·专家论坛·

2022年内镜微创切除领域新进展

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周平红，复旦大学附属中山医院内镜中心主任，上海市消化内镜诊疗工程技术研究中心和上海市内镜微创协同创新中心主任，上海市领军人才，上海市科技精英，上海市劳动模范，美国消化内镜学会会员，中华医学会消化内镜学分会副主任委员，上海医学会消化内镜专科分会委员会候任主任委员。长期致力于消化内镜微创诊疗技术的创新研究，国际首创多项内镜新技术，创建并推广内镜微创治疗消化道疾病技术体系。牵头制定内镜诊治专家共识3部，近年承担科技部、国家自然科学基金等科研项目30余项，累计经费3 000万；以第一或通信作者身份在*Gastroenterology*，*Gut*，*AJHG*，*Annals of Surgery*，*CGH*，*GIE*，*Endoscopy*，*Nature Communications*等杂志发表论文100余篇，主编专著6部。申请专利30余项，已转化20余项。获2022年度吴阶平医药创新奖。作为第一完成人，先后荣获国家科技进步奖二等奖、上海市和教育部科技进步一等奖等

【提要】 系统盘点并总结了2022年消化内镜领域微创切除方面的进展，包括食管、胃、结直肠、十二指肠病变的内镜治疗，以及内镜全层切除术、经自然腔道内镜手术、隧道内镜技术、并发症处理、器械和设备革新等方面，并在此基础上提出了未来的发展方向，以期为广大同仁提供参考。

【关键词】 内窥镜检查，消化系统；　黏膜切除术；　微创；　研究进展

Recent advances in endoscopic minimally invasive resection during 2022

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在过去的一年中，消化内镜微创切除领域取得了一系列的创新和进展。笔者系统盘点并总结了消化内镜领域重要期刊和会议有关内镜微创切除方面的进展，以期为广大同仁提供未来内镜微创治疗进一步发展的思路和方向。

一、食管早期癌的内镜治疗探索

食管早期癌内镜治疗技术发展迅速，2022年欧洲消化内镜学会（ESGE）最新指南推荐内镜黏膜下剥离术（endoscopic submucosal dissection，ESD）用于非环周临床分期T1a-M3/T1b-SM1或环周临床分期T1a-M1/M2的食管鳞状细胞癌的整块切除[1]（弱推荐，中等质量证据）。Xu等[2]报道食管早期癌ESD后复发再次行ESD虽完整切除率和治愈率与初次治疗相比略有下降，但并发症和狭窄发生率无明显差异，仍值得尝试。Nieuwenhuis等[3]研究发现黏膜下浸润、分化不良、脉管浸润是食管腺癌内镜切除后淋巴

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结转移的高危因素。然而，食管早期癌术前分期不准确仍是限制内镜治疗疗效的瓶颈之一。Joseph等[4]根据多中心数据分析发现约一半术后证实为T1b的患者术前评估为Tis/T1a，且25%非治愈性切除又无法追加手术的患者出现复发转移，需密切随访。

内镜下治疗食管早期癌安全有效，但狭窄预防仍是重要问题，尤其当食管黏膜切除范围超过3/4周时。Minamide等[5]报道了环周病变ESD后狭窄率接近90%；因此根据病变周径和浸润深度评估发生食管狭窄的高危患者，并在早期预防性使用激素或支架进行干预。有研究发现使用改良内镜下放射状切口切割法(M-RIC)[6]及在黏膜下深层隧道用自膨式金属支架重建食管腔可以治疗难治性狭窄[7]。此外在一项比较反复球囊扩张与定期球囊扩张对于治疗难治性食管狭窄的病例对照研究中发现，反复球囊扩张治疗难治性食管狭窄的成功率较定期扩张组低，两组患者在随访18个月后，对进一步扩张的需求均显著减少[8]。在一项随机对照研究中发现对于切除范围超过3/4周的患者，口服氢化可的松琥珀酸钠和磷酸铝凝胶比局部注射曲安奈德加口服泼尼松更有效[9]。

