



# 追加外科手术治疗对高风险T1期结直肠癌 内镜切除患者的预后影响\*

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**【摘要】目的** 分析内镜下切除后追加外科手术对于高风险T1期结直肠癌患者生存预后的影响。**方法** 回顾性收集高风险T1期结直肠癌患者,根据内镜下切除后是否追加外科手术分为追加外科手术(endoscopic resection+surgical resection, ER+SR)组和内镜切除(endoscopic resection, ER)组,收集患者基线信息及病变部位、大小、术后病理等资料,并通过病历系统及随访等获得患者生存相关信息,主要结局指标为总生存率以及结直肠癌特异性生存率。采用单因素Cox回归分析筛选生存相关风险因素,计算风险比(HR),并通过多因素Cox回归分析独立影响因素。**结果** 共收集109例高风险T1期结直肠癌患者,其中ER组52例,ER+SR组57例,ER组的患者平均年龄高于ER+SR组(65.21岁 vs. 60.54岁,  $P=0.035$ ),ER组内镜下病变长径中位数略小于ER+SR组(2.00 cm vs. 2.50 cm,  $P=0.026$ )。ER+SR组中位随访时间为30.00个月,最长随访119.00个月,共有4名患者死亡,1名为结直肠癌相关死亡;而ER组中位随访时间为28.50个月,最长随访78.00个月,共有4名患者死亡,1名死于结直肠癌。5年累积生存率比较中,ER+SR组及ER组总生存率分别为94.44%和81.65%,而5年累积肿瘤特异性生存率分别为97.18%和98.06%。Kaplan-Meier分析显示ER+SR组及ER组患者累积总生存率、累积肿瘤特异性生存率差异无统计学意义。Cox单因素回归分析显示年龄及复查次数为总生存率相关危险因素( $HR=1.16$ 及 $0.27$ ,  $P=0.005$ 及 $0.025$ ),进一步多因素Cox回归分析显示年龄为总生存率相关独立危险因素( $HR=1.10$ ,  $P=0.045$ )。**结论** 对于内镜切除术后存在高风险因素的T1期结直肠癌患者,也不可忽视患者年龄、自身意愿等因素,在实际临床实践过程中更加慎重地选择追加外科手术。

**【关键词】** T1期结直肠癌 高风险 内镜切除 外科手术 生存预后

**Prognosis Analysis of Additional Surgical Treatment for High-Risk T1 Colorectal Cancer Patients After Endoscopic Resection** LUO Xinyue, CHEN Yuxiang, YANG Jinlin, DENG Kai, WU Junchao, GAN Tao<sup>△</sup>. Department of Gastroenterology & Hepatology, West China Hospital, Sichuan University, Chengdu 610041, China

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**【Abstract】 Objective** To analyze the effect of additional surgery on the survival and prognosis of high-risk T1 colorectal cancer patients who have undergone endoscopic resection. **Methods** The clinical data of patients with high-risk T1 colorectal cancer were retrospectively collected. The patients were divided into the endoscopic resection (ER) plus additional surgical resection (SR) group, or the ER+SR group, and the ER group according to whether additional SR were performed after ER. Baseline data of the patients and information on the location, size, and postoperative pathology of the lesions were collected. Patient survival-related information was obtained through the medical record system and patient follow-up. The primary outcome indicators were the overall survival and the colorectal cancer-specific survival. Univariate Cox regression analysis was used to screen survival-related risk factors and hazard ratio (HR) was calculated. Multivariate Cox regression analysis was used to analyze the independent influencing factors. **Results** The data of 109 patients with T1 high-risk colorectal cancer were collected, with 52 patients in the ER group and 57 patients in the ER+SR group. The mean age of patients in the ER group was higher than that in the ER+SR group (65.21 years old vs. 60.54 years old,  $P=0.035$ ), and the median endoscopic measurement of the size of lesions in the ER group was slightly lower than that in the ER+SR group (2.00 cm vs. 2.50 cm,  $P=0.026$ ). The median follow-up time was 30.00 months, with the maximum follow-up time being 119 months, in the ER+SR group and there were 4 patients deaths, including one colorectal cancer-related death. Whereas the median follow-up time in the ER group was 28.50 months, with the maximum follow-up time being 78.00 months, and there were 4 patient deaths, including one caused by colorectal cancer. The overall 5-year cumulative survival rates in the ER+SR group and the ER group were 94.44% and 81.65%, respectively, and the cancer-specific 5-year cumulative survival rates in the ER+SR group and the ER group were 97.18% and 98.06%, respectively. The Kaplan-Meier analysis showed no significant difference in the overall cumulative survival or cancer-specific cumulative survival between the ER+SR and the ER groups. Univariate Cox regression analysis showed that age and the number of reviews were the risk factors of overall survival ( $HR=1.16$  and  $HR=0.27$ , respectively), with age identified as an

