

临床与基础
桥接研究Clinical and Basic
Bridging Research罗哌卡因竖脊肌平面阻滞联合 TIVA 用于
结直肠癌患者的临床研究Clinical trial of ropivacaine erector spinae plane block combined with TIVA in the
treatment of colorectal cancer patients

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摘要:目的 观察罗哌卡因竖脊肌平面阻滞(ESPB)联合全凭静脉麻醉(TIVA)用于结直肠癌患者的临床疗效及安全性。方法 将结直肠癌患者随机分为对照组和试验组。试验组在全麻诱导前,在竖脊肌深层面注射0.375%盐酸罗哌卡因注射液25 mL进行局部麻醉。然后,2组患者均给予0.05 mg·kg⁻¹达咪唑仑+0.4 μg·kg⁻¹舒芬太尼+1.5 mg·kg⁻¹丙泊酚+0.15 mg·kg⁻¹顺阿曲库铵进行麻醉诱导,均给予3~4 mg·L⁻¹丙泊酚+0.5~1.0 μg·kg⁻¹舒芬太尼+0.05~0.10 mg·kg⁻¹苯磺酸顺阿曲库铵进行麻醉维持。比较2组患者的舒芬太尼用量,血流动力学,视觉模拟量表(VAS)和Ramsay镇静评分,白细胞介素(IL)-6和皮质醇水平,以及安全性。结果 试验组入组57例,脱落5例,最终有52例纳入统计分析;对照组入组55例,脱落3例,最终有52例纳入统计分析。试验组和对照组拔管时的心率分别为(89.54±5.41)和(101.98±8.58) beat·min⁻¹,平均动脉压分别为(83.60±7.48)和(93.12±7.35) mmHg,在统计学上差异均有统计学意义(均P<0.05)。试验组和对照组的术中舒芬太尼用量分别为(16.35±2.54)和(23.77±3.02) μg,术后24 h VAS评分分别为(2.98±0.42)和(3.67±0.58)分,术后24 h IL-6水平分别为(17.92±2.41)和(28.12±3.81) ng·L⁻¹,术后24 h皮质醇水平分别为(154.88±24.06)和(187.46±27.51) ng·mL⁻¹,在统计学上差异均有统计学意义(均P<0.05)。试验组和对照组术后1、24 h的Ramsay评分在组间和组内比较,在统计学上差异均无统计学意义(均P>0.05)。试验组发生的药物不良反应有阻滞部位血肿和恶心呕吐,对照组发生的药物不良反应有恶心呕吐、低血压和谵妄。试验组和对照组的药物不良反应总发生率分别为11.54%和21.15%,在统计学上差异无统计学意义(P>0.05)。结论 罗哌卡因 ESPB 联合 TIVA 有助于维持结直肠癌患者术中血流动力学稳定,减少舒芬太尼用量,减轻疼痛,降低术后炎症因子和应激反应水平,且不增加药物不良反应的发生率。

关键词:罗哌卡因注射液;脊肌平面阻滞;全凭静脉麻醉;结直肠癌;安全性评价

DOI:10.13699/j.cnki.1001-6821.2025.08.003

中图分类号:R971.2 文献标志码:A

文章编号:1001-6821(2025)08-1062-05

Abstract: Objective To observe the clinical efficacy and safety of ropivacaine for erector spinae plane block (ESPB) combined with total intravenous anesthesia (TIVA) in patients undergoing colorectal cancer surgery. **Methods** Patients with colorectal cancer were randomly divided into treatment and control groups. Before the general anesthesia induction, treatment group received deep injection of 0.375% ropivacaine solution (25 mL) for local anesthesia in the erector spinae plane. Two groups received anesthesia induction with 0.05 mg·kg⁻¹ midazolam +

