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· 论著 ·

单孔腹腔镜与传统腹腔镜肾切除术治疗局限性肾癌的疗效比较：术后随访至少10年的配对研究

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[摘要] 目的 比较单孔腹腔镜根治性肾切除术（LESS-RN）与传统腹腔镜根治性肾切除术（CL-RN）后至少10年的局限性肾癌患者肿瘤疗效和肾功能结局。方法 选取2009—2012年在海军军医大学（第二军医大学）第一附属医院接受LESS-RN或CL-RN治疗的T1a~T2a期局限性肾癌患者，按患者年龄、BMI、肿瘤大小进行倾向评分匹配，共纳入31对患者，分析患者的基线特征、手术数据、病理结果和随访信息，以评估LESS-RN和CL-RN的长期预后差异。结果 LESS-RN组与CL-RN组患者在手术时间[(179.7 ± 43.0) min vs (172.6 ± 50.9) min, $P=0.349$]、估计失血量[100 (50, 200) mL vs 100 (50, 150) mL, $P=0.871$]、住院时间[6 (5, 7) d vs 7 (6, 9) d, $P=0.080$]方面差异均无统计学意义。LESS-RN组有1例患者发生术中并发症，没有患者发生术后并发症；CL-RN组有1例患者发生术中并发症，3例患者发生术后并发症。LESS-RN组随访时间为(138.0 ± 9.0)个月，CL-RN组为(137.8 ± 9.8)个月($P=0.730$)。LESS-RN组与CL-RN组患者总生存率(80.6% vs 74.2%, $P=0.181$)、肿瘤特异性生存率(93.6% vs 96.8%, $P=0.554$)、血肌酐变化水平[$32 (17, 45) \mu\text{mol/L}$ vs $20 (5, 47) \mu\text{mol/L}$, $P=0.098$]和估算的肾小球滤过率[$(60.2 \pm 20.9) \text{ mL} \cdot \text{min}^{-1} \cdot (1.73 \text{ m}^2)^{-1}$ vs $(66.7 \pm 27.8) \text{ mL} \cdot \text{min}^{-1} \cdot (1.73 \text{ m}^2)^{-1}$, $P=0.342$]差异均无统计学意义。结论 LESS-RN是一种安全、可行的治疗局限性肾癌的手术方法，其长期肿瘤疗效和肾功能结局与CL-RN相当。

[关键词] 肾肿瘤；肾细胞癌；单孔腹腔镜；腹腔镜肾切除术；根治性肾切除术

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Laparoendoscopic single-site nephrectomy compared with conventional laparoscopic nephrectomy for localized renal cancer: a matched-pair comparison with at least 10-year follow-up

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[Abstract] Objective To compare the tumor and renal function outcomes of patients with localized renal cancer at least 10 years after laparoendoscopic single-site radical nephrectomy (LESS-RN) or conventional laparoscopic radical nephrectomy (CL-RN). Methods Totally 31 pairs of T1a-T2a localized renal cancer patients treated with LESS-RN or CL-RN in The First Affiliated Hospital of Naval Medical University (Second Military Medical University) during 2009-2012 were matched by age, body mass index, and tumor size. Baseline characteristic, surgical data, pathological results, and follow-up information were analyzed to evaluate the long-term outcomes between the 2 groups. Results There were no significant differences between the LESS-RN and CL-RN groups in operative time [(179.7 ± 43.0) min vs (172.6 ± 50.9) min, $P=0.349$], estimated blood loss (100 [50, 200] mL vs 100 [50, 150] mL, $P=0.871$), or hospital stay (6 [5, 7] d vs 7 [6, 9] d, $P=0.080$). Only 1 intraoperative complication occurred in both groups, while no postoperative complication occurred in the LESS-RN group and 3 in the CL-RN group. The follow-up time was (138.0 ± 9.0) months in the LESS-RN group and

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(137.8 ± 9.8) months in the CL-RN group ($P=0.730$). The overall survival rate (80.6% vs 74.2%, $P=0.181$), cancer-specific survival rate (93.6% vs 96.8%, $P=0.554$), change in creatinine level ($32 [17, 45] \mu\text{mol/L}$ vs $20 [5, 47] \mu\text{mol/L}$, $P=0.098$) or estimated glomerular filtration rate ($[60.2 \pm 20.9] \text{ mL} \cdot \text{min}^{-1} \cdot (1.73 \text{ m}^2)^{-1}$ vs $[66.7 \pm 27.8] \text{ mL} \cdot \text{min}^{-1} \cdot (1.73 \text{ m}^2)^{-1}$, $P=0.342$) were not significantly different between the 2 groups. **Conclusion** LESS-RN is a safe and feasible surgical method for localized renal cancer with long-term tumor efficiency and renal function outcomes comparable to CL-RN.

