

我国不同手术方式治疗早期胃癌的经济学指标评价

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摘要: [目的] 对内镜黏膜下剥离术(endoscopic submucosal dissection, ESD)与外科手术两种不同手术方式治疗早期胃癌的卫生经济学指标进行系统评价。[方法] 计算机检索 Pubmed、Embase, the Cochrane Library (2018 年 4 期)、中国生物医学文献数据库、中国知网学术总库、万方数据库和维普中文科技期刊数据库, 获得关于 ESD 与外科手术治疗早期胃癌的队列研究、随机对照研究, 检索时限均为建库至 2018 年 4 月。由 2 位评价员根据纳入及排除标准独立筛选文献、提取资料并评价纳入研究的偏倚风险, 应用 Stata 12.0 软件进行 Meta 分析。[结果] 共纳入 14 项研究, 其中回顾性队列研究 12 项, 随机对照研究 2 项, 共涉及 2087 个研究对象, 其中 ESD 组 919 例, 外科手术组 1168 例。Meta 分析结果显示: 与外科手术组相比, ESD 组的手术时间[标准化均数差(SMD)=-2.26, 95%可信区间(95%CI): -2.94~-1.58, $P<0.05$]和住院时间(SMD=-1.97, 95%CI: -2.32~-1.61, $P<0.05$)缩短, 且住院费用低(SMD=-3.01, 95%CI: -3.78~-2.24, $P<0.05$)。[结论] ESD 与外科手术相比, 具有手术时间短、住院天数少、住院费用低等优势。若临床能够在严格把握适应证的前提下推广应用 ESD 治疗早期胃癌, 或可节约部分医疗资源。
关键词: 胃癌; 内镜黏膜下剥离术; 外科手术; 卫生经济学; 系统评价; Meta 分析; 中国图分类号: R735.2 文献标识码: A 文章编号: 1004-0242(2019)01-0074-07
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Health Economic Analysis of Endoscopic Submucosal Dissection Versus Open Surgery for Early Gastric Cancer in China: a Meta-analysis

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Abstract: [Purpose] To perform a health economic analysis of endoscopic submucosal dissection (ESD) versus open surgery for early gastric cancer (EGC) in China. [Methods] Pubmed, Embase, the Cochrane Library (4th issue of 2018), Chinese Biomedical Literature Database, CNKI, Wanfang Database and VIP were searched for randomized controlled clinical trials and cohort studies that assessed the health economics of ESD and open surgery for treatment of early gastric cancer in China. All studies published prior to April 2018, and were assessed the risk of bias by two reviewers independently. Meta-analysis was performed with Stata 12.0 software. [Results] Fourteen studies were included in the analysis, including 12 retrospective cohort studies and 2 randomized controlled trials involving 2087 study subjects, of whom 919 received ESD and 1168 received open surgery. The operation time and the length of hospital stay in the ESD group were shorter than those in the surgery group [standard mean difference (SMD)=-2.26, 95%CI: -2.94~-1.58, $P<0.05$ and SMD=-1.97, 95%CI: -2.32~-1.61, $P<0.05$, respectively]. Compared with the surgery group, the hospitalization costs were lower (SMD=-3.01, 95%CI: -3.78~-2.24, $P<0.05$) in ESD group. [Conclusion] Compared with open surgery, ESD has the advantages in shorter operation time and length of hospital stay, and lower hospitalization cost for treatment of early gastric cancer.

