



doi:10.7659/j.issn.1005-6947.2024.09.007
http://dx.doi.org/10.7659/j.issn.1005-6947.2024.09.007
China Journal of General Surgery, 2024, 33(9):1406-1413.

· 指南解读 ·

机器人胰腺手术国际共识指南（2023版）进展与思考

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摘要

随着机器人外科技术和应用的进步,其在胰腺手术领域的应用前景也愈加宽广。近年来研究表明,在部分方面上,机器人胰腺手术与开腹、腹腔镜手术方式相比存在其独特优势。国际微创外科领域呈现不断发展进步的态势,但机器人胰腺手术在临床上的全方面应用仍需要循证医学指导,笔者团队在2019年的《机器人胰腺手术国际共识声明》的基础上牵头更新并在 *Hepatobiliary Surgery and Nutrition* 杂志上发表了《机器人胰腺手术国际共识指南(2023版)》,汇聚来自美国、欧洲和大洋洲等国际的众多微创手术专家,采用世界卫生组织(WHO)《指南制定手册》、GRADE 网格法、德尔菲投票法和 AGREE-II 工具,就系统文献评价后纳入的176项研究进行分析,在机器人胰十二指肠切除术、机器人远端胰腺切除术、机器人胰腺中段切除术等话题上进行了详细阐述,经过专家评估和对证据质量及可信度的综合评判,提出了19个问题和14项建议,有望为我国及国际范围内的综合、专科医院安全、有效开展机器人胰腺手术推广应用提供依据。新版共识还就多个问题指出随机对照研究证据的重要性,这也是促进机器人胰腺手术安全、有效推广进一步努力的方向。

关键词

胰腺肿瘤; 机器人手术; 多数赞同
中图分类号: R735.9

Advancements and deliberation on the *International Consensus Guidelines on Robotic Pancreatic Surgery (2023 Edition)*

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Abstract

With advancements in robotic surgery technology and applications, its prospects in pancreatic surgery are becoming increasingly promising. Recent studies have shown that robotic pancreatic surgery has unique advantages over open and laparoscopic methods in certain aspects. While the international minimally invasive surgery field continues to evolve, the comprehensive clinical application of robotic pancreatic surgery still requires evidence-based medical guidance. Our team has taken the lead in updating and publishing the *International Consensus Guidelines for Robotic Pancreatic Surgery (2023 Edition)* in the journal *Hepatobiliary Surgery and Nutrition*, based on the *International consensus*

基金项目: 科技创新2030-“新一代人工智能”重大基金资助项目(2021ZD0113301);北京市AI+健康协同创新培育课题基金资助项目(Z221100003522005)。

收稿日期: 2024-09-05; **修订日期:** 2024-09-20。

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statement on robotic pancreatic surgery This effort brought together numerous experts in minimally invasive surgery from the United States, Europe, and Oceania. The analysis of 176 studies included after systematic literature evaluation was conducted using the World Health Organization (WHO) Handbook for Guideline Development, GRADE Grid method, Delphi vote, and AGREE-II instrument. Detailed discussions were provided on topics such as robotic pancreatoduodenectomy, robotic distal pancreatectomy, and robotic central pancreatectomy. Following expert assessments and a comprehensive evaluation of evidence quality and credibility, 19 questions and 14 recommendations were proposed, aiming to provide a basis for the safe and effective promotion of robotic pancreatic surgery in comprehensive or specialty medical centers both in China and elsewhere. The new consensus also emphasizes the importance of randomized controlled trial evidence for several issues, highlighting a direction for further efforts to promote the safe and effective implementation of robotic pancreatic surgery.