〔Key words〕 kidney neoplasms; renal cell carcinoma; single-site laparoscopy; laparoscopic nephrectomy; radical nephrectomy

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腹腔镜根治性肾切除术 (radical nephrectomy, RN) 是保肾手术不适用的早期肾细胞癌 (renal cell carcinoma, RCC) 患者的首选治疗方法^[1]。Clayman 等^[2]于 1991 年首次报道了传统腹腔镜 (conventional laparoscopy, CL) 在肾切除术中的应用, 后续长期随访研究表明 CL 肾切除术 (CL-nephrectomy, CL-N) 可以有效降低并发症的发生率、改善外观, 预后效果与开放式根治性肾切除术相当^[3]。为了进一步扩大腹腔镜的优势, Raman 等^[4]在 2007 年首次发表了用于肾切除术的单孔腹腔镜 (laparoendoscopic single-site, LESS) 手术方法。已有多篇文献报道了 LESS 手术具有与 CL 手术相当的疗效, 且与 CL-N 相比, LESS 肾切除术 (LESS nephrectomy, LESS-N) 疼痛更少、镇痛需求更低、住院时间更短、恢复更快, 且外观更佳^[5-7]。但是一项对 LESS-N 和 CL-N 进行比较研究的 meta 分析表明, LESS-N 的手术时间更长和开放手术转化率更高^[8]。此外, Greco 等^[9]研究了接受 LESS-RN 和 CL-RN 患者的术后急性期标志物, 结果显示与 CL-RN 相比, LESS-RN 在全身应激反应和手术创伤方面没有显著优势。Park 等^[10]的一项纳入 35 例 RCC 患者的前瞻性随机对照试验结果表明, 与 CL-RN 患者相比, 接受 LESS-RN 患者的术后恢复质量更好, 但两者在手术时间、估计失血量、住院时间和镇痛需求等方面差异均无统计学意义。因此, 目前有关 LESS-RN 和 CL-RN 的疗效对比研究结果仍存在分歧, 且尚没有随访超过 10 年的长期结局的报道。本研究通过配对研究分析了接受 LESS-RN 和 CL-RN 治疗的局限性肾癌患者的围手术期数据和至少 10 年的随访结果, 以期为 LESS-RN 和 CL-RN 术后长期的肿瘤疗效和肾功能结局提供证据。

1 资料和方法

1.1 患者资料 回顾性分析 2009—2011 年在海军军医大学 (第二军医大学) 第一附属医院行 LESS-RN 或 CL-RN 治疗的 193 例局限性 RCC (TNM 临床分期 T1~T2N0M0 期) 患者的临床数据。纳入标准: TNM 临床分期 T1~T2 期肿瘤且有 RN 指征、 $\text{BMI} \leq 30 \text{ kg/m}^2$ 的患者, 或 TNM 临床分期 T1a 期肿瘤不适合行肾部分切除术的患者 (局限于肾门、明显累及骨盆系统或患者决定行根治性手术)。未能随访的患者被排除。共有 48 例接受 LESS-RN、78 例接受 CL-RN 的患者纳入本研究。根据患者的年龄、BMI 和肿瘤大小, 采用倾向评分匹配 (propensity score matching, PSM) 对 LESS-RN 和 CL-RN 患者进行 1 : 1 匹配, 使用 SPSS 22.0 软件自带的 PSM 插件进行操作, 最终确定 31 对患者。手术前充分告知患者所有可选择的手术方式及可能的风险, 患者自愿选择手术方式。所有接受 LESS-RN 的患者均书面同意 LESS-RN 入路和辅助切口, 以及在必要时中转开放手术。手术过程的细节见本课题组既往发表的文献^[11-12]。

1.2 评价指标 使用年龄、性别、BMI、美国麻醉医师学会 (American Society of Anesthesiologists, ASA) 分类、年龄加权 Charlson 合并症指数 (age-weighted Charlson comorbidity index, CCI) 和 R.E.N.A.L. 肾脏测量评分系统评估患者基线情况^[13]。围手术期数据包括手术时间、估计失血量、围手术期输血、并发症、中转开放手术、住院时间和病理结果。根据 Clavien 评分对术后并发症进行分级^[14]。

