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◇ 心脑血管疾病 ◇

球囊后扩张同时推注对比剂评估支架贴壁的血管内超声评价

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摘要:目的 采用血管内超声(Intravascular ultrasound, IVUS)评价球囊后扩张同时推注对比剂(Balloon Post-dilatation simultaneous injection contrast, BPIC)用以判断经皮冠状动脉介入治疗(PCI)时支架的贴壁状态。方法 选取2018年1月1日至2018年10月10日, 徐州医科大学附属医院行经皮冠状动脉介入治疗术(Percutaneous coronary intervention, PCI)的原位病变冠心病病人30例。根据定量冠脉造影(Quantitative coronary angiography, QCA)结果指导支架、球囊的选择, 在PCI术中于支架释放后由远及近采用多次BPIC方法判断支架贴壁, 然后行IVUS检查评价支架释放后的贴壁情况; 以BPIC时球囊远端无前向对比剂且无分支显影时为支架贴壁良好的指标。结果 30例病例, 共计植入54枚支架, 经过BPIC, 支架最大直径大于支架型号而与后扩球囊型号相当[(3.54±0.66)比(3.21±0.55)mm, $P < 0.05$; (3.54±0.66)比(3.59±0.75)mm, $P > 0.05$], 支架对称指数为0.86±0.05; QCA与IVUS对支架最大直径的测量存在显著线性相关($r = 0.997$, $P = 0.000$); 50枚支架经BPIC与IVUS均判断为贴壁良好, BPIC与IVUS判断支架贴壁差异无统计学意义($\chi^2 = 2.25$, $P > 0.05$)。结论 BPIC方法判断支架贴壁可靠性高, 支架扩张充分, 在PCI术中采用该方法可以评估支架贴壁。

关键词:冠心病; 球囊扩张术/方法; 冠状血管造影术; 超声检查, 介入性; 顺应性; 药物洗脱支架; 支架贴壁不良; 非顺应性球囊

The Intravascular ultrasound evaluation of balloon post-dilatation simultaneous injection contrast evaluating stent adherence

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Abstract: Objective Using Intravascular ultrasound (IVUS) to evaluate the reliability of balloon post-dilatation simultaneous injection contrast (BPIC) judging the stent attachment in percutaneous coronary intervention. **Methods** From January 1, 2018 to October 10, 2018, 30 patients with coronary heart disease in situ underwent percutaneous coronary intervention (PCI) in the Affiliated Hospital of Xuzhou Medical University. The results of quantitative coronary angiography (QCA) were used to guide the choice of

stent and balloon. In PCI, multiple BPIC were used from far and near to judge the stent attachment after stent release and then the IVUS was used to evaluate the adherence of the stent. When the BPIC was used, no forward contrast agent at the distal end of the balloon and no branch development was used as a good indicator of stent adherence. **Results** In 30 cases, a total of 54 stents were implanted. After BPIC, the maximum diameter of the stent was larger than that of the stent model and was equivalent to that of the posterior balloon $[(3.54 \pm 0.66) \text{ vs. } (3.21 \pm 0.55) \text{ mm}, P < 0.05; (3.54 \pm 0.66) \text{ vs. } (3.59 \pm 0.75) \text{ mm}, P > 0.05]$, the stent symmetry index was 0.86 ± 0.05 ; there was a significant linear correlation between QCA and IVUS for measuring the maximum diameter of the stent ($r = 0.997, P = 0.000$); 50 stents were judged by BPIC and IVUS as good adherence, there was no statistical difference between BPIC and IVUS in judging stent adherence ($\chi^2 = 2.25, P > 0.05$). **Conclusion** The reliability of judging stent attachment by BPIC is high and the stent is fully expanded. This method can be used to evaluate stent adherence during PCI.