Key words Pancreatic Neoplasms; Robotic Surgical Procedures; Consensus

CLC number: R735.9

胰腺解剖位于腹膜后,因其位置深入,与众多重要器官及血管相毗邻,手术难度大,涉及器官多,对患者创伤较大,在保障、提升治疗效果的前提下开展精细、微创的胰腺手术始终是胰腺外科医生的努力方向。机器人手术系统依据其放大视野、操作稳定性和相较于腹腔镜手术操作器械的更大转向能力,为微创入路手术提供了新的方案。

为使机器人胰腺手术的安全、有效推广具备更加全面、严谨的应用前提,2019年笔者团队发起并联合世界范围内本领域各专家团队制定了《机器人胰腺手术国际共识声明》(简称“2019版共识”)^[1]。结合近年来此领域的新研究成果,团队在2019版共识的基础上牵头并在 *Hepatobiliary Surgery and Nutrition* 上发表了《2023版机器人辅助胰腺手术国际共识指南》(简称“2023版共识”)^[2],汇聚来自美国、欧洲和大洋洲等国际的众多微创手术专家,采用世界卫生组织(WHO)《指南制定手册》、GRADE网格法、德尔菲投票法和AGREE-II工具,就系统文献评价后纳入的176项研究进行分析,围绕机器人远端胰腺切除术(robotic distal pancreatectomy, RDP)、机器人胰腺实质保留手术、机器人胰十二指肠切除术(robotic pancreaticoduodenectomy, RPD)的适应证、优势及学习曲线等方面进行讨论,经过专家评估和对证据质量及可信度的综合评判,提出了19个问题和14项建议。新纳入共识中的内容还包括本团队近

些年提出的胰管修复外科理论等修补、吻合技术,并新增了新辅助治疗患者机器人胰腺手术等。有望为我国、国际范围内的综合、专科医院安全、有效开展机器人胰腺手术推广应用提供依据。本文将结合笔者团队近年来机器人胰腺手术大量实践的经验基础上对最新的共识指南展开探讨。

1 RDP

RDP适用于胰腺远端的良、恶性肿瘤切除,2023版共识在RDP可行性及总体优势的认识上与2019版共识基本一致,与开放远端胰腺切除术(open distal pancreatectomy, ODP)相比,RDP与较少的术中出血量和较短的住院时间相关;对于胰腺远端切除术(distal pancreatectomy, DP),脾切除与术后感染和心血管并发症相关,故如无脾切除适应证则尽量选择在术中保留脾脏。2019版共识指出,腹腔镜远端胰腺切除术(laparoscopic distal pancreatectomy, LDP)与RDP在保脾率上无显著差异,RDP的脾周血管保留率较LDP更高^[3];笔者团队的一项回顾性的倾向性评分研究^[4]指出,机器人手术应用于特定良性肿瘤患者的DP可以同时提高保留脾及脾周血管的概率。2023版共识对于此内容进行了更新,研究^[5-6]发现,RDP在保脾方面较LDP存在优势,同时具有更低的术中出血量并缩短患者整体住院时间。机器人手术系统具备精细操作和放大视野的优势,通过更准确有效的止血措

施和血管解剖来实现保脾的目的，从而改善患者预后。

关于RDP手术的胰腺残端封闭，2023版共识提出，吻合器和非吻合器的方式均安全可行，在RDP中使用加强型吻合器封闭胰腺残端能够潜在性地降低术后胰瘘的可能。

2019版共识在RDP手术费用一效益上进行了探讨，认为现有证据不足以支持RDP费用超过ODP或LDP。研究^[7-8]表明：虽然RDP在手术及器材上的花费更高，但住院时间更短，使患者在住院费用上节约开销，使得患者最终的整体治疗费用不存在显著差异^[9]。并且在治疗患者的前提下进行费用一效益的讨论时，不应该只从经济费用出发，还应关注治疗对于患者心理方面的影响及整体预后的差异，Anderson团队^[10]指出进行微创DP的患者更乐于接受术后辅助治疗，可能预示着术后患者可获得更佳预后。2023版共识对于这部分内容进行了重申和强调，认为应综合评估人体工程学因素、社会因素和个人因素，而不是只关注手术产生的费用。