0.4 $\mu\text{g} \cdot \text{kg}^{-1}$ sufentanil + 1.5 $\text{mg} \cdot \text{kg}^{-1}$ propofol + 0.15 $\text{mg} \cdot \text{kg}^{-1}$ cisatracurium, and anesthesia maintenance with 3–4 $\text{mg} \cdot \text{L}^{-1}$ propofol + 0.5–1.0 $\mu\text{g} \cdot \text{kg}^{-1}$ sufentanil + 0.05–0.10 $\text{mg} \cdot \text{kg}^{-1}$ cisatracurium. The sufentanil dosage, hemodynamics, visual analogue scale (VAS) and Ramsay sedation scores, interleukin (IL)–6 and cortisol levels and safety were compared between two groups. **Results** Treatment group were enrolled 57 cases, 5 cases dropped out, and 52 cases were finally included in the statistical analysis. Control group were enrolled 55 cases, 3 cases dropped out, and 52 cases were finally included in the statistical analysis. At extubation, heart rates of treatment and control groups were (89.54 ± 5.41) and (101.98 ± 8.58) $\text{beat} \cdot \text{min}^{-1}$, mean arterial pressures were (83.60 ± 7.48) and (93.12 ± 7.35) mmHg, and the differences were statistically significant (all $P < 0.05$). Intraoperative sufentanil dosages of treatment and control groups were (16.35 ± 2.54) and (23.77 ± 3.02) μg , VAS scores at 24 h after operation were (2.98 ± 0.42) and (3.67 ± 0.58) points, IL–6 levels at 24 h after operation were (17.92 ± 2.41) and (28.12 ± 3.81) $\text{ng} \cdot \text{L}^{-1}$, cortisol levels at 24 h after operation were (154.88 ± 24.06) and (187.46 ± 27.51) $\text{ng} \cdot \text{mL}^{-1}$, respectively; the differences were statistically significant (all $P < 0.05$). Ramsay scores at 1 and 24 h postoperatively showed no statistically significant differences between and within groups (all $P > 0.05$). The adverse drug reactions of treatment group were block site hematoma, nausea and vomiting, while those in control group were nausea and vomiting, hypotension and delirium. The incidences of total adverse drug reactions in the treatment and control groups were 11.54% and 21.15%, without significant difference ($P > 0.05$). **Conclusion** Ropivacaine ESPB combined with TIVA can help the patients undergoing colorectal cancer surgery to maintain stable intraoperative hemodynamics, reduce sufentanil consumption and pain, decrease postoperative inflammatory and stress responses, without increasing the incidence of adverse drug reactions.

Key words: ropivacaine injection; erector spinae plane block; total intravenous anesthesia; colorectal cancer; safety evaluation

结直肠癌手术作为一种复杂程度较高的手术类型,对麻醉的选择也具有较高的要求,从而确保术中安全及术后恢复^[1–2]。全凭静脉麻醉(total intravenous anesthesia, TIVA)因其优良的麻醉控制效果和较快的恢复时间而广泛应用于多种手术中,但其对血流动力学仍存在潜在的影响^[3–4]。脊肌平面阻滞(erector spinae plane block, ESPB)作为一种有效的区域阻滞技术,通过直接作用于相关肌肉平面来减轻疼痛,可以减少对全身麻醉药物的依赖,从而减轻对心血管系统的影响^[5]。TIVA联合ESPB的策略结合了两者的优势,不仅可以维持稳定的血流动力学状态,还可能进一步降低术后炎症和应激指标^[6],对结直肠癌手术患者的整体预后具有积极的作用。本研究旨在观察罗哌卡因ESPB联合TIVA用于结直肠癌患者的临床疗效及安全性。

材料、对象与方法

1 研究设计

本方案按前瞻性、随机、单盲、对照、单中心临床试验研究方法设计。

2 病例选择

2021年1月至2023年1月以本院就诊的结直肠

癌患者入选为研究对象。本研究经浙江大学医学院附属邵逸夫医院医学伦理委员会批准(伦理批号:20200105–11)。所有患者及家属均签署知情同意书。

诊断与入选标准 符合《内科学》^[7]中关于结直肠癌的诊断标准。符合结直肠癌手术指征,对本研究所用药品无过敏反应者,无精神疾病史或沟通交流障碍者,术前未接受过其他方式的放疗或化疗者。