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independent risk factor of overall survival in the multivariate Cox regression analysis ( $HR=1.10, P=0.045$ ).

**Conclusion** For T1 colorectal cancer patients with high risk factors after ER, factors such as patient age and their personal treatment decisions should not be overlooked. In clinical practice, additional caution should be exercised in decision-making concerning additional surgery.

**【Key words】** T1 colorectal cancer High risk factors Endoscopic resection Surgical resection Survival analysis

随着筛查技术的提高,越来越多的结直肠癌在较早阶段就被检测到<sup>[1-2]</sup>。大多数早期结直肠癌患者预后良好,通过局部切除,例如内镜下切除即可获得治愈<sup>[3-4]</sup>。然而T1期结直肠癌中仍存在1%~34%的淋巴结转移风险,对于淋巴结转移风险高(包括分化程度差、脉管侵犯、肿瘤出芽G2/G3、黏膜下深浸润及切缘阳性等)的患者,2020及2023年结直肠癌诊疗规范中均建议进行肠段切除术加区域淋巴结清扫。而在临床实践中,对于存在上述危险因素的患者,需要综合患者年龄、自身意愿及合并症等多种因素再决策,因此,存在上述高风险因素的T1期结直肠癌患者,追加手术之后的真实获益情况仍有争议。

本研究收集高风险T1期结直肠癌患者,根据患者是否选择内镜下切除后追加外科手术,分为追加外科手术(endoscopic resection+surgical resection, ER+SR)组和内镜切除(endoscopic resection, ER)组,对两组患者的基线资料、术后病理情况进行比较,讨论追加SR对高风险T1期结直肠癌患者预后的影响。

## 1 对象与方法

### 1.1 研究对象

通过回顾性的方法收集2014年1月~2023年4月在四川大学华西医院诊断为结直肠癌,并且接受内镜下切除术的患者,根据术后病理筛选出具有高风险因素的T1期结直肠癌患者共109例。本研究已经通过四川大学华西医院生物医学伦理审查[2023年审(1645)号]。

#### 1.1.1 纳入标准<sup>[5]</sup>

①根据病理学证据明确诊断为结直肠癌;②行内镜下病变切除术,术后追加或不追加外科手术;③四川大学华西医院术后病理诊断为T1期结直肠癌,并且存在以下危险因素之一:分化程度差(低分化腺癌、未分化癌、印戒细胞癌、黏液腺癌等);脉管、淋巴管侵犯;肿瘤出芽G2/G3;浸润深度为黏膜下(无蒂病变黏膜下浸润 $\geq 1000 \mu\text{m}$ ,带蒂病变Haggitt4级)或深度无法测量;切缘阳性(肿瘤距切缘 $< 1 \text{ mm}$ )或无法判断。

#### 1.1.2 排除标准

①术前进行放射治疗或化学治疗;②存在家族性腺瘤性息肉病病史;③合并远处转移。

### 1.2 研究方法与观察指标

#### 1.2.1 追加外科手术标准

追加外科手术标准参照2020版中国结直肠癌诊疗规范<sup>[5]</sup>:癌细胞穿透结直肠黏膜肌层浸润至黏膜下层,但未累及固有肌层,定义为早期(T1期)结直肠癌;如果具有预后不良的组织学特征(分化程度差、脉管侵犯、肿瘤出芽G2/G3、黏膜下深浸润),或者非完整切除、标本破碎切缘无法评价,则视为存在高风险因素,推荐追加肠段切除术加区域淋巴结清扫。

