

## ·综述 General review·

## 经导管主动脉瓣置换术治疗主动脉瓣狭窄应用进展

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**【摘要】** 主动脉瓣狭窄(AS)是在解剖层面导致心脏射血受阻、心脏负荷增加以及冠状动脉、脑血管和全身脏器供血受限的疾病,对患者产生重要影响。随着我国老龄化进程加快,老年主动脉瓣钙化、退变导致 AS 患者越来越多,针对这类患者采取合适的治疗方案非常重要。AS 根本治疗是瓣膜置换。外科主动脉瓣置换术(SAVR)对年轻 AS 患者耐受性良好,但仍存在创伤大等缺陷,对老年患者风险很高,并发症发生率也很高。微创经导管主动脉瓣置换术(TAVR)是老年 AS 患者的重要选择。该文就 AS、TAVR 手术患者、手术入路、人工瓣膜类型选择,术后抗栓策略,术后并发症及其处理及术后康复治疗等应用进展作一综述。

**【关键词】** 主动脉瓣狭窄;经导管主动脉瓣置换术;进展

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**【Abstract】** Aortic stenosis(AS) is a disease that, at the anatomical level, leads to obstruction of cardiac ejection, increase of cardiac load and restriction of blood supply to coronary artery, cerebrovascular and systemic organs, which produce important impact on the health of the patients. With the speeding up of the aging process in China, more and more AS patients have been detected in the elderly population, so it is very important to adopt appropriate treatment schemes for these patients. The fundamental treatment of AS is valve replacement. Surgical aortic valve replacement(SAVR) can be well tolerated by young patients, although it has disadvantages such as larger injury, etc. Therefore, for elderly patients SAVR carries high risks and high incidence of complications. Minimally-invasive transcatheter aortic valve replacement(TAVR) is an ideal alternative for elderly patients with AS. This paper aims to make a comprehensive review about the TAVR therapy of AS, focusing on the latest progress in TAVR applications, including operative procedure, operative approach, selection of the artificial valve type, postoperative anti-thrombosis strategy, postoperative complications and therapeutic measures, postoperative rehabilitation treatment, etc. (J Intervent Radiol, 2022, 31: 1020-1026)

**【Key words】** aortic stenosis; transcatheter aortic valve replacement; progress

经导管主动脉瓣置换术(transcatheter aortic valve replacement, TAVR)是将组装好的人工主动脉瓣经导管置入到主动脉根部并替代原有主动脉瓣,在功能上完成主动脉瓣置换,主要应用于主动脉瓣狭窄(aortic stenosis, AS)患者<sup>[1]</sup>,亦有在主动脉瓣关闭不全患者应用<sup>[2]</sup>。TAVR 是目前心血管介入治疗的重

要前沿技术。随着临床研究和实践不断深入,出现了不同类型的人工瓣膜<sup>[3-5]</sup>、不同手术入路选择的创新<sup>[6-10]</sup>,不断完善术前、术中、术后管理方案<sup>[11]</sup>,使得治疗效果不断提高<sup>[12]</sup>,同时具有较好的性价比<sup>[13-14]</sup>。临床实践中对患者治疗过程和效果进行总结分析,有助于不断提高临床理论水平和技术。本文就

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TAVR 在 AS 患者中应用进展作一综述。

## 1 AS

AS 主要由风湿热后遗症、先天性主动脉瓣结构异常或老年性主动脉瓣退变、钙化等引起,导致主动脉瓣开放受限。风湿性心脏病是引起主动脉瓣病变的重要原因,随着我国老龄化进程,主动脉瓣退变、钙化等引起的 AS 患者逐渐增加,是老年患者心力衰竭、住院等重要原因。作为一种渐进性疾病,AS 疾病终末期将会出现左心室流出道阻塞,导致心脏搏出量减少、运动能力下降、心力衰竭和心血管原因死亡等。

AS 在欧洲心脏瓣膜病中最为常见,发病率随着年龄增长逐渐增高, $\geq 65$  岁人群中约占 2%, $\geq 85$  岁人群中约占 4%<sup>[15]</sup>。我国尚无 AS 确切流行病学数据。Gao 等<sup>[16]</sup>报道一项单中心调查分析,结果显示 2010 年 1 月至 2015 年 12 月 139 496 例接受超声心动图检查患者中,严重二尖瓣关闭不全、二尖瓣狭窄、AS、主动脉瓣关闭不全检出率分别为 0.68%、0.38%、0.28%、0.27%。