排除标准 存在器官功能不全、免疫系统疾病、血液系统疾病、传染性疾病者,合并其他恶性肿瘤者。

3 药品、试剂与仪器

盐酸罗哌卡因,规格:每支10 mL/75 mg,批号:EE2408,批准文号:国药准字H20163208,浙江仙琚制药股份有限公司生产;舒芬太尼,规格:每支1 mL/50 μg ,批号:31A121912,批准文号:国药准字H20054171,宜昌人福药业有限责任公司生产。白细胞介素6(interleukin–6, IL–6)、肿瘤坏死因子– α (tumor necrosis factor– α , TNF– α)、皮质醇、肾上腺素测定试剂盒,均购自上海碧云天生物技术股份有限公司。

CX50彩色多普勒超声诊断仪,购自荷兰皇家飞利浦公司;STAR8000E病人监护仪,购自湖南博瑞药

业有限公司;BS-430全自动生化分析仪,购自成都晟达亿新医疗科技有限公司;CyFlow Cube8-Sysmex流式细胞仪,购自广州吉源生物科技有限公司。

4 分组与治疗方法

将结肠癌患者按随机数表法分为对照组和试验组。

麻醉诱导 入室后,试验组在全麻诱导前,在竖脊肌深层面注射0.375%盐酸罗哌卡因注射液25 mL进行局部麻醉。然后,2组患者均给予 $0.05\text{ mg}\cdot\text{kg}^{-1}$ 达咪唑仑+ $0.4\text{ }\mu\text{g}\cdot\text{kg}^{-1}$ 舒芬太尼+ $1.5\text{ mg}\cdot\text{kg}^{-1}$ 丙泊酚+ $0.15\text{ mg}\cdot\text{kg}^{-1}$ 顺阿曲库铵进行麻醉诱导。

麻醉维持 2组患者术中均用微量泵靶控持续输注丙泊酚,靶控浓度 $3\sim4\text{ mg}\cdot\text{L}^{-1}$,根据麻醉深度静脉推注 $0.5\sim1.0\text{ }\mu\text{g}\cdot\text{kg}^{-1}$ 舒芬太尼和 $0.05\sim0.10\text{ mg}\cdot\text{kg}^{-1}$ 苯磺酸顺阿曲库铵,使脑电双频指数维持在 $40\sim60$ 。

5 观察指标

观察并记录2组患者的麻醉起效时间、舒芬太尼用量、手术时间、术后苏醒时间等围术期指标。麻醉前10 min(T0)、气管插管后10 min(T1)、气腹后1 h(T2)、拔管时(T3)的心率和平均动脉压通过监护仪进行测定。

于术前和术后24 h,用酶联免疫吸附试验法测IL-6、TNF- α 、皮质醇和肾上腺素水平,用流式细胞仪检测T淋巴细胞亚群(CD_3^+ 和 CD_4^+)水平。

于术后1和24 h,用视觉模拟量表(visual analogue scale,VAS)和Ramsay镇静评分法评估2组患者的疼痛情况和镇静程度。VAS量表满分为10分,分数越高表示疼痛越剧烈;Ramsay总分6分,<2分表示镇静不足,2~4分为镇静满意,>4分表示镇静过度。

6 统计学处理

用SPSS 28.0软件进行统计分析。计量资料用 $\bar{x}\pm s$ 表示,比较用 t 检验,不同时间点用重复测量方差分析;计数资料用率表示,比较用 χ^2 检验。

结 果

1 一般资料

本研究共筛选178例,入组112例,其中,对照组55例、试验组57例。试验组因治疗计划改变脱落5例,最终有52例纳入统计分析;对照组因病情变化脱落3例,最终有52例纳入统计分析。2组患者的性别、年龄、体质量和病程等比较,在统计学上差异均无

统计学意义(均 $P>0.05$),组间具有可比性,见表1。

2 2组患者围术期指标的比较

试验组和对照组的手术时间分别为(173.77 ± 23.71)和(171.42 ± 23.47) min,在统计学上差异无统计学意义($P>0.05$);试验组的麻醉起效时间、舒芬太尼用量、术后苏醒时间分别为(1.12 ± 0.32) min、(16.35 ± 2.54) μg 和(10.13 ± 2.02) min,均显著低于对照组[(1.83 ± 0.45) min、(23.77 ± 3.02) μg 、(14.65 ± 2.59) min],在统计学上差异均有统计学意义(均 $P<0.05$)。