Key words: gastric cancer; endoscopic submucosal dissection; surgery; health economics; systematic review; Meta-analysis; China

胃癌是全世界最常见癌症之一^[1]。据统计, 全球

每年有 989 000 例新发病例, 其发病率居全部癌症第 4 位, 死亡率居第 2 位^[2], 严重威胁生命健康。我国胃癌发病例数和死亡例数分别占全球胃癌发病和死亡的 42.6% 和 45.0%^[3]。胃癌早期症状不典型或无

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任何症状,出现症状时已是中晚期^[4]。这不仅影响胃癌患者生存,也造成了大量医疗资源浪费。近年来,我国医疗卫生事业发展迅速,但“看病难、看病贵”、“因病致贫、因病返贫”等问题仍然突出。若患者在胃癌早期阶段得到诊治,或可对减轻胃癌相关疾病负担有重要意义。

早期胃癌是指癌组织局限于黏膜或黏膜下层者,而不论有无淋巴结转移^[5]。目前治疗早期胃癌的手术方式主要有内镜黏膜下剥离术(endoscopic submucosal dissection,ESD)及外科手术两种,但其相关风险与获益目前仍存在争议。本研究采用 Meta 分析方法对我国已经发表的关于 ESD 与外科手术治疗早期胃癌的卫生经济学指标进行综合分析,旨在为临床医师选择手术方式提供更可信的循证医学证据。

1 资料与方法

1.1 检索策略

计算机检索 Pubmed、Embase、the Cochrane Library(2018 年 4 期)、中国生物医学文献数据库、中国知网学术总库、万方数据库和维普中文科技期刊数据库,以获得关于 ESD 与外科手术治疗早期胃癌疗效的队列研究、随机对照研究,检索时限均为建库至 2018 年 4 月。采用主题词和自由词结合的方式检索。中文检索词包括早期胃癌、胃早癌、内镜黏膜下剥离术、内镜治疗、外科手术、手术治疗等;英文检索词包括 early stomach neoplasm、early gastric cancer、endoscopic submucosal dissection、general surgery 等。

1.2 纳入与排除标准

1.2.1 纳入标准

①研究类型:ESD 与外科手术治疗早期胃癌疗效的队列研究、随机对照研究;②研究对象:经病理学或者细胞学证实的早期胃癌患者,诊断标准参考人民卫生出版社《病理学》第 8 版标准^[6];③干预措施为 ESD 与外科手术;④评价指标:手术时间、住院时间、住院费用;⑤早期胃癌手术在中国进行,文献第一作者为中国学者;⑥文献所发表杂志若为国内期刊,则须为中国科技核心期刊(具体参照 2017 年中国科技核心期刊目录),或为研究生学位论文。

1.2.2 排除标准

①动物实验;②病例诊断标准不明确;③重复发

表或资料类同的研究;④会议摘要、综述、会议报道等;⑤文献第一作者非中国学者;⑥论文发表在国内期刊上,但非中国科技核心期刊;⑦无法获取相关有效数据的文献或原始数据不完整且不能通过计算获得。

1.3 文献筛选及资料提取

由 2 位研究者根据纳入与排除标准独立筛选文献、提取资料,若不能达成一致意见需与第三方进行商议、讨论达成一致意见。资料提取内容包括:研究题目、第一作者、第一作者所在省份、发表杂志、发表时间、样本量、手术方式、手术时间、住院时间、住院费用等。

1.4 统计学处理

采用 Stata 12.0 软件进行 Meta 分析,通过 Q 检验和 I^2 值分析各研究间的异质性,当 $P_Q > 0.10$ 且 $I^2 < 50\%$,说明各研究间一致性良好或异质性较低,采用固定效应模型,反之则采用随机效应模型^[7,8]。计量采用标准化均数差(standardized mean difference, SMD)为效应指标,各效应均采用点估计及 95%CI 表示。统计量 SMD 采用 Inverse Variance(IV)法分析,发表偏倚采用 Begg's 漏斗图结合 Egger's 线性回归分析, $P < 0.05$ 为差异有统计学意义^[9]。

2 结果

2.1 文献检索结果

初检获得相关文献 3160 篇,其中 Pubmed ($n=2083$)、Embase($n=739$)、the Cochrane Library($n=0$)、知网($n=101$)、万方($n=212$)、维普($n=25$),中文文献 338 篇,英文文献 2822 篇,采用 EndNote 软件剔除重复文献 302 篇。阅读题目和摘要后排除不符合纳入标准文献 2809 篇,共获 49 篇;阅读全文后排除 35 篇,最终共有 14 篇文章纳入分析。包括回顾性队列研究 12 篇,随机对照研究 2 篇。文献检索结果及检索流程见图 1(Figure 1),纳入研究的基本资料见表 1(Table 1)。