胰腺远端恶性肿瘤起病隐匿，整体预后差，手术切除及手术切缘阴性是为数不多的预后改善手段，实现手术R₀切除自始至终是胰腺外科医生努力的方向^[11]。顺行模块化胰脾切除术（radical antegrade modular pancreato-splenectomy, RAMPS）最早于2003年由Strasberg团队^[12-13]提出，相比于常规DP，RAMPS能获得更高比例的R₀切除、实现更多淋巴结清扫，改善患者预后。既往研究^[14]表明，在学习曲线期，从易到难循序渐进开展机器人胰腺手术安全、可行。2023版共识中推荐越过学习曲线的外科医生可以常规进行机器人RAMPS（R-RAMPS），对处于学习曲线中的医生来说也是安全且可行的^[15]，能获得与常规开腹手术相当的无病生存率和总体生存率^[16]。笔者团队开展了“环血管法根治性上翻式胰脾切除术”，充分利用机器人手术视野和操作优势，在R-RAMPS步骤结构化和标准化上取得新的进展^[17]。

2 机器人胰腺部分切除术

术后胰瘘是胰腺手术最严重的并发症之一^[18]。2019版共识和2023版共识均指出机器人胰腺部分切除术、肿瘤切除术可应用于治疗与主胰管不毗

邻的良性、表浅肿瘤^[19-20]，2023版共识进一步肯定了其应用价值，认为其相比于腹腔镜手术展现出较小的中转开腹率，且两者短期预后相当^[21]，机器人手术与更小损伤、较快术后恢复、较少术中出血、较短的住院及手术时间相关，并具有与传统开放手术相当甚至更低的胰瘘等主要并发症发生率^[22-25]，有助于患者胰腺实质及内外分泌功能的保留^[26]。但存在术中出现胰腺管损伤、胰瘘的风险，影响患者预后。依据过去认知对患者行补救性DP、胰腺断端—十二指肠吻合术、胰十二指肠切除术等大范围消化道重建往往会扩大损伤，导致更多围手术期并发症，增加患者预后不良的风险。

3 机器人胰管修复外科

在胰腺部分切除、摘除及肿瘤切除术中，尤其在对深部病变的处理上，主胰管存在损伤风险。2019版共识和2023版共识均认为应对术中引起的主胰管损伤进行胰腺切除或胰肠吻合^[1-2]。很多团队也在此领域进行了探索，除应用术前影像及术中超声外，2023版共识鼓励通过术前手段减少来自胰管损伤的潜在胰瘘风险。Misawa等^[27-28]探索性地应用了术前内镜胰管支架置入的方式预防术中损伤，但存在继发胰腺炎风险，未能广泛应用。通过防止漏出的胰液与周遭大血管接触避免胰瘘出血，损伤部位的充分引流和可靠缝合理论上安全可行的。对于这一构想，笔者团队结合临床经验及效仿工程中桥梁合拢，提出了“胰管（修复）外科”概念，包括胰管架桥修复术、胰腺中段切除后胰腺端—端吻合术、主胰管替代术和分支胰管型胰腺导管内乳头状黏液肿瘤局部切除术等，减少补救性手术并发症，保留原始解剖结构，有望改善患者预后^[29]。关于胰管架桥修复术，笔者团队报道了1例创新性使用直径适宜的支撑管连接受损主胰管两侧断端，随后再将胰腺创面对合，实现主胰管原位修复，避免胰腺—消化道吻合所导致的医源性损伤^[30]，虽然其应用的安全性和长期预后仍需更多研究进一步证明^[2]，但该术式的成功实施能够改变胰管损伤后只能行补救性消化道重建的固有认知，扩大胰腺良性手术实施切除术的适应证，使更多患者避免不必要的手术损伤。

4 机器人胰腺中段切除术(robotic central pancreatectomy,RCP)