由独立调查人员对患者的血肌酐数据和生存结局进行了至少 10 年的电话随访, 随访的细节见

本课题组既往发表的文献^[15]。对于无法告知具体血肌酐数据的,如未引起医师的注意,则定义为正常。如未进行规律的检查,则按照最近1次随访的结果或出院前最后1次血肌酐值作为其最近随访肌酐值。肌酐变化水平定义为最近随访肌酐值与术前肌酐值的差值。慢性肾脏病(chronic kidney disease, CKD)分期根据国家肾脏基金会肾脏疾病结局质量倡议分类进行定义^[16]。估算的肾小球滤过率(estimated glomerular filtration rate, eGFR)使用慢性肾脏疾病流行病学合作研究(Chronic Kidney Disease Epidemiology Collaboration, CKD-EPI)方程计算^[17]。

1.3 统计学处理 应用SPSS 22.0软件进行数据统计分析。连续型计量资料以 $\bar{x} \pm s$ 表示,离散型计量资料以中位数(下四分位数,上四分位数)表示,组间比较均采用Mann-Whitney U检验。计数资料以频数和百分数表示,组间比较采用Pearson χ^2 检验,当理论指数 ≥ 1 且 ≤ 5 时使用连续性校正 χ^2 检验。用Kaplan-Meier法计算总生存率和肿瘤特异性生存率。所有的统计分析均为双侧检验,检验水准

(α)为0.05。

2 结 果

2.1 围手术期情况和病理结果 LESS-RN与CL-RN组局限性肾癌患者各31例,两组基线数据差异无统计学意义(表1)。在LESS-RN组中,有4例患者术中增加辅助孔;有1例患者术中出血(Clavien II级),给予输血处理;没有患者发生术后并发症。在CL-RN组中,1例患者术中出血(Clavien II级)并接受输血,未进行手术转换,该患者发生术后肺动脉栓塞(Clavien II级),应用华法林进行治疗,术后住院11 d;1例患者术后出现总胆红素升高(Clavien II级),给予异甘草酸镁保护肝脏;1例患者术后继发出血(Clavien II级),给予输血处理。术后病理结果显示,LESS-RN组有29例肾透明细胞癌(clear cell renal cell carcinoma, ccRCC),1例肉瘤样癌,1例未分类癌;CL-RN组有27例ccRCC,1例乳头状RCC,2例嫌色RCC,1例肉瘤样癌。具体手术数据及病理结果见表2。

表1 LESS-RN和CL-RN组局限性肾癌患者的基线数据
Tab 1 Baseline data of patients with localized renal cancer in LESS-RN and CL-RN groups

Characteristic	LESS-RN group	CL-RN group	Statistic	P value
Age/year, $\bar{x} \pm s$	58.4 ± 12.4	57.0 ± 14.3	$Z=0.444$	0.657
Gender, n (%)			$\chi^2=0.295$	0.587
Male	20 (64.5)	22 (71.0)		
Female	11 (35.5)	9 (29.0)		
BMI/(kg·m ⁻²), $\bar{x} \pm s$	23.2 ± 2.6	24.1 ± 3.3	$Z=1.056$	0.291
ASA score, M (Q_L, Q_U)	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	$Z=0.796$	0.426
CCI, M (Q_L, Q_U)	1.0 (0.0, 2.0)	1.0 (0.0, 2.5)	$Z=0.625$	0.532
Tumor size/cm, $\bar{x} \pm s$	4.8 ± 1.3	4.9 ± 1.4	$Z=0.395$	0.693
Tumor laterality, n (%)			$\chi^2=1.640$	0.200
Left	20 (64.5)	15 (48.4)		
Right	11 (35.5)	16 (51.6)		
TNM stage, n (%)			$\chi^2=0.293$	0.864
T1a	10 (32.3)	12 (38.7)		
T1b	19 (61.3)	17 (54.8)		
T2a	2 (6.5)	2 (6.5)		
R.E.N.A.L. score, M (Q_L, Q_U)	9 (8, 10)	8 (8, 10)	$Z=1.617$	0.106

LESS-RN: Laparoendoscopic single-site radical nephrectomy; CL-RN: Conventional laparoscopy radical nephrectomy; BMI: Body mass index; ASA: American Society of Anesthesiologists; CCI: Age-weighted Charlson comorbidity index; M (Q_L, Q_U): Median (lower quartile, upper quartile).