2.2 效应指标分析

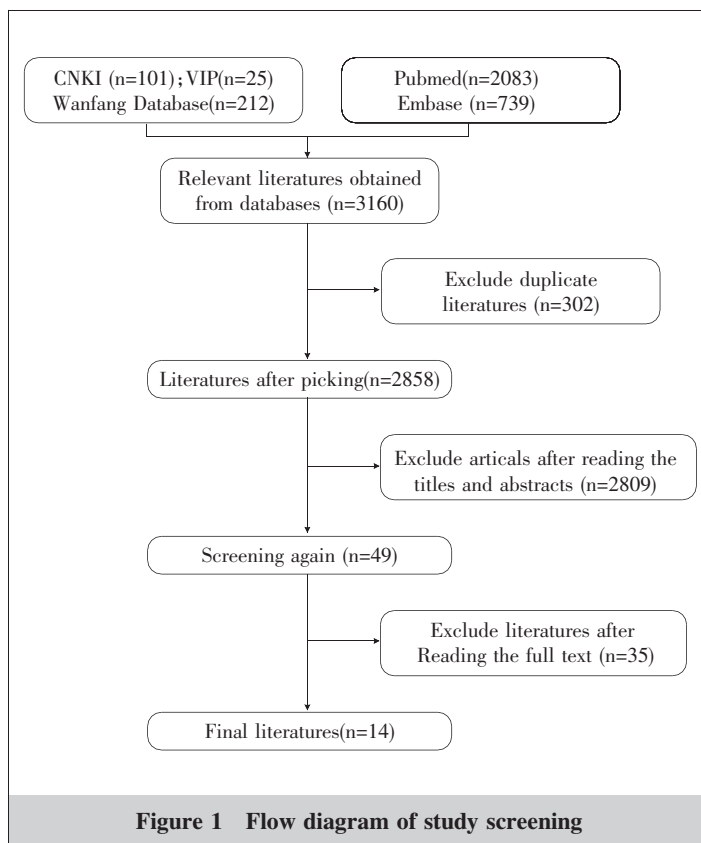
2.2.1 手术时间

有 12 篇文献涉及手术时间,对其进行异质性分析,结果显示各研究之间存在异质性($P=0.000$, $I^2=95.8\%$)。采用随机效应模型合并效应量,结果显示与外科手术组相比,ESD 组手术时间明显缩短,差异

Table 1 Characteristics of the included articles

Authors	Year	Province	Cases		Age(years)		Gender(male/female)		Size(mm)		Study design
			ESD	Surgery	ESD	Surgery	ESD	Surgery	ESD	Surgery	
Shi DM ^[10]	2017	Sichuan	69	79	58.6±13.7	59.3±14.3	37/32	44/35	18.3±8.2	17.6±9.0	RECT
Xu G ^[11]	2016	Jiangsu	45	45	55.7±5.1	56.5±6.2	27/18	31/14	13±5	15±5	RCT
Ye CR ^[12]	2017	Fujian	28	28	46.0±21.0	45.8±21.1	14/14	14/14	13±8	14±10	RECT
Zhu JY ^[13]	2017	Shandong	86	72	58.2±8.7	61.2±6.2	58/28	47/25	18.2±5.2	20.1±4.0	RECT
Zheng XL ^[14]	2016	Hubei	40	40	47.3±5.4	48.5±5.5	27/13	25/15	25±13	25±12	RECT
Wu YX ^[15]	2012	Anhui	14	16	60.7±5.8	57.2±6.6	8/6	11/5	32	U	RECT
Yao ZD ^[16]	2016	Shanghai	27	110	64.6±11.6	59.7±8.9	13/14	65/45	U	U	RECT
You Y ^[17]	2015	Xinjiang	106	73	49.8±5.2	48.1±5.4	71/35	49/24	U	U	RECT
Peng ZH ^[18]	2015	Sichuan	91	91	52.3±5.22	51.5±5.1	47/44	43/48	U	U	RCT
Liu X ^[19]	2017	Beijiang	208	226	61.4±9.3	55.5±10.6	159/49	153/73	24.1±13.5	38.1±17.4	RECT
Sun Y ^[20]	2016	Gansu	81	153	59.9±9.8	58.8±9.1	53/28	110/43	18.4±10.0	20.3±11.4	RECT
Rong L ^[21]	2018	Beijing	81	165	U	U	U	U	U	U	RECT
Song WC ^[22]	2015	Shandong	29	59	65.3±7.5	45.8±6.7	15/14	38/21	27±19	35±16	RECT
Xu Y ^[23]	2017	Hunan	14	11	52	55	8/6	6/5	16±4	17±3	RECT