尽管无症状 AS 不增加病死率,但出现症状 2 年后病死率高于 50%。由于老年 AS 患者多体质弱,对外科主动脉瓣置换术(surgical aortic valve replacement,SAVR)耐受性差,风险大,而采取创伤小的 TAVR 成为一种重要选择。

## 2 TAVR

2002 年,法国 Cribier 等<sup>[1]</sup>开展首例人类 TAVR 治疗,随后 TAVR 开始在世界范围内进入临床研究,获得了众多临床数据,在患者选择、介入入路、瓣膜类型等方面不断取得进展,丰富了治疗方案和技术。

### 2.1 患者选择

AS 患者多伴有心功能减退,接受 SAVR 治疗创伤大、耐受性差,因此风险大。TAVR 作为新近发展起来的技术,起初选择的是 SAVR 高危 AS 患者。随着临床研究进展,对 SAVR 中危、低危 AS 患者行 TAVR 亦取得了较好疗效。在高危 AS 患者中,5 年研究结果显示行 TAVR 和 SAVR 术后患者中位生存率和脑梗死发生率相似,而瓣膜退化和再手术干预并不常见<sup>[17]</sup>。TAVR 对患者初始健康状况有很大改善,在术后 3 年随访中得以维持;尽管这一人群晚期病死率很高,但研究结果表明,TAVR 为存活患者提供了实质和持久的健康状况改善<sup>[18]</sup>。研究发现,TAVR 入路与每搏量指数、左心室射血分数(LVEF)状态存在显著交互作用,LVEF 或每搏量指

数降低时,无论是何种 TAVR 入路,预后与 SAVR 相比相似。LVEF 或每搏量指数保留的患者中,TAVR 预后比 SAVR 更好<sup>[19]</sup>,且自扩张瓣膜 TAVR 与 SAVR 相比更为有利<sup>[20]</sup>。

在中危 AS 患者中,行 TAVR 与 SAVR 患者术后 5 年随访显示,两组间死亡、致残性脑卒中发生率差异均无统计学意义<sup>[21]</sup>。SAPIEN 临床研究中中危 AS 患者 TAVR 治疗与 SAVR 相比,有较低死亡、脑卒中、主动脉瓣反流发生率,倾向性评分分析表明 TAVR 综合疗效明显优于 SAVR,提示 TAVR 可能是中危 AS 患者首选治疗方案<sup>[22]</sup>。有研究通过 2 年随访发现,TAVR 和 SAVR 均能显著改善中危 AS 患者健康状况;认为 TAVR 对早期健康状况的改善更大,但仅限于股动脉入路治疗患者<sup>[23]</sup>。

在低危 AS 患者中,30 例患者行 TAVR 结果显示术后 30 d 病死率,脑卒中、心肌梗死、瓣周漏发生率及起搏器植入比例均较低<sup>[24]</sup>。有研究发现,低危 AS 患者主动脉瓣球囊扩张型瓣膜置换后 1 年内死亡、脑卒中、再入院等复合终点均较 SAVR 低<sup>[25]</sup>。采用自扩张瓣膜患者与 SAVR 患者相比亦不增加 2 年内死亡、脑卒中等复合终点事件<sup>[26]</sup>。TAVR 与 SAVR 相比,对患者早期和晚期健康状况有显著益处<sup>[27]</sup>。

随着手术经验积累、手术设备操作越来越简单及瓣膜型号越来越多,适合 TAVR 治疗的 AS 患者逐渐增多<sup>[28]</sup>。

### 2.2 手术入路选择

对于拟行 TAVR 患者,一般选择股动脉入路。但对于股动脉、髂动脉和腹主动脉等血管严重动脉硬化、钙化、狭窄和迂曲不能通过患者,临床研究证实亦可选择颈动脉、锁骨下动脉/腋动脉、心尖入路等。股动脉入路 TAVR(TF-TAVR)是 AS 患者常规选择手术入路<sup>[29]</sup>。一项关于低流速、低跨瓣压差 AS 患者大型前瞻性观察研究显示,早期 TAVR 对经典低流速和反常低流速患者的生存率有很大益处,这种获益似乎延伸到不严重 AS 亚组,TF-TAVR 与 SAVR 相比,可能是这些患者最佳治疗策略<sup>[6]</sup>。