#### 1.2.2 基线资料

患者年龄、性别、合并症、复查次数、随访时间、肿瘤部位、肿瘤长径、分型、病理信息,包括肿瘤分化程度、浸润深度、切缘情况、脉管浸润、出芽。病变肉眼形态上以发育形态分型为标准,即隆起型、平坦型、表浅凹陷型<sup>[6]</sup>。

#### 1.2.3 随访和观察指标

随访数据通过回顾患者电子病历、电话咨询患者/患者家属获得,随访时间截至2023年9月20日。随访过程中统计患者死亡情况,包括全因死亡及结直肠癌特异性死亡(结直肠癌引起的并发症等)。主要结局指标为总生存率以及结直肠癌特异性生存率。

### 1.3 统计学方法

采用Stata 17.0进行数据分析。正态分布的定量资料以 $\bar{x} \pm s$ 表示,采用两样本独立 $t$ 检验比较组间差别。非正态分布的资料定量资料以中位数( $P_{25}, P_{75}$ )表示,两组间比较采用秩和检验。分类资料以例数(%)表示,采用卡方检验比较组间差别。使用Kaplan-Meier法绘制生存曲线、计算累积生存率,采用Log-rank检验比较组间生存差异,采用单因素Cox回归分析分析筛选生存相关风险因素,计算风险比( $HR$ ),构建多因素Cox回归模型分析独立相关因素。 $P < 0.050$ 为差异具有统计学意义。

## 2 结果

### 2.1 基线情况

收集到的109例高风险T1期结直肠癌患者中ER组52例,ER+SR组57例。109名患者中女性37名(33.94%),男性72名(66.06%),其中25名(22.94%)患者合并多系统病

变,6名(5.50%)患者合并其他系统恶性肿瘤,包括肺癌、肾癌、前列腺癌及血液系统恶性肿瘤。43例(39.45%)患者病灶位于结肠,64例(58.72%)患者病灶位于直肠,2例(1.83%)患者病灶位于直乙交界。诊断时的平均年龄为(62.77±11.58)岁,随访时间中位数为29.00(13.00, 50.00)个月。所有病变均接受内镜下切除术。

两组患者性别比、随访时间、复查次数、合并症、合并恶性肿瘤、病变部位、病变分型、R0切除情况差异均无明显统计学意义( $P>0.050$ )。ER组患者平均年龄高于ER+SR组( $P<0.050$ ),ER组内镜下病变长径短于ER+SR组( $P<0.050$ ),具体见表1。

## 2.2 术后病理

109例高风险病变中,70例(64.22%)合并两个及两个以上高风险因素,其中ER+SR组中有39例,占比为68.42%,ER组31例,占比为59.62%。两组患者在分化程度及脉管浸润方面占比差异有统计学意义,在ER+SR组,中-低或低分化患者占比高于ER组患者( $P=0.041$ ),而脉

管浸润阳性患者占比22.81%,同样高于ER组患者( $P=0.002$ )。

两组患者中肿瘤浸润深度、切缘阳性、Grade分级情况差异无统计学意义。详见表2。

## 2.3 随访及预后分析

ER+SR组57名患者中位随访时间为30.00个月,最长随访时间为119.00个月,其中共有4名患者死亡,1名为结直肠癌相关死亡。ER组中位随访时间为28.50个月,最长78.00个月,共有4名患者死亡,1名死于结直肠癌,而其余3名死于其他疾病。5年累积生存率比较中,ER+SR组及ER组总生存率分别为94.44%〔95%置信区间(CI):79.57%~98.58%〕和81.65%(95%CI:52.68%~93.79%),而5年累积肿瘤特异性生存率分别为97.18%(95%CI:81.64%~99.60%)和98.06%(95%CI:87.00%~99.72%)。

Kaplan-Meier中ER+SR组及ER组患者累积总生存率、累积肿瘤特异性生存率差异无统计学意义( $P=0.223$ ,  $P=0.903$ ,图1、图2)。单因素Cox回归分析显示年龄、复查次数为总生存率相关风险因素,而进一步多因素回归

