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·指南解读·

《胰腺肿瘤的荧光手术导航：国际专家共识》解读与思考

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摘　要　吲哚菁绿（ICG）是目前临床获批用于荧光引导手术的近红外造影剂之一，尽管已被广泛应用，但其目前仍有一些局限性。近年来，已有多种靶向荧光造影剂在胰腺癌患者中展开探索性研究，然而，关于胰腺癌荧光引导手术的标准化实践，外科领域尚未形成统一共识。2023 年，国际上首次发布《胰腺肿瘤的荧光手术导航：国际专家共识》，汇集了来自全球 38 位胰腺外科专家关于当前应用现状与未来发展方向的意见，并通过德尔菲法对 76 条相关声明进行了匿名投票，最终形成 61 条推荐意见。该共识为我国开展胰腺肿瘤荧光引导手术提供了重要参考，但在临床推广过程中，仍需结合国内专家的意见及本土患者特点加以优化。本文围绕共识中关于 ICG 的使用、术中荧光成像技术以及胰腺肿瘤的荧光异质性等关键内容，结合笔者临床经验加以解读与思考，以期为胰腺肿瘤荧光手术导航的临床实践提供借鉴与启示。

关键词　胰腺肿瘤；吲哚花青绿；手术导航；多数赞同
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Interpretation and reflections on the international consensus report on fluorescent surgery navigation for pancreatic tumors

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Abstract　Indocyanine green (ICG) is one of the near-infrared fluorescent contrast agents approved for clinical use in fluorescence-guided surgery. Although widely applied, it still has some limitations. In recent years, various targeted fluorescent agents have been explored in pancreatic cancer patients; however, there is still no standardized consensus among surgeons regarding fluorescence-guided surgery for pancreatic cancer. In 2023, the first the international consensus report on fluorescent surgery navigation for pancreatic tumors was published, gathering perspectives from 38 pancreatic surgeons worldwide on current practices and future directions. A total of 76 statements were anonymously voted on using the Delphi method, resulting in 61 recommended statements. This consensus offers valuable guidance for the implementation of fluorescence-guided surgery in pancreatic tumor operations in China, yet its clinical

application should be adapted in consideration of local expert opinions and patient-specific factors. This article interprets key aspects of the consensus, including the use of ICG, intraoperative fluorescence imaging techniques, and the fluorescence heterogeneity of pancreatic tumors, in combination with the authors' clinical experience, with the aim of providing reference and insight for the application of fluorescence-guided surgery in pancreatic tumors.

胰腺癌作为高度恶性肿瘤，其 5 年生存率低于 5%[1-3]。手术联合系统治疗是目前主要的治疗方式，术前 CT、MRI、PET 是评估肿瘤边界和转移灶主要成像方式[4-9]。但借助 CT、MRI、PET 很难在术前准确评估肿瘤边界、识别转移病灶和评估新辅助疗效，导致 R_1 切除率升高和术后复发风险增加[10-12]。近红外荧光导航系统能够增强肿瘤的可视化、解剖结构的识别和组织灌注的评估，吲哚菁绿（indocyanine green，ICG）作为荧光造影剂，被广泛应用于胰腺肿瘤荧光引导手术[13-21]。尽管胰腺引导荧光手术在世界范围内不断被推广，但在实际临床应用中缺乏统一标准。《胰腺肿瘤的荧光手术导航：国际专家共识》是由莱顿大学医学中心发起，由来自 7 个国家不同机构的胰腺外科专家组成研究小组，对胰腺癌荧光引导手术的术前患者准备和 ICG 使用禁忌证、ICG 的给药方案、荧光成像的优劣势、荧光成像在胰腺外科手术中的具体应用领域和荧光成像的未来发展五个方面进行了德尔菲调查，在关于胰腺癌荧光引导手术的 76 条陈述中达成了 61 条共识[22]。笔者根据 76 条陈述中的热点问题并结合我国胰腺癌荧光引导手术的临床实际，对该共识进行解读，以期帮助我国胰腺外科专家更好地实践胰腺癌荧光引导手术，提高 R_0 切除率和减少肿瘤复发率。