临床实践发现,直接心尖入路 TAVR 在技术上是安全有效的,且放射辐射、手术时间更短,这是经皮穿刺入路外另一方法,可减少微栓塞形成<sup>[7]</sup>。SAVI 注册研究证实,采用 ACURATE-TATM 装置经心尖入路 TAVR 治疗 AS 患者安全有效,并发症发生率低,近期和 1 年内疗效稳定,SAVI-1 研究和 SAVI-2 研究结果相似<sup>[8]</sup>。

颈动脉入路对于不适合股动脉入路患者是另一 TAVR 入路选择<sup>[9]</sup>。Kirker 等<sup>[30]</sup>研究显示,颈动脉

入路 TAVR 患者术后无院内脑卒中、短暂性脑缺血发作或心肌梗死发生,住院病死率与股动脉入路患者相同;尽管心尖入路患者住院病死率显著较高,但 30 d 病死率较低,颈动脉入路患者与之相比差异无统计学意义。对 15 项非随机研究的系统分析显示,颈动脉入路具有较高的手术成功率,脑卒中和起搏器植入率低,30 d 和 1 年病死率低;与主动脉入路(主动脉?)相比 30 d 病死率显著较低<sup>[31]</sup>。

锁骨下动脉/腋动脉入路是另一选择。Anselmi 等<sup>[10]</sup>对连续 15 例接受 CoreValve Evolut R 瓣膜锁骨下动脉入路 TAVR 治疗患者研究分析显示,直接将无鞘 14 F 输送系统引入动脉,手术均获成功;术后(1.66±0.89) h 拔管,血红蛋白下降(6.40±2.80) g/L,无并发症发生,患者可早期活动;住院时间为(4.53±1.24) d,11 例患者出院回家,4 例接受康复治疗。另一研究显示,锁骨下动脉/腋动脉入路 TAVR 术后主要发病率和病死率与 TF-TAVR 相当<sup>[32]</sup>。与 TF-TAVR 相比,锁骨下动脉入路不仅是股动脉入路的替代入路,而且应用于某些有股动脉损伤风险增加患者可能更佳。一项对 2006 年 1 月至 2017 年 1 月 TAVR 治疗症状性 AS 患者的研究分析显示,锁骨下动脉/腋动脉入路患者手术成功率、30 d 脑卒中发生率、植入新起搏器必要性、主要血管并发症发生率、1 年病死率及急性肾损伤需要透析等 6 项指标与股动脉入路患者相比,差异均无统计学意义<sup>[33]</sup>。经锁骨下动脉入路和颈动脉入路具有相似的安全性和有效性,两组患者住院期或 30 d 病死率、脑卒中或血管并发症发生率差异均无统计学意义<sup>[34]</sup>。因此,锁骨下动脉/腋动脉入路可作为 TAVR 首选的二级入路,因为它提供了与 TF-TAVR 相当的程序和临床结果,并适用于大多数非股动脉入路候选患者。

### 2.3 人工瓣膜类型选择

将瓣膜牢牢固定在瓣环结构上而不出现并发症是 TAVR 术的理想结果。随着临床 TAVR 需要,出现了自扩张瓣膜、机械扩张瓣膜和球囊扩张瓣膜,它们有着不同的原理和操作流程,亦有不同的疗效特点。自扩张瓣膜的出现减少了球囊扩张操作过程,从而减少手术时间、放射暴露时间、提升心率时间,减少对患者的影响。对一款 CoreValve 自扩张生物瓣膜研究发现,其用于治疗严重 AS 患者安全有效<sup>[3]</sup>。另一款 Centera-EU 自扩张瓣膜临床应用结果显示,术后 30 d 内安全有效,病死率低,血流动力学显著改善,不良事件发生率低,尤其是植入永久起搏器后不良事件发生率低<sup>[35]</sup>。自扩张 CoreValve 瓣膜术后 2 年全因病死率、总病死率或致残性脑卒中发