Notes:U:unknown;RECT:retrospective cohort trial;RCT:randomized controlled trial.



有统计学意义 (SMD=-2.26, 95%CI: -2.94~ -1.58, $P<0.05$) (Figure 2)。通过敏感性分析后 (Figure 3), 发现有 2 篇文献^[11,17]存在明显异质性, 剔除后, 再次分析发现结果与前相似, 差异有统计学意义 (SMD=-2.40, 95%CI: -2.70~-2.11, $P<0.05$) (Figure 4)。

2.2.2 住院时间

对纳入了住院时间的 14 篇研究进行异质性分析, 各研究之间有异质性 ($P=0.000$, $I^2=89.8\%$), 采用随机效应模型进行 Meta 分析, 结果显示外科手术组住院时间长于 ESD 组, 差异有统计学意义 (SMD=-1.97, 95%CI: -2.32~-1.61, $P<0.05$) (Figure 5)。行敏感性分析后 (Figure 6), 发现有 2 篇文献^[17,18]异质性较明显, 剔除后再次分析, 差异有统计学意义 (SMD=-1.73, 95%CI: -1.98~-1.48, $P<0.05$) (Figure 7)。

2.2.3 住院费用

有 10 篇文献提到住院费用, 经过异质性分析, 发现存在异质性 ($P=0.000$, $I^2=96.8\%$), 选用随机效应模型进行分析。Meta 分析结果显示: ESD 组的住院费用低于外科手术组, 差异有统计学意义 (SMD=-3.01, 95%CI: -3.78~-2.24, $P<0.05$) (Figure 8)。敏感性分析 (Figure 9), 剔除异质性较高的 6 篇^[2,5,11,14,17,20]后再次合并效应量, 表明 ESD 组住院费用较低, 差异有统计学意义 (SMD=-2.0, 95%CI: -2.16~-1.85, $P<0.05$) (Figure 10)。

2.3 发表偏倚分析

通过 Begg's 漏斗图结合 Egger's 回归法验证 Meta 分析是否存在发表性偏倚, 结果提示: 在手术时间 (Figure 11)、住院时间 (Figure 12) 以及住院费用 (Figure 13) 文献分析中无发表偏倚 ($P>0.05$), 结果真实可信 (Table 2)。

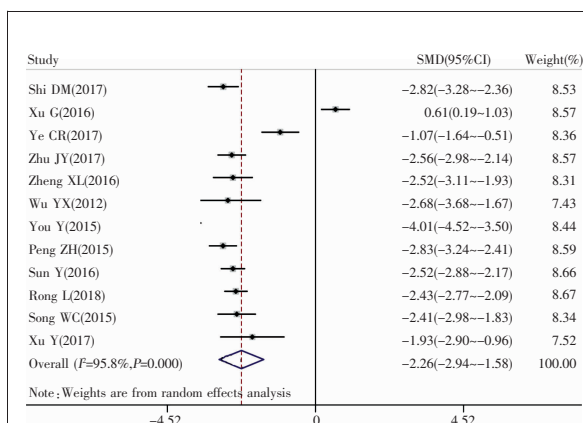


Figure 2 Meta-analysis of comparison of operative time between ESD and surgery groups