3 2组患者血流动力学的比较

T1、T2、T3时刻与T0相比,2组患者术中的心率和平均动脉压均出现先降低后升高,但试验组的心率和平均动脉压波动程度均显著小于对照组,在统计学上差异均有统计学意义(均 $P<0.05$),见表2。

4 2组患者疼痛和镇静情况的比较

试验组和对照组术后1 h的VAS评分分别为(2.42 ± 0.50)和(2.85 ± 0.36)分,术后24 h的VAS评分分别为(2.98 ± 0.42)和(3.67 ± 0.58)分,试验组的VAS评分均显著低于对照组(均 $P<0.05$)。试验组和对照组术后1 h的Ramsay评分分别为(3.44 ± 0.50)和(3.48 ± 0.54)分,术后24 h的Ramsay评分分别为(3.19 ± 0.44)和(3.15 ± 0.41)分,2组患者Ramsay评分的组间和组内比较,在统计学上差异均无统计学意义(均 $P>0.05$)。

5 2组患者炎症水平、应激指标和免疫功能的比较

2组患者术后24 h的IL-6、TNF- α 、皮质醇和肾上腺素水平均较术前显著升高, CD_3^+ 和 CD_4^+ 水平均较术前显著降低,在统计学上差异均有统计学意义(均 $P<0.05$);术后24 h,试验组的IL-6、TNF- α 、皮质醇和肾上腺素水平均较对照组显著降低, CD_3^+ 和

表1 2组患者的一般资料比较($\bar{x}\pm s$)

Table 1 Comparison of general information in two groups($\bar{x}\pm s$)

Item	Control ($n=52$)	Treatment ($n=52$)
Sex (M/F)	29/23	27/25
Age (year)	51.04 ± 5.41	51.21 ± 5.69
Weight (kg)	61.05 ± 7.53	61.44 ± 7.70
BMI ($\text{kg}\cdot\text{m}^{-2}$)	23.82 ± 3.14	23.63 ± 3.21
Duration of illness (year)	2.79 ± 0.50	2.63 ± 0.49
Disease type (colon cancer/ rectal cancer)	28/24	31/21

BMI: Body mass index; Control group: Total Intravenous anesthesia; Treatment group: Total intravenous anesthesia combined with erector spinae plane block anesthesia.

表 2 2 组患者血流动力学的比较($\bar{x} \pm s$)

Table 2 Comparison of hemodynamic between the two groups($\bar{x} \pm s$)

Item	Control (n = 52)			
	T0	T1	T2	T3
HR (time · min ⁻¹)	87.52 ± 6.47	79.23 ± 5.69 [#]	71.40 ± 5.26 [#]	101.98 ± 8.58 [#]
MAP (mmHg)	81.83 ± 7.40	72.02 ± 6.98 [#]	72.56 ± 6.54 [#]	93.12 ± 7.35 [#]

Item	Treatment (n = 52)			
	T0	T1	T2	T3
HR (time · min ⁻¹)	87.25 ± 6.33	84.19 ± 5.12 ^{*#}	82.58 ± 4.63 ^{*#}	89.54 ± 5.41 [*]
MAP (mmHg)	81.62 ± 7.43	78.04 ± 7.11 ^{*#}	77.56 ± 7.04 ^{*#}	83.60 ± 7.48 [*]

T0: 10 minutes prior to anesthesia induction; T1: 10 minutes after endotracheal intubation; T2: 1 hour after pneumoperitoneum establishment; T3: Extubation; HR: Heart rate; MAP: Mean arterial pressure; Compared with control group at the same time, ^{*} $P < 0.05$; Compared with T0 in the same group, [#] $P < 0.05$.