胰腺实质保留手术旨在对良性、交界性肿瘤行切除的同时保留更多胰腺实质,达到最大程度保留胰腺内、外分泌功能的目的。

2019版共识和2023版共识均推荐对胰颈、胰体近端的良性、交界性肿瘤、转移瘤行胰腺中段切除术(central pancreatectomy,CP)。但CP在保留胰腺内外分泌功能上存在争议:有研究^[31]显示,RCP与RDP相比可实现较少的术中出血,但存在较多术后胰瘘等并发症,且未出现显著的术后内、外分泌功能改善;另有研究^[32]显示,CP在治疗胰颈部或近端体部良性或低度恶性肿瘤能最大限度保留胰腺内外分泌功能,伴随相对较高的胰瘘发生率。

目前临床普遍应用的CP术式是通过胰腺近端残端缝合、远端胰腺进行胰肠或胰胃吻合从而解

决胰腺外分泌的问题。然而这样的术式不仅破坏了消化道的生理完整性,还改变了胰液正常的流出路径,增加了患者的手术创伤,不利于患者消化功能的恢复。鉴于此,笔者团队^[33]最初报道了1例RCP、胰管支架置入、胰腺端-端吻合术(荣式CP)(图1),用简化手术操作避免胰腺和消化道吻合,即使发生胰瘘,胰酶也不会被肠液激活。为了进一步证实其应用价值,笔者团队陆续开展了RCP后胰腺端-端吻合与胰腺断端-肠吻合的对比研究,2023版共识中指出端-端吻合可具有更短的手术时间及较少术中出血量,但与术后胰瘘相关^[34-35]。为了探索胰腺端-端重建在生物力学上的可行性,笔者团队建立了不同缝合方式的3种有限元模型,进行拉伸模拟实验证实荣式CP能够在拉伸时达成更均匀的应力分布(图2),减少拉伸时缝线对胰腺组织的切割力,从而使胰腺端-端对拢时可耐受更大的拉力^[36]。其推广应用亟待更大样本的后续研究。

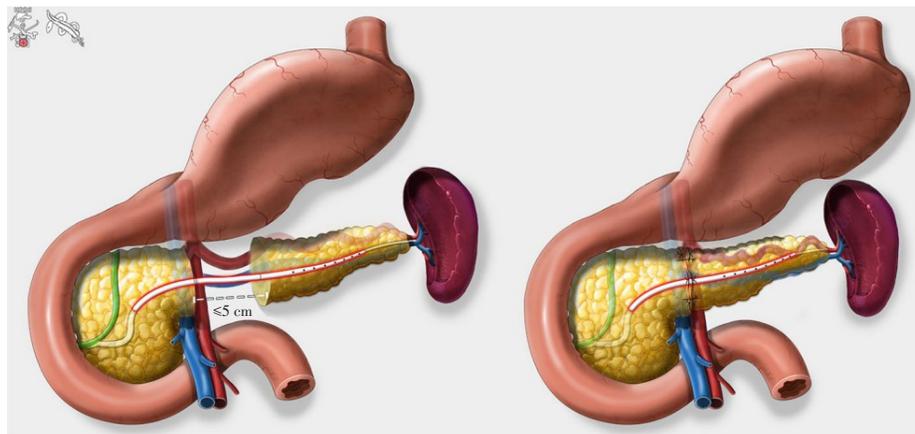


图1 胰腺端-端吻合术示意图^[34]

Figure 1 Schematic of end-to-end pancreatic anastomosis^[34]

