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· 文献综述 ·

药物涂层球囊治疗股腘动脉支架内再狭窄的研究进展

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摘要

支架内再狭窄 (ISR) 是治疗周围血管疾病中比较常见的临床问题, 然而, 目前通过介入技术治疗 ISR 尚没有统一、有效的方法。药物涂层球囊 (DCB) 为股腘动脉 ISR 的治疗提供了一种新思路, 近年来已得到初步尝试, 与普通球囊相比, DCB 治疗股腘动脉 ISR 术后 6 个月甚至 1 年血管通畅率更高, 靶血管干预率更低, 但其中远期效果尚需进一步研究验证。且研究发现支架内长段狭窄或闭塞性病变管腔内更容易再次发生狭窄。DCB 与“减容”技术联合治疗股腘动脉 ISR 被寄予很大希望, 但目前尚缺少充分的研究报道。而且在治疗股腘 ISR 时, 目前尚缺少 DCB 与新一代金属裸支架、药物释放支架、覆膜支架等的疗效对比, 且 DCB 与这些方式的联合作用效果是否会更加理想还不清楚。尚需要高证据级别的临床随机对照试验来回答这些问题。

关键词

移植闭塞, 血管; 药物涂层球囊; 综述文献
中图分类号: R654.3

Drug-coated balloon for femoropopliteal in-stent restenosis: current research progress

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Abstract

In-stent restenosis (ISR) is the common clinical problem in treatment of peripheral vascular diseases. However, there is no uniform and effective interventional method for ISR at present. Drug-coated balloon (DCB) provides a new strategy in treatment of femoropopliteal ISR and some preliminary attempts have been done in recent years. For ISR, DCB has higher patency rate and lower target lesion revascularization rate at postoperative 6 months and even 1 year compared with common balloon, but its long-term efficacy still needs further verification. Studies demonstrated that long segment stenosis in the stent or in the lumen of occlusive disease have higher rate of recurrent stenosis. The combination of DCB and debulking technique has been given great expectation, but it currently lacks enough study results. Besides, for femoropopliteal ISR, no study comparing the effects between DCB and new metal stent, drug-eluting stent or covered stent and so on has been performed as yet, and whether the combination of DCB with those techniques will bring better results is not clear. Thus, more high-quality randomized controlled trials are urgently needed to answer these questions.

Key words

Graft Occlusion, Vascular; Drug-Coated Balloon; Review
CLC number: R654.3

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随着人口老龄化的加剧,周围血管病的发病率在不断增加,尤其在老年人中,发病率可达15%~20%^[1],而下肢动脉,尤其是股腘动脉,是周围血管病变的好发部位。近年来,随着介入技术的不断发展,腔内技术在治疗复杂股腘动脉疾病方面的成功率和远期效果得到不断提高,然而,因为弹性回缩、夹层、内膜增生等特点,普通球囊血管成形术(plain old balloon angioplasty, POBA)在治疗复杂股腘动脉病变时效果并不理想,而配合行支架植入术具有较高的成功率和可靠的短期通畅率^[2-3],但与之而来的支架内再狭窄(instant-restenosis, ISR)却是一个非常严重的临床问题,12、24个月发生率可达30%、50%^[4-7],对于复杂病变,ISR发生率会更高^[8]。然而,目前通过介入技术治疗股腘动脉ISR尚无统一认可的有效方法。

股腘动脉ISR是指股腘动脉支架植入后血管内出现的以内膜增生为主的狭窄,多见于长段弥散型病变、支架断裂处及支架重叠区域,一般直径狭窄>50%有临床意义,早期ISR多由内皮损伤引起的血小板聚集和血栓形成产生,晚期多因支架长期刺激内皮引起炎症反应,导致平滑肌细胞增生、细胞外基质形成,产生新生内膜引起管腔内径丢失^[9-10]。Tosaka等^[11]根据股腘动脉ISR的特点进行分型:I型为局灶性狭窄组,病变段<50 mm;II型为弥散性狭窄组,病变段>50 mm;III型为支架闭塞组。而药物涂层球囊(drug-coated balloon, DCB)是一种球囊壁表面负载抗增生药物的球囊,它能够将涂层药物有效持续的扩散到血管壁,通过阻止细胞内微管形成,达到限制内皮细胞增殖、阻止内膜增生,降低管腔再狭窄发生风险的目的。目前临床上应用的涂层药物主要为脂溶性紫杉醇^[12]。相关研究^[13-16]表明,在治疗冠状动脉和股腘动脉狭窄、闭塞性病变时,DCB能取得显著效果,且在治疗冠状动脉ISR方面DCB已得到广泛的推广^[17-18],然而,在治疗股腘动脉ISR方面DCB还未得到广泛的认可,本文将就目前DCB在治疗股腘动脉ISR方面的应用现状、发展趋势进行综述分析。