生率与机械扩张 Lotus 瓣膜相比相似,在瓣膜血流动力学、血栓形成和永久起搏器植入方面占有优势,但在脑卒中失能、功能分级、瓣膜移位和瓣周漏方面,机械扩张 Lotus 瓣膜占有优势<sup>[36]</sup>。新一代自扩张瓣膜临床应用显示,其与球囊扩张瓣膜相比有较高的瓣膜反流、较长的住院时间和较高的 2 年病死率,这些数据强烈支持对新一代自扩张瓣膜和球囊扩张瓣膜进行进一步随机对照研究<sup>[37]</sup>。

AS 高危患者中应用机械扩张瓣膜与自扩张瓣膜相比并未导致主要安全性终点或主要有效性终点结果较差,提示机械扩张瓣膜可能是高危患者 TAVR 治疗的有益辅助手段<sup>[4]</sup>。

球囊扩张瓣膜应用旨在预扩张主动脉瓣区,然后在选定位置扩张瓣膜支架而植入瓣膜。临床研究发现,直接、无球囊预扩张经导管植入的球囊并扩张瓣膜并不劣于预扩张处理,与新一代球囊扩张瓣膜相比亦无明显差异<sup>[5]</sup>。但三代球囊扩张瓣膜在释放区严重钙化,尤其是左心室流出道严重钙化患者中的成功率低,预扩张球囊延长这一过程,但不改善介入瓣膜表现,因此遇到此类患者时需谨慎选择和操作<sup>[38]</sup>。CHOICE 临床试验研究 5 年随访结果显示,早期球囊扩张瓣膜和自扩张瓣膜 TF-TAVR 术后 5 年内均有半数患者病死,但两组全因病死率、心血管病死率、脑卒中发生率、因心力衰竭再入院率以及瓣周漏、瓣膜血栓并发症发生率差异均无统计学意义,生物瓣膜失败率均较低且差异无统计学意义,而不足 2%病例中记录到瓣膜结构退化,中度或严重瓣膜结构恶化,且更常发生在球囊扩张瓣膜,自扩张瓣膜的正向血流动力学改善更明显<sup>[39]</sup>。

### 2.4 术后抗栓策略

脑卒中是 TAVR 术后患者常见并发症,术后采取何种预防措施是重要考量。研究发现,TAVR 术后对无抗凝指征患者单独应用阿司匹林治疗具有更大的安全效益,与应用双联抗血小板药物的瓣膜功能相似,较联合应用氯吡格雷的出血风险、复合出血及栓塞事件发生率低,降低严重事件发生而不增加心肌梗死、脑卒中发生<sup>[40-42]</sup>。这些结果表明,TAVR 术后患者单独应用阿司匹林抗栓治疗是一种可接受的方案。

单独应用氯吡格雷患者血管并发症发生率与未负荷患者相比更高,其他临床事件发生率相似<sup>[43]</sup>。同时,应用氯吡格雷患者相当多存在高血小板反应性,替卡格雷能达到更好更快的效果,为这些患者提供持续的高血小板反应性抑制<sup>[44]</sup>。

有抗凝指征患者抗血小板加或不加抗凝治疗



与 TAVR 术后 2 年脑卒中风险降低相关,这与该人群多因素脑卒中机制有关<sup>[45]</sup>。选择新型口服抗凝药利伐沙班 10 mg/d 治疗,比抗血小板治疗增加死亡和血栓事件风险<sup>[46]</sup>。尽管 TAVR 术后利伐沙班治疗与传统阿司匹林治疗相比可减少瓣膜活动异常,但有研究显示利伐沙班与阿司匹林相比增加病死率、栓塞事件发生率和大出血风险<sup>[47]</sup>。

### 3 TAVR 术后并发症及其处理

TAVR 术治疗成功与否的重要方面是认识手术相关并发症并减少其发生。

#### 3.1 脑栓塞

脑栓塞是 TAVR 主要并发症。研究发现,AS 患者近三分之二在 TAVR 期间发生脑栓塞<sup>[48]</sup>。尤其是早期脑卒中或短暂性脑缺血发作风险最高,且与 1 年病死率增加有关<sup>[11]</sup>。有队列研究证实,TAVR 术后患者大多发生脑梗死,1/5 患者有可测量的神经功能受损,1/3 患者蒙特利尔认知评估量表(MoCA)评分下降,并强调减少 TAVR 期间脑损伤风险方法的必要性<sup>[49]</sup>。TAVR 术中应用改良栓塞预防装置和更好的术中药物保护措施,有助于减轻这种风险<sup>[11]</sup>。