2.2 随访情况 LESS-RN组和CL-RN组的平均随访时间分别为(138.0 ± 9.0)个月和(137.8 ± 9.8)

个月,差异无统计学意义($P=0.730$)。随访期间,LESS-RN组有2例患者分别发生肺转移和肠转移

并死亡；CL-RN组有1例患者发生肺转移但经肺部手术后恢复，1例患者发生胰腺转移并死亡。LESS-RN和CL-RN组的总生存率分别为80.6%和74.2%（ $P=0.181$ ），肿瘤特异性生存率分别为

93.6%和96.8%（ $P=0.554$ ）。两组患者的血肌酐变化水平、eGFR和CKD分期差异均无统计学意义（均 $P>0.05$ ）。见表3。

表2 LESS-RN和CL-RN组局限性肾癌患者的手术情况和病理结果

Tab 2 Surgical features and pathological results of patients with localized renal cancer in LESS-RN and CL-RN groups

Characteristic	LESS-RN group	CL-RN group	Statistic	N=31 P value
Operative time/min, $\bar{x}\pm s$	179.7±43.0	172.6±50.9	Z=0.937	0.349
Estimated blood loss/mL, $M(Q_L, Q_U)$	100 (50, 200)	100 (50, 150)	Z=0.162	0.871
Transfusion, n (%)	1 (3.2)	2 (6.5)	$\chi^2<0.001$	1.000
Intraoperative complication, n (%)	1 (3.2)	1 (3.2)	$\chi^2<0.001$	1.000
Postoperative complication, n (%)	0	3 (9.7)	$\chi^2=1.401$	0.237
Hospital stay/d, $M(Q_L, Q_U)$	6 (5, 7)	7 (6, 9)	Z=1.752	0.080
Tumor histology, n (%)			$\chi^2=0.738$	0.390
ccRCC	29 (93.5)	27 (87.1)		
Others	2 (6.5)	4 (12.9)		
Fuhrman grade, n (%)			$\chi^2=2.166$	0.539
I	2 (6.5)	0		
II	21 (67.7)	22 (71.0)		
III	5 (16.1)	5 (16.1)		
Unknown	3 (9.7)	4 (12.9)		

LESS-RN: Laparoendoscopic single-site radical nephrectomy; CL-RN: Conventional laparoscopy radical nephrectomy; ccRCC: Clear cell renal cell carcinoma; $M(Q_L, Q_U)$: Median (lower quartile, upper quartile).

表3 LESS-RN组和CL-RN组局限性肾癌患者的随访信息

Tab 3 Follow-up information for patients with localized renal cancer in LESS-RN and CL-RN groups

Characteristic	LESS-RN group	CL-RN group	Statistic	N=31 P value
Change in creatinine level/($\mu\text{mol}\cdot\text{L}^{-1}$), $M(Q_L, Q_U)$	32 (17, 45)	20 (5, 47)	Z=1.655	0.098
eGFR/($\text{mL}\cdot\text{min}^{-1}\cdot[1.73 \text{ m}^2]^{-1}$), $\bar{x}\pm s$	60.2±20.9	66.7±27.8	Z=0.950	0.342
CKD stage, n (%)			$\chi^2=8.681$	0.070
I	1 (3.2)	4 (12.9)		
II	16 (51.6)	15 (48.4)		
III	11 (35.5)	10 (32.3)		
IV	1 (3.2)	0		
V	2 (6.5)	2 (6.5)		

LESS-RN: Laparoendoscopic single-site radical nephrectomy; CL-RN: Conventional laparoscopy radical nephrectomy; eGFR: Estimated glomerular filtration rate; CKD: Chronic kidney disease; $M(Q_L, Q_U)$: Median (lower quartile, upper quartile).

3 讨论

泌尿外科医师减少手术损伤的愿望和患者对外观的需求使腹腔镜技术越来越完善，LESS逐渐被接受成为一种可行的手术选择。已有多篇文献报道了接受LESS手术的患者具有与接受CL手术患者相当的无病生存率和总生存率，但在外观效果和

疼痛方面更有优势^[8,18-19]。然而，这些研究仅限于3~5年的短期随访，缺乏长时间的随访研究。本研究回顾性分析了10年前接受LESS-RN和CL-RN患者的临床数据并通过PSM筛选出31对患者，通过长期随访来评估手术的可行性和安全性。本研究为国内率先比较LESS-RN与CL-RN至少10年随访结果的配对研究。