Key words: Coronary disease; Balloon dilation/methods; Coronary angiography; Ultrasonography, interventional; Compliance; Drug-eluting stent; Stent malapposition; Non-compliant balloon

由于近年来冠脉支架的发展及其在介入领域的广泛应用,冠心病病人的生活质量及预后得到明显的提高。但研究表明^[1-4],药物洗脱支架(DES)的支架贴壁不良发生率明显高于裸金属支架,支架贴壁不良经研究^[5-8]证实与支架内血栓形成存在一定的相关性。因此,不管是即刻还是晚期支架贴壁不良,都是临床医师关注的重点。本研究旨在以血管内超声(Intravascular ultrasound, IVUS)作为金标准评价球囊后扩张同时推注对比剂(Balloon Post-dilatation simultaneous injection contrast, BPIC)方法判断支架贴壁的可靠性。

1 资料与方法

1.1 一般资料 本研究经徐医附院伦理委员会审核批准,审批文号:XYFY2018-KL084;病人或其近亲属术前签署知情同意书。选取2018年1月1日至2018年10月10日,徐州医科大学附属医院行经皮冠状动脉介入治疗术(PCI)的原位病变冠心病病人30例。纳入标准:冠状动脉原位性病变;无心源性休克等严重疾病;同意并可耐受IVUS检查。排除标准:拒行IVUS检查;不能耐受长时间手术;无须球囊后扩张。

1.2 研究方法 首先对病人行冠状动脉造影,采用计算机辅助定量冠脉造影(Quantitative coronary angiography, QCA)测量血管直径、狭窄程度及病变长度来指导支架、后扩球囊型号的选择,根据QCA测量结果及支架、后扩球囊的“压力-直径”表决定支架的释放压力、球囊的后扩压力。每个支架后扩(2.7 ± 0.7)次,由支架远端向近端后扩,每次均采用BPIC方法判断支架贴壁情况。为简化评价方式,缩短手术时间,若支架释放后经BPIC判断为贴壁不良,则增加后扩球囊压力或者更换直径更大的球囊后扩,直到BPIC判断为贴壁良好,采用BPIC方法评价完整枚支架后行IVUS检查。

以下为BPIC与IVUS各自判断支架贴壁的标准:

(1)BPIC方法判断支架贴壁:球囊后扩张同时推注对比剂时,如果对比剂不能越过球囊近端标记而且血管远端、边支血管均未显影则判断为本次后扩部位支架贴壁良好;反之则判断为贴壁不良。(2)血管内超声判断支架贴壁 本次研究采用的IVUS机器为(Boston Scientific, opticross 机械式探头超声导管,40 MHz),在进行IVUS检查前常规给予肝素2000 U,首先将机械超声导管于体外充分采用生理盐水冲洗,将导管内气体完全排出,于体外测试超声影像,直至图像清楚。然后将机械超声导管送入冠脉血管内,导管前端探头需送至支架远端10 mm处,采用自动回撤,速度为0.5 mm/s,通过对景深及增益的微调获得清晰的超声图像。将得到的IVUS图像每隔1 mm为一个横截面进行分析,若支架小梁与管壁内膜完全贴合且后方无血流信号,判断为支架贴壁良好;反之则判断为贴壁不良。全部IVUS操作由二位术者、同一台IVUS机器实施。见图1。

1.3 观察指标 BPIC:观察造影图像,得到BPIC方法判断的各支架贴壁情况。通过QCA测量支架最大、最小直径。IVUS:若支架与血管内膜完全贴合,贴壁不良距离记录为零;反之则记录每枚支架最大的贴壁不良距离、贴壁不良面积,支架最大、最小直径。最大贴壁不良距离是指由支架小梁垂直至冠脉血管内膜的最大长度。贴壁不良面积为支架小梁与血管内膜之间存在血流信号的面积。

对称指数 = 支架最小直径/最大直径;贴壁不良的面积比例 = 贴壁不良面积/管腔面积。

1.4 统计学方法 采用软件SPSS 18.0进行统计学分析。计量资料数据结果采用 $\bar{x} \pm s$ 表示,比较采用 t 检验(成组 t 检验或配对 t 检验)。计数资料以例数或率表示,比较采用 χ^2 检验。相关性分析采用Pearson相关分析。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 基线资料 本研究共计30例符合纳入标准病