表1 ER组和ER+SR组的基线资料比较

Table 1 The baseline information of the ER group and the ER+SR group

Baseline information	ER group (n=52)	ER+SR group (n=57)	P
Age/yr.	65.21±11.02	60.54±11.73	0.035
Male/case (%)	35 (67.31)	37 (64.91)	0.792
Follow-up time <sup>*</sup> /month	28.50 (10.00, 41.50)	30.00 (14.00, 60.00)	0.099
Number of reviews <sup>*</sup>	2.00 (0.00, 3.00)	1.00 (0.00, 3.00)	0.747
Comorbidity/case (%)			0.096
Cardiovascular	4 (7.69)	8 (14.04)	
Respiratory	3 (5.77)	3 (5.26)	
Digestive	9 (17.31)	5 (8.77)	
Others	7 (13.46)	11 (19.30)	
More than one system	17 (32.69)	8 (14.04)	
Other malignancies/case (%)	3 (5.77)	3 (5.26)	0.908
Location/case (%)			0.061
Colon	16 (30.77)	27 (47.37)	
Rectum	36 (69.23)	28 (49.12)	
Rectosigmoid junctions	0 (0.00)	2 (3.51)	
Lesion diameter <sup>*</sup> /cm <sup>3</sup>	2.00 (1.70, 3.00)	2.50 (2.00, 3.50)	0.026
Classification/case (%)			0.697
Protruded type	39 (75.00)	44 (77.19)	
Flat type	9 (17.31)	7 (12.28)	
Superficial depressed type	4 (7.69)	6 (10.53)	
R0 resection/case (%)			0.678
Yes	27 (51.92)	27 (47.37)	
No	16 (30.77)	22 (38.60)	
Hard to evaluate	9 (17.31)	8 (14.04)	

<sup>\*</sup> Median (P<sub>25</sub>, P<sub>75</sub>).

表 2 ER组和ER+SR组的术后病理比较

Table 2 The postoperative pathology of the ER group and the ER+SR group

Index	ER group (n=52)	ER+SR group (n=57)	P
Differentiation/case (%)			0.041
Moderate/high differentiation	35 (67.31)	44 (77.19)	
Moderate-to-low/low differentiation	6 (11.54)	10 (17.54)	
Not reported/hard to evaluate	11 (21.15)	3 (5.26)	
Depth of invasion/case (%)			0.295
<1 000 $\mu\text{m}$	15 (28.85)	10 (17.54)	
$\geq 1 000 \mu\text{m}$	25 (48.08)	35 (61.40)	
Not reported/hard to evaluate	12 (23.08)	12 (21.05)	
Margin/case (%)			0.678
Positive	16 (30.77)	22 (38.60)	
Negative	27 (51.92)	27 (47.37)	
Hard to evaluate	9 (17.31)	8 (14.04)	
Vessel/case (%)			0.002
Positive	3 (5.77)	13 (22.81)	
Negative	47 (90.38)	35 (61.40)	
Not reported/hard to evaluate	2 (3.85)	9 (15.79)	
Grade classification/case (%)			0.069
Negative/Grade 1	41 (78.85)	35 (61.40)	
Grade 2-3	8 (15.38)	11 (19.30)	
Not reported	3 (5.77)	11 (19.30)	
At least two risk factors/case (%)			0.338
Yes	31 (59.62)	39 (68.42)	
No	21 (40.38)	18 (31.58)	
Overall survival/case (%)	48 (92.31)	53 (92.98)	0.893
Cancer specific survival/case (%)	51 (98.08)	56 (98.25)	0.948

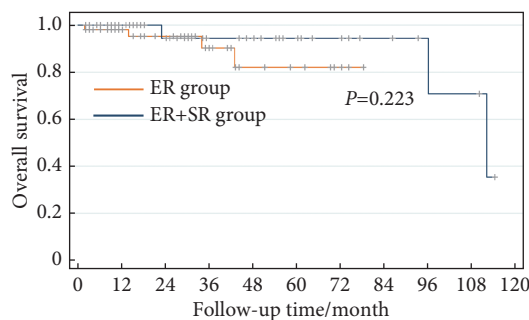


图 1 患者总生存率的Kaplan-Meier生存曲线

Fig 1 Kaplan-Meier survival curve for overall survival

分析显示年龄为总生存率的独立相关风险因素(表3)。由于肿瘤相关死亡例数较少,因此对肿瘤特异性生存率的相关风险因素仅进行单因素Cox回归分析(表4),未发现与肿瘤特异性生存率相关的风险因素。