早期的3项小型回顾性研究结果表明,LESS-RN和CL-RN的手术时间、估计失血量、并发症发生率、住院时间和镇痛需求均无明显差异^[20-22]。然而,这些研究受到样本量小和潜在混杂因素的限制。在Raman等^[23]的研究中,根据年龄、手术指征和肿瘤大小将11例接受LESS-N的患者与22例接受CL-N手术的患者进行匹配,结果显示LESS-N组的估计失血量显著减少(20 mL vs 100 mL, $P=0.001$)。同样,Park等^[24]根据性别、年龄、手术部位和肿瘤大小对19例接受LESS-RN的患者和38例接受CL-RN的患者进行了匹配,分析显示与CL-RN组相比,LESS-RN组术后住院时间较短(2.7 d vs 3.9 d, $P<0.001$),术后1~3 d疼痛视觉模拟量表评分较低。2项前瞻性研究结果也表明,与CL-N组相比,LESS-N组的住院时间更短,疼痛评分更低^[25-26]。Bazzi等^[27]进行了一项LESS和CL根治性和部分性肾切除术的前瞻性非随机研究,结果发现与CL组相比,LESS组的镇痛药物使用更少,出院时疼痛评分更低(1.7分 vs 2.7分, $P<0.01$)。Inoue等^[28]开展的一项多中心研究比较了LESS-N和CL-N在供体肾切除术中的应用效果,结果显示LESS-N组的手术时间更短、切口更小。此外,一项纳入13项研究的meta分析结果表明,与CL-N相比LESS-N具有更长的手术时间^[6]。然而,本结果显示,LESS-RN组与CL-RN组患者的手术时间、估计失血量和住院时间差异均无统计学意义,与上述研究结果不一致,而与Park等^[10]的前瞻性研究结果一致。该研究共纳入35例患者,结果显示LESS-RN组与CL-RN组患者在手术时间、估计失血量、住院时间、镇痛需求和并发症发生率方面无显著差异,但40项恢复质量评分量表(quality of recovery-40, QoR-40)测量表明LESS-RN组具有更好的术后恢复质量^[10]。本研究中TNM临床分期为T1b和T2a期患者占64.5%(40/62),这表明LESS-RN在治疗较大肿瘤方面与CL-RN具有相当的结果。这与Rosoff等^[29]报道的结果一致,该研究验证了LESS在直径≥7 cm的肿瘤中的安全性。同样,Hassan等^[7]对63例行LESS-RN和133例行CL-RN的临床分期T1b和T2a期患者进行了比较,结果显示两组患者手术时间、估计失血量和并发症发生率差异无统计学意义,而LESS-RN组

的住院时间和麻醉药需求量明显减少。Springer等^[22]的一项纳入25例有合并症的肾癌患者的研究表明,LESS-RN对有复杂合并症的患者也具有与CL-RN相当的效果。

Chantada等^[30]开展了一项纳入102例肾肿瘤患者的前瞻性研究,比较了LESS-N和CL-N的疗效,平均随访时间为23.3个月,结果表明CL-N组肿瘤复发和/或进展更加频繁(8.2% vs 17%, $P=0.0013$),这种偏倚可能归因于CL-N组中病理分期为T3~T4的患者比例较高。Antonelli等^[5]根据年龄、适应证和肿瘤大小匹配了47例行LESS手术和94例行CL手术的患者,平均随访时间为3年,结果表明两组的肌酐变化值、无病生存率和总生存率差异均无统计学意义。本研究结果与上述结果一致,表明LESS-RN和CL-RN之间的长期肿瘤预后效果相当。Inoue等^[28]对供体肾切除术的多中心研究表明,与CL-N组相比,LESS-N组供体在术后第7天、第30天和第90天均表现出更高的血肌酐值,但是术后6个月和1年的血肌酐值差异无统计学意义,提示两组短期肾功能可能存在差异,但长期肾功能结局相似。与该研究结果一致,本研究结果表明接受LESS-RN与CL-RN的局限性肾癌患者长期肾功能结局没有明显差异。

综上所述,LESS-RN是一种安全、可行的治疗局限性肾癌的手术方法,其长期肿瘤预后和肾功能结局与CL-RN相当。但本研究仍具有局限性。首先,回顾性研究固有的局限性会给结果带来偏倚,这不能完全克服,本研究通过匹配年龄、BMI和肿瘤大小来最小化偏倚的影响。其次,有些患者不能准确回忆最近的血肌酐值,只能用最后1次记录的血肌酐值代替,这会影响肾功能的评价;但本研究中所有回忆不良的患者均无明显症状,且近期检查时泌尿科医师并未特别注意其血肌酐水平,因此本研究的肾功能结局仍较为可信。最后,符合纳入标准的患者群体规模较小,很难在单一机构中招募到满足统计功效计算所需的大量患者,本研究是来自单一中心的小样本研究,仍需要多中心的随机对照试验来确定LESS-RN在良性和恶性泌尿系统疾病治疗中的优势。未来考虑开展更大样本量和更长期随访的研究,以更准确地评估2种手术方法的长期效果。

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