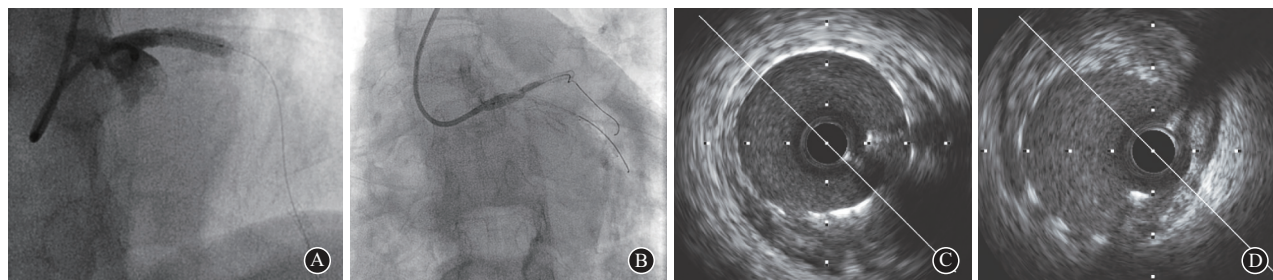


图1 球囊后扩张同时推注对比剂(BPIC)与血管内超声(IVUS)各自判断支架贴壁的典型图片:A为BPIC方法示支架贴壁良好,球囊后扩同时推注对比剂时球囊远端、侧支未见血流信号;B为BPIC方法示支架贴壁不良,球囊后扩同时推注对比剂时球囊远端血管仍可见血流信号;C为IVUS示支架贴壁良好;D为IVUS示支架贴壁不良,支架钢梁外侧仍可见血流信号

人,支架54枚,年龄为 (66.2 ± 10.7) 岁,男性病人23例(77%),女性病人7例(23%),高血压病人19例(63%),高脂血症病人7例(23%),糖尿病病人7例(23%),吸烟病人9例(30%);病变血管以左前降支所占比例最高,达25例(46%),其次分别为回旋支病变12例(22%),右冠状动脉病变9例(17%),左主干病变8例(15%)。

2.2 比较支架最大直径与支架、球囊型号 根据QCA结果选择支架型号(直径)为 (3.21 ± 0.55) mm,采用后扩球囊的型号(直径)为 (3.59 ± 0.75) mm,经IVUS测量支架最大直径为 (3.54 ± 0.66) mm。将三组数据行正态性检验,各组数据均服从正态分布($P > 0.05$),支架最大直径大于支架型号 $[(3.54 \pm 0.66)$ mm比 (3.21 ± 0.55) mm, $t = 2.823$, $P = 0.006$]而与后扩球囊型号相当 $[(3.54 \pm 0.66)$ mm比 (3.59 ± 0.75) mm, $t = 0.368$, $P = 0.714$]。

2.3 比较QCA与IVUS对支架直径的评价 首先将QCA与IVUS对支架最大、最小直径的测量数据进行正态性检验,四组数据均服从正态分布($P > 0.05$)。BPIC后,经QCA测量出支架最大直径为 (3.48 ± 0.66) mm,经IVUS测量出支架最大直径为 (3.54 ± 0.66) mm,两者存在显著线性相关, $r = 0.997$, $P = 0.000$;经QCA测量出支架最小直径为 (2.97 ± 0.59) mm,经IVUS测量出支架最小直径为 (3.03 ± 0.58) mm,两者同样存在显著线性相关($r = 0.992$, $P = 0.000$)。

2.4 IVUS评价支架贴壁 经过多次BPIC后行IVUS评价,54枚支架对称指数为 0.86 ± 0.05 ,4枚支架出现贴壁不良,其中3枚支架贴壁不良部位位于支架边缘,1枚支架贴壁不良部位位于支架体部。最大支架贴壁不良距离为510 μ m,最小支架贴壁不良距离为280 μ m;最大贴壁不良面积为1.92 mm²,最小支架贴壁不良面积为0.67 mm²;最大支架小梁贴壁不良率为9%,最小支架小梁贴壁不良率为2%。见表1。