1 ICG 的给药策略

专家们一致认为，ICG 对胰腺癌不具有选择性是荧光引导手术导航的局限性，需要研究确定胰腺癌手术中 ICG 使用的最佳剂量和时机。专家认为肿瘤成像的最佳剂量 ≤5 mg/kg，并且给药时间要提前于手术时间。几乎所有专家（94.12%）都同意 ICG 可以评估器官保留术中的血流量评估—例如保留脾脏的远端胰腺切除术和保留十二指肠的胰头切除术。目前 ICG 在肝脏和胆道手术中使用剂量是在安全阈值之内的，很少发生不良反应。在本专家共识中，所有专家一致认为，一般使用 ICG 是安全的，副作用少。在胰腺癌的肿瘤显影中，Hutteman 等[23]对 8 例胰腺癌患者在术中静脉注射 5 mg 或 10 mg ICG，未观察到明显肿瘤荧光标记。而 Newton 等[24]对 12 例胰腺癌患者在术前 1 d 给予 2.5~5 mg/kg ICG，在 11 例患者呈现了肿瘤荧光标记，这表明小剂量的 ICG 难以在乏血供、基质致密的胰腺癌中通过增强渗透和滞留效应（the enhanced permeability and retention，EPR）实现肿瘤荧光标记。在胰腺神经内分泌肿瘤中，Shirata 等[25]在胰腺切除术中静脉注射 2.5 mg ICG，实现了肿瘤荧光标记，肿瘤信背比平均为 1.91。而在另外一项胰腺神经内分泌肿瘤荧光手术导航中的研究[26]中，10 例胰腺神经内分泌肿瘤患者在术中注射 ICG，连续 5 min 内每 1 min 注射 1 次，每次注射剂量为 5 mg。结果显示肿瘤荧光显影率为 100%，注射 ICG 最后 1 次 20 min 后达到肿瘤可视化的峰值，肿瘤信背比平均可达到 7.7，这表明加大荧光剂的剂量可能是提高胰腺神经内分泌肿瘤信背比的有效方式。ICG 对于胰周血管网的显影与保护具有重要意义，但是合适的剂量就显得尤为重要，剂量过高，容易造成背景信号干扰，胰周血管网信背比低。Hutteman 等[23]在对 8 例胰腺癌患者术前静脉注射 5 mg 或 10 mg ICG，在给药后 20 min 仅观察到 1 例患者出现高信背比的胰腺肿瘤荧光成像，这表明胰腺癌和正常胰腺组织有相同的 ICG 摄取率和清除率，因此无法观察到 ICG 在胰腺癌组织的 EPR 效应。Ebihara 等[27]在 3 例行 Warshaw 手术的胰腺肿瘤患者中，在离断脾动静脉后静脉注射 5 mg ICG，可见胃网膜左血管荧光显影，可以有效避免胰体尾游离过程中损伤血管造成的脾脏缺血。Shibuya 等[28]也在 1 例行 Warshaw 手术的实性假乳头状瘤患

者中，在夹闭脾动脉后静脉注射 5 mg ICG，也可见胃网膜左血管荧光显影，同时胃短血管在荧光下也有清晰的荧光显影。通过比较术中荧光胃网膜左血管的信背比，可以发现术中静脉注射 2.5 mg ICG 能够更好实现胰周血管的荧光显影，但这需要进一步研究。

2　胰腺肿瘤术中荧光成像

对于术中荧光实时成像的优点，大多数专家一致认为荧光成像在视觉检查和触诊受限时具有重要作用，它提高了术中可视化效果，并且胰腺癌手术期间的额外好处，能实时评估有助于避免偏差。大多数（88.9%）专家不同意"术中冷冻切片分析不足以确定切缘，但荧光成像可以"的说法，77.8% 的专家同意术中冷冻切片分析虽然足够，但可以通过整合荧光成像技术提高分析精度与准确性。笔者认为，对于手术切缘的评估，胰腺癌术中荧光成像技术尚不能取代术中冷冻切片病理检查，主要原因是 ICG 尚不能特异性聚积胰腺肿瘤之中，而且 ICG 也有可能在非肿瘤结节中聚积，产生假阳性荧光。72.2% 的专家同意术中荧光可区分活的肿瘤组织和新辅助治疗引起的组织坏死和纤维化。笔者认为这个应用十分重要，大多数胰腺肿瘤的患者在确诊时，分期属于交界可切除/不可切除，往往需要接受新辅助治疗。目前评估胰腺癌新辅助治疗效果采用 1.1 版 RECIST 指南[29]，该指南是根据增强 CT 中肿瘤的大小来评估新辅助治疗效果，并分为完全缓解（complete response，CR），部分缓解（partial response，PR），疾病进展（progressive disease，PD），疾病稳定（stable disease，SD）。但胰腺癌在新辅助治疗后通常是纤维化和炎性组织混杂在活性肿瘤组织中，这可导致 CT 高估肿瘤体积，从而低估了新辅助的治疗效果[30–33]。Katz 等[34]在评估 129 例交界可切除胰腺癌患者的新辅助治疗效果中发现，仅 1 例患者（<1%）通过新辅助治疗实现血管侵犯程度的影像学降期，达到了 AHPBA/SSO/SSAT（Hepato-pancreaticobiliary Association/Society of Surgical Oncology/Society for Surgery of the Alimentary Tract）分类中可切除胰腺癌的标准，随后 Katz 等[34]对没有 PD 的 85 例患者实施了胰腺切除术。术后病理结果提示 81 例患者（95%）达到了 R_0 切除，且影像学