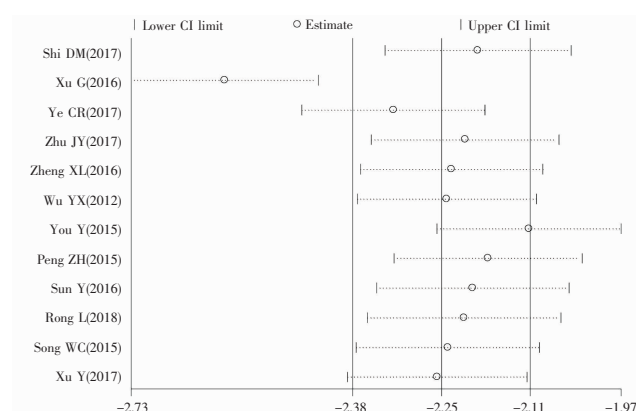


Figure 3 Sensitivity analysis of the operative time comparison between ESD and surgery groups

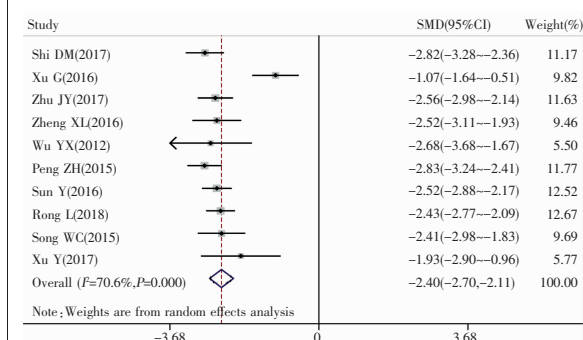


Figure 4 A secondary analysis of the surgical time between ESD and surgery groups

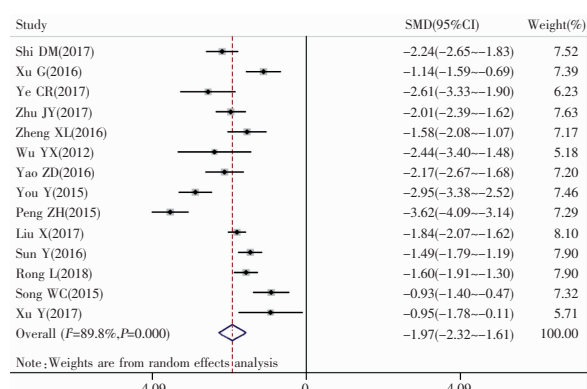


Figure 5 Meta-analysis of comparison of hospitalization time between ESD and surgery groups

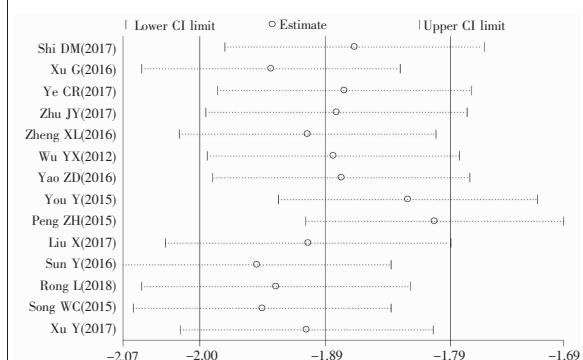


Figure 6 Sensitivity analysis of the hospitalization time comparison between ESD and surgery groups

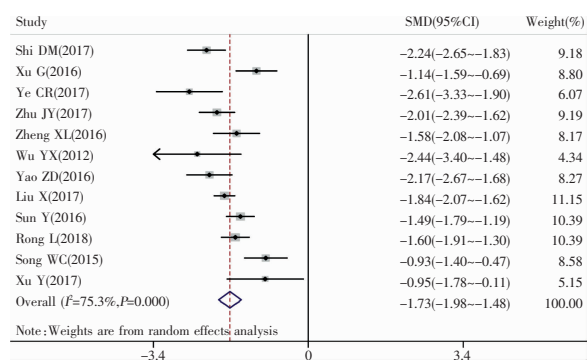


Figure 7 A secondary analysis of the hospitalization time between ESD and surgery groups