二、胃病变的内镜切除

胃ESD扩大适应证标准的提出受到了极大的关注，Yang等[10]系统评价了ESD与手术治疗符合扩大标准的未分化型早期胃癌的长期疗效，发现两者总生存期无差异，Yang等[11]还开发了一种预测模型用于预测ESD治疗未分化型早期胃癌的治疗效果。Kim等[12]证明未分化型早期胃癌ESD非治愈性切除后追加手术具有与直接手术相当的效果。Chiba等[13]发现ESD切除>5 cm的胃病灶是安全可行的，但治愈性切除仅为2/3，并且迟发性穿孔更为常见。此外，胃ESD后出血仍然是一个重要问题，Hayashi等[14]发现非重度胃黏膜萎缩是幽门螺杆菌阴性患者ESD后出血的独立危险因素。Shiratori等[15]基于全国人群的回顾性队列研究分析发现富马酸伏诺拉生用于胃ESD后出血率低于质子泵抑制剂。Nishiyama等[16]前瞻性研究证明了O形环闭合内镜结扎在预防抗栓治疗下胃ESD后出血的有效性，可用于高危人群胃ESD后黏膜缺损的闭合。

三、结直肠病变的内镜切除

随着内镜微创技术的发展，内镜切除术已成为结直肠息肉及早期癌的首选治疗方式，对于具体切除方式的选择及操作的细节也有了越来越多的证据支持，主要总结为4个方面：(1)冷切除术：多项研究证实冷切除术对于无蒂息肉在降低术后迟发性出血及提高完整切除率方面均有一定的优势[17-18]，“冷切革命”也入选2022年*GIE*杂志评选的内镜领域十大进展。(2)内镜黏膜切除术(endoscopic mucosal resection，EMR)：EMR操作简便并应用广泛，在操作方面的研究也越来越细节。Rex等[19]发现黏膜下注射液添加肾上腺素显著增加术后疼痛，并增加术后观察时间。对于EMR后创面是否预防性夹闭仍然存在较多争论[20-21]。(3)ESD：2022年结直肠病变ESD操作方面进展主要集中在各种牵引和缝合技术。与此同时，来自瑞典的单中心研究发现，在合适的患者中门诊行ESD安全可靠，为进一步降低医疗成本提高医疗效率指明了新的方向[22]。(4)水下操作(underwater)：多项研究表明水下操作较传统EMR或冷切除术可能能够降低复发率、提高标本回收率[23-25]。

T1期大肠癌的内镜切除是近年来内镜微创切除的一大热点。Ito等[26]总结了不同特征T1期大肠癌内镜切除术后淋巴结转移风险，为适应证的选择和术后管理策略提供了新的参考。Ha等[27]比较了高危T1期大肠癌的内镜及外科手术疗效，发现虽然外科局部手术组总生存率明显优于内镜组，但在合适选择的亚组中两者相当，对于符合条件的患者内镜切除治疗仍值得尝试。Moons等[28]提出对于深浸润性T1期直肠癌，在固有肌层的环行肌和纵行肌之间进行内镜肌间剥离是可行和安全的，R0切除率高达45%，创造了保留直肠肛门的治疗机会。此外，Leung等[29]报道局部晚期大肠癌放化疗后再分期评估判断ESD局部切除可能性。

四、十二指肠病变的内镜切除

十二指肠病变由于其解剖位置特殊，内镜下操作通常较为困难，相关内镜切除的安全性和有效性数据不足。最新研究以多中心数据回顾性比较不同内镜下切除方式治疗十二指肠病变的安全性和有效性。Kato等[30]纳入18个中心3 107例十二指肠浅表肿瘤患者，发现对于<19 mm的病灶，ESD组的迟发性不良事件显著高于非ESD组，但局部复发率明显低于非ESD组，特别是>30 mm的病灶。Takizawa等[31]进行了一项前瞻性临床试验，提出小浅表非壶腹部十二指肠上皮肿瘤的冷切除术是安全的，而Tashima等[32]认为牵引辅助ESD可显著提高小浅表非壶腹部十二指肠上皮肿瘤的R0切除率。Okimoto等[33]比较了水下EMR与透明帽辅助EMR治疗≤20 mm的小浅表非壶腹部十二指肠上皮肿瘤的疗效，发现水下EMR与传统EMR相比R0切除率更高，术后出血发生率更低；与透明帽辅助EMR相比复发率更低。EMR切除大的十二指肠息肉通常伴随较高的穿孔和出血发生率，Almario等[34]使用新型缝合(through-the-scope suture，TTSS)

