lumen diameter; Secondary end points: combined major adverse cardiac events (MACE), TLR, TVR, MI, and stent thrombosis at 1, 6, 9, 12, and 24 months	Primary end point in favor of the IVUS group Positive: 2.70 mm ± 0.46 mm vs. 2.51 ± 0.46 mm; P = .0002)
Kim ⁵ 2013	IVUS-guided vs. angiography guided DES implantation	Long coronary lesion >= 28 cm	543	MACE = cardiovascular death, MI, target vessel revascularization or stent thrombosis at 1 year	Negative

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RCTs	Design	Indication	N	Primary Outcome	Outcome
IVUS-XPL ⁶ 2015	IVUS-guided superior to angiography guided DES implantation	Long coronary lesion >=28 cm	1323	MACE = cardiac death, target lesion-related MI, or ischemia-driven target lesion revascularization at 1 year	Positive: absolute difference = -2.97%
Tan et al ⁷ 2015	IVUS-guided vs. angiography guided DES implantation	unprotected left main coronary artery stenting	123	MACE = death, non-fatal myocardial infarction, or target lesion revascularizations at 2 year	Positive : IVUS guidance was independent factor of survival free of MACE (HR: 0.414, CI: 0.129-0.867; p=0.033).
AIR-CTO ⁸	IVUS-guided vs. angiography guided DES implantation	CTO lesions	230	in-stent late lumen loss (LLL) at 1 year	Positive: In-stent LLL in the IVUS-guided group was significantly lower compared to the angiography-guided group at one-year follow-up (0.28±0.48 mm vs. 0.46±0.68 mm, p=0.025), with a significant difference in restenosis of the “in-true-lumen” stent between the two groups (3.9% vs.13.7%, p=0.021).
CTO-IVUS Study ⁹	IVUS-guided vs. angiography guided DES implantation	CTO lesions	402	cardiac death and a major adverse cardiac event defined as the composite of cardiac death, myocardial infarction, or target-vessel revascularization at 1 year	Negative results in cardiac death and target-vessel revascularization. Positive results in major adverse cardiac event rates were significantly lower in the IVUS-guided group than that in the angiography-guided group (2.6% versus 7.1%; P=0.035; hazard ratio, 0.35; 95% confidence interval, 0.13 - 0.97). Occurrence of the composite of cardiac death or myocardial infarction was significantly lower in the IVUS-guided group (0%) than in the

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RCTs	Design	Indication	N	Primary Outcome	Outcome
DEFINITION trial subgroup analysis ¹⁰ 2018	IVUS guidance is superior to angiography guidance	true and complex bifurcation lesions	1465	composite MACE= cardiac death, MI, or clinically-driven target vessel revascularization at 1-year and at the end of study 7 years after indexed procedure.	angiography-guided group (2.0%; P=0.045). Positive: MACE occurred in 10.0% of patients at 1-year follow-up and 15.2% at the 7-year follow-up in the IVUS group, significantly different from 15.0% (p = 0.036) and 22.4% (p = 0.01) in the angiography group, respectively.
ULTIMATE trial ¹¹ 2018	IVUS guidance is superior to angiography guidance	Simple lesion as well as complex lesions	1448	target vessel failure (TVF) at 12 months, including cardiac death, target vessel myocardial infarction (TV-MI), and clinically-driven target vessel revascularization (TVR).	angiography-guided group (2.0%; P=0.045). Positive: 60 (4.2%) TVFs occurred, with 21 (2.9%) in the IVUS group and 39 (5.4%) in the Angiography group (HR= 0.530, 95%-CI [0.312-0.901; p=0.019). In the IVUS group, TVF was recorded in 1.6% of patients with 17 successful procedures, compared to 4.4% in patients who failed to achieve all optimal criteria 18 (HR: 0.349; 95%CI: 0.135-0.898; p=0.029). The significant reduction of clinically-driven target 19 lesion revascularization (TLR) or definite stent thrombosis (HR: 0.407; 95% CI: 0.188-0.880; 20 p=0.018) based-on lesion level analysis

表一、既往各项围绕 IVUS 的 RCT 研究梳理

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张俊杰主任在 TCT 2018 主会场汇报 ULTIMATE 研究成果

张俊杰，博士，副主任医师，南京市第一医院心内科副主任，导管室主任。2004 年度作为访问学者被派新加坡国立大学医院心脏中心研修“心血管介入治疗”。现任美国心血管造影与介入协会委员（FSCAI）、中国医师协会心血管内科医师分会血栓防治专业委员会委员、中国医疗保健国际交流促进会心血管病管理专业委员会、卫计委冠脉介入培训基地导师，江苏省医学会心血管专科分会青年委员、南京医学会心血管专科分会委员。获得中华人民共和国教育部科学技术进步奖、江苏省科技进步奖、江苏省医学新技术引进奖、南京市科技进步奖；2014 年度被评为江苏省“名医民选”百姓信任的医疗专家。张主任临床主攻治疗及研究方向为冠心病介入诊断与治疗，尤其是复杂高危病变包括左主干病变、多支病变、慢性完全闭塞病变、重度钙化病变旋磨术、急性冠状动脉综合征等介入治疗方面具有丰富的经验和娴熟的技术，以及肥厚性梗阻型心肌病的介入治疗。

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