Table 2 Results of publishing bias test

Variables	t	P
Surgical time	-0.05	0.959
Hospitalization time	-0.63	0.539
Hospitalization cost	-2.07	0.072

3 讨论

外科手术对胃癌的治疗作用已被普遍认可；ESD 是 30 年前在日本开展的内镜治疗新技术,后被逐渐应用于消化道早癌的治疗^[24,25]。本研究对

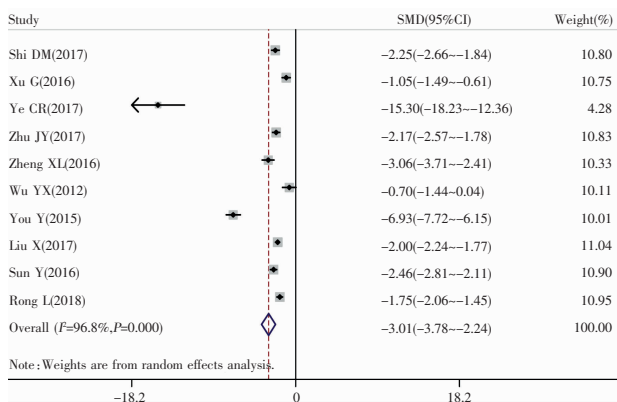


Figure 8 Meta-analysis of comparison of hospitalization cost between ESD and surgery groups

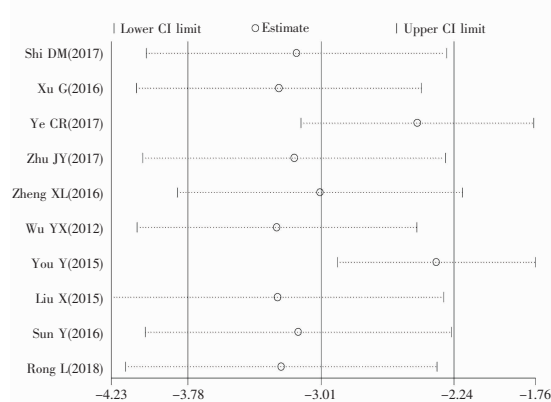


Figure 9 Sensitivity analysis of hospitalization cost comparison between ESD and surgery groups

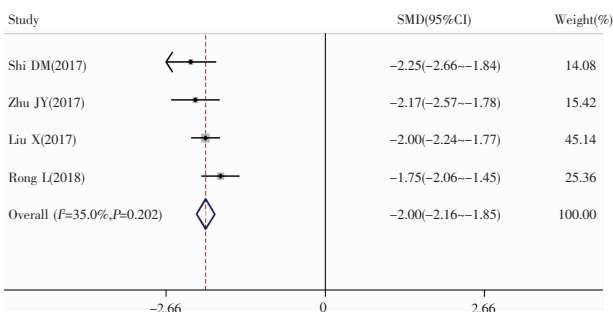


Figure 10 A secondary analysis of the hospitalization cost between ESD and surgery groups