系统缝合十二指肠EMR后大的黏膜缺损成功率为71.4%，可有效减少迟发性不良事件；Minamide等[35]报道适宜的缝合对于十二指肠大于半圈的病变可以预防狭窄。对于十二指肠黏膜下肿瘤，Zhang等[36]认为其大小与并发症显著相关，ESD对于<2 cm的十二指肠黏膜下肿瘤是安全可行的。涉及乳头部位的腺瘤切除是内镜操作中较棘手的问题，Singh等[37]纳入143个患者，中位随访7.8年，观察家族性腺瘤性息肉病壶腹腺瘤的自然病程，发现壶腹腺瘤癌变率低，多数患者无需内镜治疗。

五、内镜全层切除术（endoscopic full-thickness resection，EFTR）

有关EFTR的最新研究主要关注于结直肠EFTR的适应证和并发症。Didden等[38]分析了行EFTR治疗的T1期大肠癌患者数据，发现有着较高的技术成功率和R0切除率，但病灶大小与R1/Rx切除显著相关，>20 mm的病变不推荐采用内镜治疗。而Høgh等[39]提出EFTR适用于圈套器、EMR或ESD获得的标本病理检测出癌的患者，不适用于>30 mm的结直肠病变。Zwager等[40]纳入1 892例德国和荷兰病例，分析结肠EFTR并发症的数据，发现总体并发症发生率为11.3%，其中穿孔最多见（2.5%），需要急诊手术的严重并发症发生率为2.2 %，无手术相关死亡。这些数据进一步支持EFTR作为复杂结直肠病变的微创治疗替代方案是可行的。而对于≤1.5 cm的小胃肠间质瘤，Yang等[41]认为透明帽辅助EFTR在缩短手术时间、降低并发症发生率、减少住院天数方面显著优于传统EFTR，建议作为小胃肠间质瘤的首选治疗方法。

全层缺损的缝合依然是EFTR技术中至关重要的部分，最新系列研究报道了新型缝合方法及设备具有良好的应用前景，如Apollo OverstitchSx系统[42]，Over the scope suturing（OSS）系统[43]和TTSS系统[34]。Sun等[44]提出在胃EFTR剥离过程中间断闭合缺损是安全可行的；Goto等[45]使用V-loc可吸收倒刺缝合线分别手工连续缝合胃EFTR后肌层及黏膜层；Chiba等[46]应用新型内镜缝合装置Zeosuture M进行了EFTR后胃壁缺损闭合，均提示这些方法和设备具有巨大的临床应用价值，然而仍需更多的临床研究来证明其安全性和有效性。

六、经自然腔道内镜手术（natural orifice transluminal endoscopic surgery，NOTES）

NOTES的研究仍然令人瞩目，涉及部位包括纵隔、阑尾、胆囊等。Gao等[47]报道了经自然腔道内镜纵隔手术的新技术，通过食管壁全层切除解剖纵隔腔内的肿瘤，用于治疗食管上段周围的纵隔肿瘤。Liu等[48]在犬身上成功实施了黏膜下隧道盲肠切除术，随着经验的积累，可能进一步应用于患者的内镜下阑尾切除。Ma等[49]评估了上消化道腔外肿瘤内镜下切除的安全性和有效性，发现肿瘤大小、形状和位置影响手术的难度和安全性，为腔外肿瘤的内镜下安全切除提供了指导。Ullah等[50]利用倾向性分数匹配比较了NOTES保胆取石术与腹腔镜下胆囊切除术治疗有症状的胆囊结石的安全性和有效性，两者技术成功率、术后疼痛、住院时长相当，但NOTES后结石复发率和胆囊炎发生率分别为9.6%和3.2%，提示NOTES可以作为一种微创无瘢痕的替代技术用于有症状的胆囊结石患者的治疗，但如何减少复发仍然是内镜保胆取石临床推广应用中值得思考和关注的问题。