#### 3.2 房室传导阻滞

由于瓣膜植入后对周围心肌组织的影响,房室传导阻滞发生率较高。范嘉祺等<sup>[50]</sup>研究发现,瓣膜植入后房室传导阻滞发生高达 30.56%,这可能与瓣膜大小及瓣膜植入深度相关。Lotus 瓣膜植入时注意其大小和植入深度,有助于降低永久起搏器植入率,这在接受股动脉入路 Lotus 瓣治疗的严重 AS 患者中亦得到证实<sup>[51]</sup>。有研究显示,先前存在的 I 度房室传导阻滞、完全性右束支传导阻滞及植入深度指标是永久起搏器植入的独立预测因素;强调谨慎放置瓣膜的重要性<sup>[52]</sup>。接受 Edwards-Sapien 3 瓣膜治疗的严重 AS 患者中, I 度房室传导阻滞、完全性右束支传导阻滞与术后永久起搏器植入率独立相关,但植入深度、尺寸过大对永久起搏器植入无影响<sup>[53]</sup>。Edwards-Sapien 瓣膜植入术后有相当比例传导异常在出院前得到改善,通常在 24 h 内;慢性肾脏疾病与其持续存在和永久起搏器植入需要有关;顺行入路增加新的室内传导延迟,包括左束支传导阻滞风险<sup>[54]</sup>。这些研究结果显示,选取不同瓣膜应对房室传导阻滞时可采取不同应对方案。

研究发现,TAVR 术后同日出现房室传导阻滞患者植入永久起搏器安全可行,减少囊袋血肿策略对于高出血风险患者必不可少<sup>[55]</sup>。REPRISE III 临床研究显示,永久起搏器植入与严重的临床预后不相

关,大多数 30 d 植入永久起搏器与 1 年植入无区别;永久起搏器依赖或不依赖患者病死率、脑卒中发生率与未植入永久起搏器患者相似<sup>[56]</sup>。这些研究结果显示,永久起搏器植入可根据临床需要决定,不需考虑何时植入。

#### 3.3 人工瓣膜心内膜炎

TAVR 术广泛应用及在 AS 低危患者中应用,使得了解瓣膜衰竭机制越来越重要。一大型 TAVR 临床试验研究表明,人工瓣膜心内膜炎在现代 TAVR 经验中仍罕见,但往往是致命的,且 TAVR 术与 SAVR 术在人工瓣膜心内膜炎发生率、预测因素或风险方面差异均无统计学意义<sup>[57]</sup>。手术过程和介入手术用品严格灭菌、严格无菌操作,积极预防医源性感染对预防本病有重要意义。对于已发生感染者给予有效抗生素治疗,必要时行二次 SAVR 治疗。

#### 3.4 瓣周漏

减少瓣周漏,对于最大限度实现主动脉瓣功能非常重要。一代瓣膜应用中瓣周漏是常见并发症。中度以上瓣周漏在自扩张 CoreValve 瓣膜可达 16.0%,球囊扩张式 Sapien 瓣膜为 9.1%<sup>[58]</sup>。随着采取防瓣周漏技术的新一代瓣膜开发并临床应用,该并发症发生率越来越低<sup>[59]</sup>。瓣膜选择过小、钙化过于严重或巨大钙化团块、瓣膜置入过浅或过深是瓣周漏发生的危险因素<sup>[58]</sup>。瓣膜植入后应通过主动脉根部造影、血流动力学测定(可用主动脉反流指数)、多普勒超声等综合评估瓣周漏程度、发生部位、血流动力学影响;对于中度以上瓣周漏,应尽量积极干预,可采用球囊后扩张(瓣膜膨胀不全或贴合欠佳时)、再次置入瓣膜支架(瓣膜位置过高或过低时)、封堵器封堵瓣周漏等技术,严重患者需外科干预<sup>[60]</sup>。