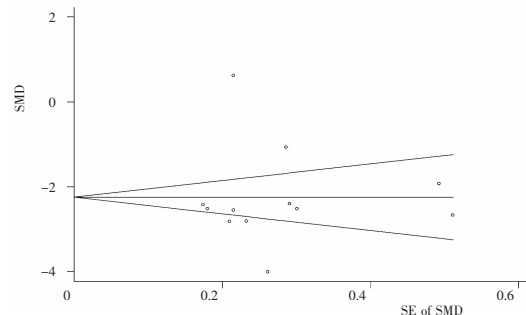


Figure 11 Bias analysis of surgical time between ESD and surgery groups

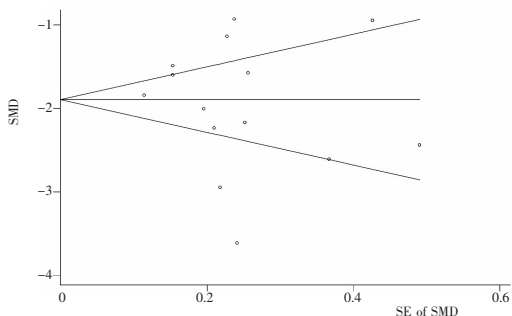


Figure 12 Bias analysis of hospitalization time between ESD and surgery groups

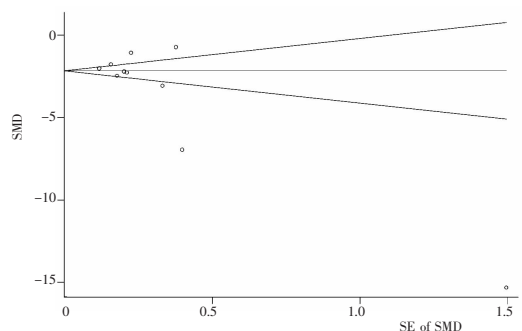


Figure 13 Bias analysis of hospitalization cose between ESD and surgery groups

ESD 和外科手术治疗早期胃癌在卫生经济学方面的相关指标(手术时间、住院时间、住院费用)进行综合性分析,系统评价二者的优劣性。本 Meta 分析结果显示:与外科手术相比,ESD 术具有手术时间短、住院时间短、住院费用低等优势。

一般认为,ESD 治疗具有创伤小、恢复快、时间短、费用低等优势,并可保留正常解剖结构和生理功能^[26,27]。但目前关于 ESD 手术与外科手术治疗消化

道早癌对比的 Meta 分析或系统评价中相关卫生经济学指标并不完全统一。本研究结果显示:ESD 组手术时间短于外科手术所需时间,住院时间短于外科手术组,住院费用也相对较低,这与文献报道^[28,29]一致。但赵飞等^[30]的 Meta 分析结果显示,两组在手术时间、住院费用方面无显著差异,这可能与其所分析的病变部位及手术方式不同有关。其分析了 ESD 在早期消化道肿瘤中的应用,就胃早癌外科术式包

括 Billroth I 式、Billroth II 式、胃大部切除后 Roux-en-Y 吻合、全胃切除以及腹腔镜手术等。ESD 组的住院时间较短,这可能与 ESD 术创伤小、术后并发症相对较少,患者恢复快有关。同理,患者恢复快,住院时间短,治疗、陪护、护理等方面所花费的人力、物力等也会减少。

此外,本研究纳入研究结果间存在较大异质性。一般地,异质性可能来源于临床异质性、方法学异质性和统计学异质性等方面^[31]。为分析异质性来源,本研究进行了敏感性分析^[32],剔除异质性较大的研究后,仍存在较大异质性,继续采用随机效应模型合并效应量,分析后均具有统计学意义。分析其原因,可能与我国各地区医疗发展水平差异大、医疗资源分配不均衡、外科手术所采用具体术式不同等因素有关。

本研究存在一定的局限性:①缺乏灰色文献(如专题讨论会记录、未发表的资料、政府研究报告和其他非传统文献来源的证据),可能会导致发表偏倚;②按纳入标准,本研究纳入的原始文献均为国内研究,不可避免地会造成发表偏倚;③所纳入研究进行的外科手术方式不完全一致;④由于原始文献数据的限制,有些文献没有纳入研究所需的所有效应指标;⑤研究间存在异质性,采用随机效应模型进行了分析。

综上所述,ESD 具有创伤小、住院时间短、花费少等优势。随着微创理念的深入及内镜技术的发展,未来在严格掌握其适应证,不降低患者生存率及生活质量的前提下,尽可能开展 ESD 手术治疗早期胃癌可减少患者费用负担、节约部分医疗资源,同时可优化资源配置、提高病床周转利用率。在治疗早期胃癌方面,ESD 术较外科手术具有更好的卫生经济学效益。

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