表1 血管内超声(IVUS)评价4枚贴壁不良支架

支架编号	支架型号/mm	小梁贴壁不良率/%	贴壁不良距离/ μ m	贴壁不良面积/mm ²	贴壁不良面积比例/%
01	2.5×29	5	280	0.67	9.3
02	3.5×23	2	510	1.92	13.8
03	3.5×33	3	320	0.96	9.7
04	4.0×18	9	490	1.15	8.9

2.5 对比BPIC与IVUS判断支架贴壁 本研究中54枚支架经BPIC均判断为贴壁良好,经IVUS检查后,50枚支架贴壁良好,4枚支架贴壁不良,BPIC与IVUS诊断符合率达92.6%(50/54)。将BPIC与IVUS两组资料行卡方检验,计算 $\chi^2 = 2.25$, $P = 0.13$,表明两种方法判断支架贴壁差异无统计学意义。

3 讨论

目前评价冠脉支架贴壁情况的金标准仍然是依靠腔内影像学,包括IVUS、光学相干断层扫描(optical coherence tomography, OCT)等,但因其价格昂贵,延长手术时间等原因,不可能对每一位病人均行上述检查,尤其是无IVUS或OCT设备的县级医院。在腔内影像学尚未普及时,有医院采用BPIC方法进行对支架贴壁情况的大致判断,但该方法的可靠性如何尚无明确定论。所以本研究的目的即使用IVUS评价该方法的可靠性。

高支架对称指数、贴壁良好率依赖于:①支架型号合理选取:研究证实支架尺寸不合理,扩张不充分是支架贴壁不良的重要原因^[9]。②非顺应性球囊(non-compliant balloon, NCB)后扩张:在DES释放时,由于支架囊多为半顺应性球囊,支架扩张并不理想,而经NCB后扩可明显改善其扩张效果,获取更大的支架直径^[10]。③斑块性质:冠状动脉斑块根据其密度不同将其分为脂质、纤维、混合以及钙化斑块。研究表明,急性支架贴壁不良多发生于钙化性冠脉动脉病变病人^[11],术前斑块成分与晚期支架贴壁不良相关^[12],钙化斑块是支架贴壁不良的独立预测因素^[13-15]。④血管重构:研究证实,血管正性重

构在支架贴壁不良发生中起到重要作用^[16-17]。本次临床研究共包含 54 枚支架, 支架释放后的实际直径与其型号相符, 最大直径大于支架型号而与采用的后扩球囊型号相当, 对称指数为 0.86 ± 0.05 , 支架贴壁良好率达 92.6%。在本研究中, 支架及 NCB 型号选择源自病人 QCA 测量结果, 支架释放后均采用 NCB 进行后扩, 每枚支架后扩至支架边缘, 根据造影及球囊的“压力-直径”表决定后扩压力。冠脉斑块类型多以混合斑块、脂质斑块、纤维斑块为主, 钙化斑块较少。4 枚支架经 IVUS 检查示贴壁不良, 其中 3 枚支架贴壁不良部位位于支架边缘, 1 枚支架贴壁不良部位位于支架体部。

BPIC 时, 由于支架长于后扩球囊, 虽然近端支架贴壁良好, 但远端仍有贴壁不良可能, 球囊远端、边支血管同样无对比剂通过, 此时 BPIC 会得到假阴性的结论。但血管通常为近端直径大于远端, 在 BPIC 时, 近端支架贴壁良好时, 若无严重钙化、扭曲, 推测远端很少会出现贴壁不良。另外, 长支架后扩张可以采用多次 BPIC 或近端更换更大直径的球囊再次行 BPIC 来解决。

54 枚支架经 BPIC 与 IVUS 判断支架贴壁的符合率达 92.6% (50/54), 两者对于支架贴壁的判断差异无统计学意义 ($\chi^2 = 2.25, P > 0.05$)。在 PCI 术中若无 IVUS 可用, 可以采用 BPIC 方法对支架贴壁进行大致评价。

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