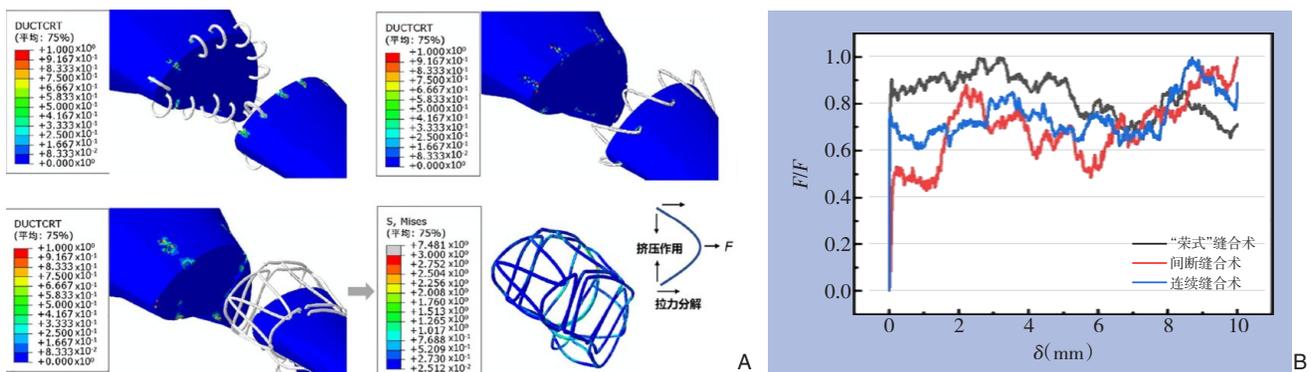


图2 胰腺缝合模型拉伸模拟结果^[36]

A: 胰腺缝合模型拉伸载荷下的应力分布云图; B: 拉伸力-位移曲线

Figure 2 Stretching simulation results of the pancreas suture model^[36] A: Stress distribution nephogram of pancreas suture model under tensile load; B: Tensile force-displacement curve

A: Stress distribution nephogram of pancreas suture model under tensile load; B: Tensile force-displacement curve

在2019版共识中,由于众多研究显示RCP和开放胰腺中段切除术(open central pancreatectomy, OCP)的比较存在争议,认为没有充分证据表明RCP的短期预后优于OCP^[1]。2023版共识肯定了RCP的应用价值,相较于OCP, RCP能获得更少的术中出血量,并在术后糖尿病、术后胰瘘和整体并发症情况上与OCP相当^[37-38]。此外有研究^[39]表明, RCP与较低围手术期病死率相关,但整体各级术后胰瘘概率增加。综上所述, RCP安全有效,并有望促进保留胰腺颈部及近端体部良性、交界性肿瘤患者术后胰腺内、外分泌功能。

5 RPD

2023版共识在RPD适应证上相较2019版共识没有明显变化。但进一步明确了RPD的安全性和可行性,相较于传统开放胰十二指肠切除术(open pancreaticoduodenectomy, OPD), RPD具有更少的术中出血量和更短的患者住院时间,在R₀切除率和淋巴结获取率等肿瘤学指标方面与OPD相当,甚至在部分经验丰富的医师操作下优于OPD。

PD术后胰瘘是影响患者预后的主要并发症之一, RPD可实现多种胰肠吻合技巧,和传统开放式手术类似, RPD中最常用的胰肠吻合方式为胰腺空肠吻合,且胰腺空肠吻合、胰胃吻合两种吻合方式的术后胰瘘率无显著差异^[40]。结合当前研究,仍无对于胰腺消化道吻合的标准技巧的明确推荐^[41],2023版共识认为具体选择应根据医生专业技术和偏好而定^[2]。目前常用的胰肠吻合方式包括套入式胰肠吻合、胰管黏膜胰肠吻合、Blumgart吻合等。其中,有研究^[42]显示,改良Blumgart胰肠吻合是一种能加速胰肠吻合操作且不增加术后并发症发生率的一种胰肠吻合方式有效改良。笔者团队创新性提出“L孔”“R孔”的概念^[43],并在“L孔”“R孔”概念的基础上提出了一种“单针全层胰肠吻合(“301”胰肠吻合)”术式^[44-45],可在胰管大小、胰腺质地异质性程度高的患者群体中实现较好的吻合效果,同时具有易于操作的优势,学习曲线较短,与改良Blumgart吻合效果相当^[46-47]。