### 3 讨论

目前,对于早期结肠癌,国内外指南都建议在评估肿瘤大小、预测浸润深度、分化程度之后尝试内镜下切除<sup>[3-4,7-8]</sup>。相较于外科手术,内镜下切除病变创伤小,术后

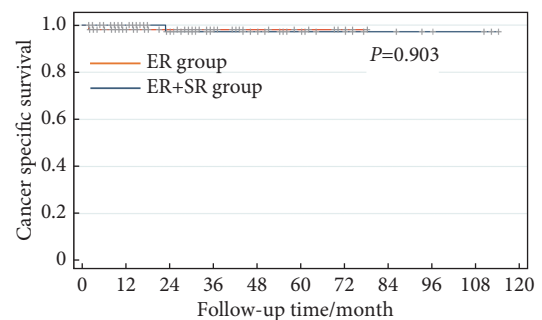


图 2 患者肿瘤特异性生存率的Kaplan-Meier生存曲线

Fig 2 Kaplan-Meier survival curve for cancer-specific survival

并发症少,对于部分低位直肠癌患者来讲,内镜下切除可以避免造瘘,提高生活质量。既往研究指出外科手术前进行内镜下切除并不影响患者生存预后。然而,内镜下切除后的T1期结肠癌患者中,约19%~29%存在黏膜下深浸润、分化程度差、脉管浸润、出芽频繁等肿瘤复发及淋巴结转移相关危险因素<sup>[9-12]</sup>。目前,各指南对于此类高风险患者治疗方案的推荐意见仍存在争议。例如,NCCN指南建议对于3或4级病变(2019 WHO),淋巴管浸润,切缘阳性或标本破碎,无法评估边缘的患者追加外

表 3 总生存率相关单因素及多因素Cox回归分析  
Table 3 Univariate and multivariate Cox regression for overall survival

Factor	Univariate Cox regression			Multivariate Cox regression		
	HR	95% CI	P	HR	95% CI	P
Age	1.16	1.05-1.28	0.005	1.10	1.00- 1.21	0.045
Sex (male/famle)	1.74	0.35-8.75	0.503	-	-	-
Number of reviews	0.27	0.09-0.85	0.025	0.37	0.12-1.19	0.094
Comorbidity (yes/no)	0.65	0.16- 2.63	0.542	-	-	-
Other malignancies (yes/no)	2.61	0.30-22.40	0.383	-	-	-
Location (rectum and rectosigmoid junctions/colon)	1.69	0.33-8.78	0.530	-	-	-
Lesion diameter	1.34	0.85-2.09	0.203	-	-	-
Classification (noprotruded type/protruded type)	0.50	0.06-4.20	0.527	-	-	-
Additional surgery (ER+SR/ER)	0.36	0.07-1.99	0.243	-	-	-

HR: hazard ratio; CI: credibility interval.

表 4 肿瘤特异性生存率单因素Cox回归分析  
Table 4 Univariate Cox regression for cancer-specific survival

Factor	Univariate Cox regression		
	HR	95% CI	P
Age	1.08	0.95-1.23	0.239
Sex (male/famle)	0.50	0.03-8.01	0.625
Number of reviews	5.30e <sup>-17</sup>	0-+∞	1.000
Comorbidity (yes/no)	8.67e <sup>-17</sup>	0-+∞	1.000
Other malignancies (yes/no)	1.53e <sup>-15</sup>	0-+∞	1.000
Location (rectum and rectosigmoid junctions/colon)	0.63	0.04-10.00	0.740
Lesion diameter	1.74	0.93-3.28	0.085
Classification (noprotruded type/protruded type)	3.85e <sup>-16</sup>	0-+∞	1.000
Additional surgery (ER+SR/ER)	0.84	0.05-13.50	0.904

HR: hazard ratio; CI: credibility interval.