提示 PR 患者的中位生存时间与 SD 无显著差异（P=0.78），这表明单纯依赖 CT 可能低估新辅助治疗的实际价值。有文献[23]首次提出将荧光强度与肿瘤坏死程度相关联，进一步与新辅助治疗疗效建立联系（疗效差：肿瘤残余>90%，荧光信号强；疗效中等：肿瘤残余 10%~90%，荧光信号中等；疗效好：肿瘤残余<10%，荧光信号弱）。笔者认为，在术中利用荧光成像技术来识别新辅助化疗之后胰腺肿瘤的活性，是其在胰腺外科的重要应用价值，但目前 ICG 缺乏肿瘤特异性，且也可能在肿瘤周围未失活炎性组织中聚集，因此荧光成像用于新辅助治疗后肿瘤坏死程度的评估需要进一步研究。

3　不同胰腺肿瘤之间的荧光异质性

在专家共识中，83.3% 专家同意荧光手术导航对胰腺肿瘤的另一个限制是不同类型的胰腺肿瘤，例如胰腺导管腺癌与胰腺神经内分泌肿瘤，可能具有不同类型的荧光特征。笔者认为，这主要是基于不同胰腺肿瘤的生物学特征–血供方式不同，肿瘤荧光成像的特征也有所差异。胰腺癌作为典型乏血供肿瘤，常规剂量 ICG 难以通过 EPR 效应在肿瘤组织有效富集[35–37]。而胰腺神经内分泌肿瘤在动脉期具有特征性的强化，属于富血供肿瘤，因此其相比于胰腺癌，ICG 更容易在肿瘤中聚积[38–40]。Shirata 等[24]在包含 5 例神经内分泌肿瘤和 7 例胰腺癌的研究中，采用术中静脉注射 2.5 mg ICG 方案，发现胰腺癌的荧光信号强度和周围正常胰腺组织无明显差异（77.9 $vs.$ 72.1，P=0.41），而神经内分泌肿瘤的荧光信号强度要显著高于周围正常胰腺组织（141 $vs.$ 73.5，P=0.03）。而 Newton 等[23]在胰腺切除术前 1 d 静脉给予 ICG（2.5 mg/kg，5 mg/kg），在 12 例胰腺癌有 11 例患者实现术中肿瘤荧光标记，肿瘤信背比平均为 4.62 ± 1.74。这表明相比于胰腺癌，ICG 更容易在胰腺神经内分泌肿瘤中聚集。

4　胰腺癌荧光成像的展望

在专家共识中，超过 80% 的专家认为，ICG 在胰腺外科的主要应用前景在于：(1) 在肠系膜上动脉侧缘解剖过程中通过荧光来可视化肝外胆管的

解剖结构，避免损伤；(2) 侦测和准确定位转移性病灶，确定准确的切缘，可视化胆管等周围区域结构和淋巴结。75%~80% 的专家认为结合荧光以及其他技术如术中超声等，来准确定位病灶、可视化血管结构（如肠系膜上血管）、区分肿瘤组织活性，并确定吻合口和周围器官的活力。笔者注意到，在该份专家共识之中，有 50% 专家从事胰腺癌手术 10 年以上，但是有 66.7% 的专家开展荧光胰腺肿瘤手术导航的时间不到 5 年，表明胰腺肿瘤荧光手术导航是一种新型手术方式，未来还有很多发展与改进空间。笔者认为：(1) 未来需要有更多 ICG 在胰腺手术中的应用报道。(2) 探索肿瘤成像和血管显影的标准化流程与个体化荧光参数，目前对于 ICG 的给药策略仍需进一步探讨，对于胰腺癌而言，术前 1 d 大剂量 ICG 的注射有助于术中肿瘤的荧光显影[23]；而对于胰腺神经内分泌肿瘤，术中小剂量 ICG 注射有助于肿瘤的显影[24-25,41]；对于胰背动脉、胃网膜左动脉、左膈下动脉以及血管吻合口通畅性检验的荧光成像尚未统一标准流程[27,42-44]。(3) ICG 与其他多模影像技术如术中超声、虚拟现实技术等多模态融合，可实现深部肿瘤成像、三维成像和术中人工智能决策[45-48]。(4) 胰腺肿瘤荧光手术导航可减少术中胰管损伤或者预测术后胰瘘的风险，术者可通过评估胰腺残端吻合口荧光显影来反应残余胰腺的灌注情况，从而评估术后胰瘘的风险，同时也可通过向胰腺导管注射造影剂来识别未关闭副胰管，从而有效避免术后胰瘘[49-50]。(5) 研发具有靶向性、可用于人体的近红外二区荧光造影剂，目前仅有近红外一区的靶向表皮生长因子受体、癌胚抗原等造影剂和近红外二区成像的非靶向 ICG 用于临床研究[23,51-52]，对靶向二区荧光造影剂有待进一步研发。

笔者认为，荧光成像技术在胰腺外科的应用是安全、有效的，有望为胰腺手术的进步带来新的希望。但目前由于流程标准化和个体差异化等原因，对于 ICG 的使用浓度和注射时间窗仍需要更多的研究。拓展和优化 ICG 在胰腺外科中的应用范围，将有助于肿瘤切除、器官保护和患者更好的预后。

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