1 DCB在股腘动脉ISR中的单独应用

Stabile等^[19-20]首次用DCB治疗股腘动脉ISR,研究共纳入39例患者,均行DCB治疗,病变长度

为(82.9±78.9)mm。术后12个月一期通畅率为92.1%,24个月一期通畅率为70.3%,该研究初步说明了DCB在治疗支架内狭窄的有效性,并发现Class II、III再狭窄发生率比Class I高,提示复杂ISR再狭窄发生率较高,但本研究样本含量偏少、病变长度较短,且缺乏对照组,其结论有待进一步验证。Liistro等^[21-22]对股腘动脉ISR的糖尿病患者进行分析,DCB组44例,POBA组42例,1、3年的靶病变血流重建率(target lesion revascularization, TLR)分别为13.6%、31.0%($P<0.05$)和40%、43%($P=0.8$),Tosaka class III患者在DCB和POBA组出现支架内再狭窄发生的风险均较高。该研究发现在治疗股腘动脉ISR方面,短期内DCB效果较POBA显著,但长期效果DCB并没有表现出明显的优势,研究者认为这可能是由于抗增生药物的抑制作用,使内膜组织出现延迟增长现象,造成晚期管腔丢失严重。

为了进一步验证药物涂层球囊在治疗支架内狭窄的有效性,Krankenberget^[23]进行了一项多中心、前瞻性、随机对照临床试验,共纳入119例患者,随机分配到DCB组62例,POBA组57例,病变长度为(82.2±68.4)mm,6个月支架内再狭窄发生率分别为15.4%(DCB组)和44.7%(POBA组)($P=0.002$),12个月Rutherford分级至少提高1级并且靶病变免于重建率分别为77.8%、52.3%($P=0.015$)。本研究发现DCB在治疗股浅动脉ISR方面比POBA更有优势,再狭窄率和TLR均较低,临床改善方面DCB也较明显。但本研究未对影响再狭窄发生的危险因素进行分析,且随访时间较短。另一项前瞻性、随机对照临床试验共纳入74例股腘动脉ISR患者^[24],DCB组35例,POBA组39例,平均病变长度分别为(17.3±11.3)cm、(18.4±8.8)cm,12个月一期通畅率分别为40.7%、13.4%($P=0.02$),对于TASC A和B型患者,两组患者的差异更加明显。在两组患者中,Class III ISR血管通畅率均比Class I、II低,说明复杂病变类型出现支架内再狭窄的可能性较大,与之前研究相比,本研究平均病变长度较长,通畅率也较前研究偏低,且本研究发现病变长度与TLR有一定相关性,说明病变长度是影响血管通畅率的危险因素。本研究再次证明了DCB在治疗支架内狭窄的优越性,且对于病变类型相对简单的病例效果更加显著。

一项在中国人群中开展的AcoArt1研究^[25],

用以观察DCB在治疗股腘动脉病变的疗效。对其亚组进行分析,共有股腘动脉ISR 46例(DCB 26例,POBA 20例),平均病变长度分别为 (23.7 ± 10.0) cm、 (24.3 ± 11.4) cm,DCB组和POBA组12个月再狭窄发生率分别为23%、95% ($P < 0.01$),TLR分别为0%、95% ($P < 0.01$)。本研究是针对DCB在国内开展的第一个多中心、前瞻性、随机对照研究,结果令人满意,再次肯定了DCB在治疗股腘动脉ISR的中短期疗效,但因样本量受限,该研究未对不同分级的ISR患者通畅率进行对比分析,且其长期效果尚需要进一步随访观察。