科手术。EMSO指南则认为淋巴脉管阳性、3级病变、肿瘤出芽(G2/G3)为预后不良相关危险因素,而阳性切缘(< 1 mm)只是增加局部复发的风险,可以通过重复内镜切除或密切随访来进行管理。JSCCR指南指出SM ≥ 1 000 μm,淋巴脉管阳性, BD2/3, 高级别病变,垂直切缘阳性为追加外科手术的适应证。我国指南建议对于分化程度差,脉管侵犯,肿瘤出芽G2/G3,黏膜下深浸润,非完整切除或标本破碎切缘无法评价均视为存在高风险因素,建议追加外科手术。

最近的一项研究显示,对于追加手术的高危T1期结直肠癌患者,仅15.6%出现淋巴结转移,其余患者则可能存在过度治疗的风险<sup>[13-14]</sup>。同样,在本研究中,109名高危T1期结直肠癌患者中有57名患者(52.29%)根据我国指南推荐意见选择追加外科手术,其中4名患者死亡,仅1名死于结直肠癌及其相关并发症。在有限的样本量内,本研究进行了log-rank检验及Cox回归分析,结果显示在33个

月的中位随访时间内,ER组与ER+SR组在总体生存以及肿瘤特异性生存方面未发现明显差异。此外,多因素及单因素Cox回归分析显示,年龄可能是总生存预后独立相关危险因素。由于临床实践中,内镜术后存在高风险因素的T1期结直肠癌患者相对较少,因此本研究中样本量以及在此基础上阳性事件发生有限。尽管进一步的分析显示检验效能不足80%,但是本研究尝试进行非劣效性检验分析,仍显示ER组总生存率不劣于ER+SR组。既往几项回顾性研究同样显示,部分非治愈性ESD切除后可能导致较高的淋巴结转移率或肿瘤复发率,但长期生存预后并无差异<sup>[15-17]</sup>。OUCHI等<sup>[18]</sup>的一项多中心研究认为,未追加外科手术组肿瘤复发率以及5年肿瘤特异性生存率与追加外科手术组没有差异,但未追加手术组5年总生存率更低,可能是由于未追加手术组存在部分患者因合并症或基础状况差而无法接受外科手术。另外,本课题组前期发表的一项纳入2 961例高危T1期结直肠癌的

meta分析结果提示若患者存在较多合并症或预期寿命 $< 10$ 年,追加手术的净获益并不明显<sup>[19]</sup>。

近期两项研究显示黏膜下深浸润并非淋巴结转移的独立危险因素,因此,对于仅有黏膜下深浸润时是否应追加外科手术仍需进一步探究<sup>[9,12]</sup>。此外,为了在高危T1期结肠直肠癌患者中更精准地识别合适追加手术患者,一些研究也提出通过基于病理信息的人工智能或基于相关危险因素的列线图来预测淋巴结转移风险,并取得一定的准确性。与目前指南相比,这些风险预测模型在一定程度上降低了不必要的外科手术追加率,进而改善患者的生存预后<sup>[20-23]</sup>。

由于本研究纳入的研究对象例数较少,未来仍需要更多大样本量、长随访间期的研究去进一步探索追加外科手术的生存获益,并筛选出更适合追加外科手术的人群。在实际临床决策过程中,对于部分年龄较大的高危T1期结肠直肠癌患者,或许需要更谨慎地推荐追加外科手术。

\*            \*            \*

**作者贡献声明** 罗鑫悦负责论文构思、数据审编、正式分析、调查研究、研究方法、初稿写作和审读与编辑写作,陈宇翔负责论文构思、数据审编、正式分析、调查研究、研究方法和审读与编辑写作,杨锦林和邓凯负责论文构思、数据审编、经费获取、提供资源、验证和审读与编辑写作,吴俊超负责数据审编、经费获取、研究方法和提供资源,甘涛负责论文构思、数据审编、经费获取、研究方法、提供资源、验证和审读与编辑写作。所有作者已经同意将文章提交给本刊,且对将要发表的版本进行最终定稿,并同意对工作的所有方面负责。

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