#### 3.5 冠状动脉阻塞

冠状动脉阻塞是 TAVR 少见(0.66%)却是致命性并发症<sup>[61]</sup>,也是术前影像学筛选重点及患者被排除行 TAVR 的主要原因之一。术前 CT 评估应从瓣叶情况、主动脉窦解剖及拟植入瓣膜特性等三方面综合考虑,对于解剖结构不合适患者应避免行 TAVR。术中选择合适的球囊,在球囊扩张的同时行主动脉根部造影,观察冠状动脉显影情况,有助于进一步评估冠状动脉堵塞风险。对于冠状动脉阻塞高风险患者,情况允许下宜选择小一号瓣膜,植入适度深一些,可降低冠状动脉堵塞风险,但瓣周漏发生可能会增多;亦可采取冠状动脉保护策略,如在冠状动脉预置导丝、球囊或支架。术中若发生冠状动脉急性或延迟性闭塞,可予急诊冠状动脉介入或外科开胸行冠状动脉旁路移植术进行补救。

### 3.6 其他并发症

心房颤动:TAVR 术后发生率较高,超过三分之一 TF-TAVR 患者出现先前或新发心房颤动,深入研究其预测因子有利于提高 TAVR 术后安全性;尽管心房颤动患者基线并存疾病与非心房颤动患者相比更高,但心房颤动与调整后 30 d 预后风险并不显著相关<sup>[62]</sup>。BRAVO-3 临床试验研究显示,无论各组抗凝策略如何,早期结果均相似<sup>[63]</sup>。

亚临床小叶血栓形成:TAVR 和 SAVR 术后常见,可由正常小叶血栓发展为较严重影响运动的低衰减(hypo-attenuation affecting motion, HAM)情况。这种现象在瓣膜植入后会以不同时间间隔发展和消退。抗凝剂可能对低衰减瓣叶增厚(hypo-attenuating leaflet thickening, HALT)的发展有保护作用,但 HALT 也可在无抗凝治疗情况下消退<sup>[64]</sup>。

局部血管并发症:主要包括入经股动脉、髂动脉、腹主动脉引起夹层、闭塞、破裂出血等,既往发生率可达 16.7%<sup>[65]</sup>。随着 18 F 及以下输送系统应用,该并发症发生率降低至 4.2%<sup>[66]</sup>。术前应采用多层螺旋 CT 全面仔细评估入经血管,选择血管条件较好的入路,避免选择内径过小、过于扭曲血管,避免粗暴操作。一旦出现血管并发症,可采用外周血管球囊、外周覆膜支架等处理,必要时行血管外科手术。

心脏压塞:发生率为 1%~2%<sup>[67]</sup>。为了减少该并发症发生,应将加硬导丝头端塑形呈圆圈状,在球囊扩张、进输送鞘管时固定好加硬导丝;直头导丝进入左心室时,应避免用力过猛,引起主动脉窦部或左心室穿孔。

主动脉夹层、撕裂:是 TAVR 术致命并发症。准确测量主动脉瓣瓣环大小、勿使用过大的扩张球囊,可减少这一并发症发生。

### 4 术后康复治疗

TAVR 术后康复治疗对加速患者恢复、改善患者预后非常重要。TAVR 术后康复锻炼可改善患者运动能力和生活质量<sup>[68]</sup>。有研究显示,TAVR 术后进行 8 周短时间锻炼可保持无氧阈而对摄氧平台无影响,可改善肌肉强度和生活质量;强调术后持续锻炼干预具有维持最初改进的长期性作用<sup>[69]</sup>。同时,临床心理治疗实践发现,TAVR 患者术前抑郁和焦虑较为常见,短期床边认知行为治疗后患者术后 1 个月随访中表现出抑郁和焦虑评分自发改善;需要进一步研究确定更具针对性的短期床边认知行为治疗,是否可改善患者心理和医疗结果<sup>[70]</sup>。

### 5 结语

AS 是心脏瓣膜病中威胁人类健康的重要心血管疾病。随着人口老龄化加重,AS 患者越来越多,病情多复杂,对 SAVR 耐受性差,因此采取合适的治疗方案对于改善患者预后非常重要。随着医疗技术不断进步、TAVR 技术进展,越来越多证据显示 TAVR 术是 AS 患者,尤其是年老体弱患者的重要治疗选择。

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