近年来,对于交界性可切除和局部进展胰腺癌患者,新辅助化疗能够增加手术R₀切除率,筛选对辅助治疗敏感的患者,在改善患者预后方面

具有优势,逐渐成为术前的标准措施^[48-49]。2023版共识在这方面进行了拓展:相比于新辅助化疗后行OPD, RPD与更短的住院时间和更高比例的术中足量淋巴结清扫率相关,且患者接受后续辅助化疗比例高,这可能与机器人微创手术创伤小,患者恢复快相关^[50]。在交界性可切除肿瘤治疗中,新辅助化疗通过使肿瘤缩小和微转移灶控制争取手术机会,但可能会由于局部化疗药物作用引起的肿瘤组织损伤坏死修复、周围炎性增生,局部失去生理膜性解剖结构,而在一定程度上增加手术难度。借助机器人手术放大视野和精细操作优势有望克服这一困难。对比新辅助化疗后RPD和OPD的另一项研究^[51]提示, RPD与更短的手术时间、更少的术中出血量和更低的术中输血率相关,同时拥有较高R₀切除率, AlMasri团队^[52]开展对技术难度要求高的交界性可切除胰头癌患者行新辅助化疗术后RPD,进一步肯定了RPS在新辅助治疗患者中的应用价值。

6 机器人胰腺手术学习曲线

2019版共识认为需要80例RPD手术经验才能达到与OPD相当的手术时间,需要120例RPD手术经验才能实现最少的术中出血量和与OPD相当的90 d生存率^[53]。2023版共识则认为拥有40例RPD手术经验后即可在低风险患者中达到与OPD相似的预后,50例RPD手术经验即能越过学习曲线^[2,54]。另外,2023版共识认为手术时间作为学习曲线评估的最常用指标并不足够有效,需要更精确的综合评估加强对于RPD学习曲线的认识。

2019版共识和2023版共识均指出,越过RPD学习曲线的医生有能力进行涉及门静脉、肠系膜上静脉血管的切除和重建的RPD手术。在2023版共识中,比起单纯行RPD,涉及门静脉、肠系膜上静脉切除、重建的RPD手术和更长的手术时间、更高的中位淋巴结检出数量相关,并在切缘阳性方面无显著差异^[55]。在术后胰瘘、主要并发症及病死率等方面无显著差异^[56]。关于涉及血管切除重建的RPD病例报告发表数量较少,侧面体现了其对术者有较高技术要求^[1]。个别研究中,RPD相比于OPD再入院率增加,虽然对比显示两组间患者基线无显著差异,但该研究中RPD患者肿瘤恶性程度、进行血管相关操作的比例较低,提示纳

入病例来自初始阶段学习曲线可能性较大,机器人手术在医生越过学习曲线后能进行更为复杂的手术^[57]。

7 总结与展望

综上所述,机器人在PD、DP、CP等术中多个方面的安全性、可行性上与传统开放手术方式和腹腔镜手术相当,在部分方面具有独特优势。但2023版共识引用文献中回顾性研究数量偏多,部分结论仍有一定局限性,多个问题仍需更多随机对照研究证据对其优势进行证明,这也是促进机器人胰腺手术安全、有效推广的进一步努力方向。

利益冲突:所有作者均声明不存在利益冲突。

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(本文编辑 熊杨)

本文引用格式:曹雨,张修平,刘荣.机器人胰腺手术国际共识指南(2023版)进展与思考[J].中国普通外科杂志,2024,33(9):1406-1413. doi:10.7659/j.issn.1005-6947.2024.09.007

Cite this article as: Cao Y, Zhang XP, Liu R. Advancements and deliberation on the *International Consensus Guidelines on Robotic Pancreatic Surgery (2023 Edition)* [J]. *Chin J Gen Surg*, 2024, 33(9): 1406-1413. doi: 10.7659/j.issn.1005-6947.2024.09.007