2 DCB与“减容”技术在股腘动脉ISR中的联合应用

“减容”技术可以通过腔内旋切斑块和过度增生的内膜组织,达到增加管腔内径,降低支架植入率,提高血管通畅率的目的^[26],然而对于复杂下肢病变,单独行“减容”技术效果并不理想^[27-28],多数患者仍需要配合行血管成形术。相关研究^[29-30]表明,在治疗下肢动脉硬化闭塞性疾病,尤其是长段、钙化性病变时,“减容”技术和DCB联合使用效果更加显著。而在治疗股腘动脉ISR时,两者联合是否也取得更满意的效果,相关学者已进行了初步的研究。

Sixt等^[31]对89例股腘动脉ISR患者进行评价,所有患者均行斑块旋切术,其中29例患者(93%为ISR)联合DCB治疗,另60例患者联合PTA治疗(60%为ISR),术后12个月再狭窄发生率分别为DCB组15.3%,POBA组56.2%,针对再狭窄进行Cox回归分析发现,DCB和POBA风险比为0.28,本研究说明斑块切除术和DCB联合使用可以使再狭窄发生率明显降低。van den Berg等^[32]针对股腘动脉ISR进行了一项小样本前瞻性队列研究,共纳入14例患者,均行激光旋切联合DCB治疗,术后平均随访19个月,仅有1例患者出现支架内再狭窄(>50%),一期通畅率为91.7%,7例严重肢体缺血的患者术后恢复良好,没有出现截肢等并发症,效果令人满意,该研究初步说明了激光旋切与DCB联合治疗股腘动脉ISR的有效性。此外,Gandini等^[33]将48例股浅动脉ISR患者随机分配到DCB组和激光旋切联合药物涂层球囊组(LD+DCB),发现LD+DCB组6、12个月

血管一期通畅率均高于DCB组($P < 0.05$),LD+DCB组和DCB组12个月TLR分别为16.7%和50% ($P = 0.01$),截肢率分别为8%和46% ($P < 0.01$),该研究表明在治疗股腘动脉ISR病变时,联合应用激光旋切和DCB较单独应用DCB效果更加理想,具有更高的中短期通畅率和更低的截肢率。

目前,“减容”技术和DCB联合使用治疗股腘动脉ISR的研究较少,但多数学者对其寄予很大希望,这可能是“减容”技术可以有效清除血管内壁血栓和过度增生的内膜组织,降低血管壁的厚度,有利于紫杉醇被血管壁吸收,从而能够更加有效的抑制内膜增生,提高血管通畅率,但其效果尚有待于多中心、大样本临床研究进一步验证。另外,“减容”技术并发症(远端动脉栓塞、血管串通等)发生率高、耗时长^[34-36],且与DCB联合应用费用高,对其临床应用和推广带来一定的困难。

在治疗股腘动脉ISR方面,普通球囊和切割球囊的效果均不太理想^[37],而新一代金属裸支架^[38]、药物释放支架^[39]、覆膜支架^[40]等在治疗股腘动脉ISR方面具有一定的疗效,12个月一期通畅率在60%~80%左右。然而,因研究的设计不同、患者的选择不同、病变的特点不同以及随访的时间不同,DCB与其它治疗方式之间的直接对比难以做到,目前缺乏这方面的报道,尚需要多中心、大样本、随机对照试验进一步研究,而且,DCB与其它治疗方式之间的联合使用效果与单一治疗方式的对比仍需要进一步研究。

3 小结

在治疗股腘动脉ISR时,DCB与POBA相比具有更理想的短期疗效,具有较高的通畅率和较低的TLR,但其中远期效果有待于进一步验证;研究发现,支架内长段狭窄或闭塞性病变管腔更容易再次发生狭窄,故未来的研究应针对不同分型患者分别进行研究,从而选择出不同类型ISR最有效的治疗方式;DCB与“减容”技术的联合使用在股腘动脉ISR的治疗中有望取得更显著疗效,但DCB与其它治疗方式之间的直接对比以及DCB和其它治疗方式的联合应用效果尚需要进一步研究分析。随着AcoArt I研究取得满意的临床效果,国内首款外周药物涂层球囊已经上市,随着其在临床

上的广泛应用, 相信 DCB 的临床效果会不断得到对比和验证。

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