七、隧道内镜技术

隧道内镜应用最成功的典范依然是经口内镜下肌切开术（peroral endoscopic myotomy，POEM）治疗贲门失弛缓症，最新研究集中于技术细节的创新、特殊患者的处理以及术后反流的管理等。Simsek等[51]报道了使用新型射频或微波热凝切割刀，手术成功率100%，其中76.4%无需其他内镜设备辅助剥离或止血。Shiwaku等[52]提出了术中保留套索纤维的POEM，成功率达90%，可降低POEM后反流性食管炎的发生概率。Saleh等[53]通过多中心随机对照临床试验比较POEM与球囊扩张对贲门失弛缓症腹腔镜下Heller肌切开术后持续或复发患者的疗效，结果显示POEM的成功率明显高于球囊扩张，且反流性食管炎和反流症状没有增加。Shiwaku等[54]开展的多中心队列研究，纳入14个中心2 905名POEM后患者，发现年龄≥65岁、既往治疗、Eckardt评分≥7分、乙状结肠型食管和食管肌切开>10 cm与术后严重反流性食管炎相关。Gandhi等[55]报道了POEM同期胃底折叠术的短期、中期、长期疗效，胃食管反流性疾病的发生率仍然高达10%。

隧道内镜的诸多衍生技术也不断拓展和丰富了消化内镜微创治疗的适应证。Zhang等[56]总结了中国3个中心的数据，证实胃POEM（gastric POEM，G-POEM）治疗新生儿先天性幽门肥厚狭窄安全有效。Labonde等[57]报道了G-POEM治疗难治性胃瘫患者选择的评分系统，为难治性胃瘫患者的个体化治疗提供了新的工具。Wang等[58]将G-POEM拓展用于切除十二指肠球部黏膜下肿瘤，保持十二指肠黏膜完整性的同时减少了术后并发症。Al Ghamdi等[59]及Albéniz等[60]报道了环咽经口内镜肌切开术，提示环咽经口内镜肌切开术能显著缓解口咽狭窄导致的吞咽困难。Dellestable等[7]创新性将隧道内镜技术用于难治性食管狭窄，其在黏膜下隧道置

入自膨式金属支架，重建新的食管腔，取得了良好的效果。隧道内镜技术在隧道法ESD的应用方面也得到了广泛的认可，其中Fan等[61]通过随机对照临床试验比较了隧道法和传统方法ESD用于食管黏膜病变的治疗，结果显示隧道法减少了肌层损伤，且在大于半周病变中减少手术时间。

八、内镜切除术后并发症处理

随着内镜微创治疗适应证的不断拓展，对内镜切除术后并发症的经验积累也不断丰富，尤其是各种新型缝合技术和器械的创新，不仅显著降低了并发症的发生，对于迟发性穿孔的补救处理也显示了较为满意的效果。Jung等[62]评估了内镜真空疗法（endoscopic vacuum therapy，EVT）治疗上消化道漏和穿孔的疗效。此外，Jung等[63]报道与EVT相比，双猪尾支架内镜内引流在治疗上消化道术后瘘方面的成功率更高。微创治疗理念不断深入，内镜微创诊疗继续被拓展应用于外科治疗后的并发症，如Fang等[64]报道了EFTR联合荷包缝合治疗腹腔镜袖状胃切除术后瘘管；Wang等[65]报道了ESD用于上消化道外科术后吻合口病变，尽管在技术上具有挑战性，但短期和长期结果良好。

九、内镜器械和设备革新

内镜治疗设备、配件的发展推动了内镜切除技术的进步，内镜技术的优化和创新也对内镜器械的革新提出了更高的要求。2022年内镜设备较为振奋人心的革新主要在新型能量平台和内镜机器人方面。Cai等[66]及Jawaid等[67]分别报道了新型的等离子及电外科能量平台，均显示良好的安全性，有待进一步临床应用。Ji等[68]、Chiu等[69]、Yang等[70]分别报道了不同的机器人辅助ESD系统的动物实验结果，均显示机器人辅助能显著加快剥离速度。Cui等[71]发表了内镜治疗中机器人的应用的综述，指出机器人有望在临床实践中促进ESD的实施和发展。

综合分析近几年内镜切除领域的创新和进展，主要体现在NOTES及隧道内镜新技术、已有技术适应证的拓展、成熟技术操作的简单化、内镜切除术后的全程管理、内镜设备器械的创新。笔者展望，在未来继续技术创新的基础上搭建多层协同研究网络和高质量真实世界数据资源整合、储存、利用与共享平台，通过大数据及高质量临床研究为技术应用及患者管理提供证据，加强个体化诊疗的分层管理可能是未来的发展方向。

利益冲突　所有作者声明不存在利益冲突

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