表 3 2 组患者炎症水平、应激指标和免疫功能的比较($\bar{x} \pm s$)

Table 3 Comparison of inflammation levels, stress indicators and immune function between two patient groups($\bar{x} \pm s$)

Item	Control (n = 52)		Treatment (n = 52)	
	Before operation	24 h after operation	Before operation	24 h after operation
IL-6 (ng · L ⁻¹)	13.97 ± 2.72	28.12 ± 3.81 [△]	13.90 ± 2.84	17.92 ± 2.41 ^{*△}
TNF-α (ng · L ⁻¹)	2.71 ± 0.55	4.01 ± 0.67 [△]	2.73 ± 0.60	2.94 ± 0.64 [*]
Cortisol (ng · L ⁻¹)	134.88 ± 20.82	187.46 ± 27.51 [△]	134.33 ± 20.39	154.88 ± 24.06 ^{*△}
Adr (ng · mL ⁻¹)	35.71 ± 4.42	80.14 ± 8.39 [△]	35.14 ± 4.41	52.35 ± 6.42 ^{*△}
CD ₃ ⁺ (%)	54.81 ± 6.23	30.03 ± 4.18 [△]	54.90 ± 6.38	39.92 ± 5.06 ^{*△}
CD ₄ ⁺ (%)	38.21 ± 4.28	18.34 ± 2.05 [△]	38.19 ± 4.01	26.47 ± 3.29 ^{*△}

IL: Interleutin; TNF-α: Tumor necrosis factor alpha; CD: Cluster of differentiation; Compared with control group at the same time, ^{*} $P < 0.05$; Compared with before operation in the same group, [△] $P < 0.05$.

CD₄⁺ 均较对照组显著升高,在统计学上差异均有统计学意义(均 $P < 0.05$)。结果见表 3。

6 安全性评价

试验组出现阻滞部位血肿 3 例和恶心呕吐 3 例,总药物不良反应发生率为 11.54%;对照组出现恶心呕吐 5 例、低血压 3 例和谵妄 3 例,总药物不良反应发生率为 21.15%。2 组患者的总药物不良反应发生率比较,在统计学上差异无统计学意义($P > 0.05$)。

讨 论

在结直肠癌手术中,TIVA 因能提供稳定的麻醉深度和较快的术后恢复被广泛应用^[8-9],但对呼吸系统可能存在一定影响。ESPB 通过注入盐酸罗哌卡因起到了局部镇痛效果,这种区域阻滞技术不仅能够减轻术后疼痛,而且有助于减少对全身麻醉药物的依赖,从而降低药物不良反应的发生风险^[10-11]。TIVA 联合 ESPB 能够更好地优化术后恢复,是一种安全、有效的麻醉管理策略^[12]。

本研究发现,试验组的麻醉起效时间较对照组明显缩短。因为通过局部注射盐酸罗哌卡因到竖脊肌

平面,阻断传导痛觉信号的神经纤维,从而减轻手术刺激对患者的影响,使得整体麻醉过程更加高效和快速^[13-14]。SIFAKI 等^[15] 研究显示,用 ESPB 的患者可减少 60% 以上阿片类药物用量,与本研究结果相符合。同时,本研究发现,试验组对全身麻醉药物的依赖性降低,这提高了患者术后恢复速度,从而缩短术后苏醒时间。此外,减少丙泊酚和阿片类药物的使用可以降低患者心血管和呼吸系统的药物不良反应风险,从而提高治疗的安全性^[16-18]。KOTANI 等^[19] 研究表明,全麻患者应用丙泊酚后,发生低血压的概率高达 21.6%。ESPB 能够提供有效的局部镇痛,通过减少患者对全身麻醉药物的依赖,从而降低呼吸抑制的风险^[20-21]。因此,试验组患者术中的血流动力学更稳定。此外,局部阻滞可以降低手术引发的应激反应,进一步维持术中血流动力学的稳定^[22-23]。JIANG 等^[24] 研究也指出,过高的应激激素水平可能会增加免疫抑制的风险,影响患者术后恢复进程。本研究发现,试验组术后 24 h 的皮质醇、肾上腺素和炎症因子水平均显著低于对照组,且术后 24 h 的 CD₃⁺ 和 CD₄⁺ 均较对照组显著升高。这也进一步说明了较低的应激状态和良好的疼痛控制有助于维持免疫系统的功

能,防止手术和麻醉引起的免疫抑制,从而提高患者的抗感染能力,促进术后恢复。

本研究提示:罗哌卡因 ESPB 联合 TIVA 用于结直肠癌手术有助于减少全身麻醉药物用量,维持术中血流动力学稳定,且不增加药物不良反应的发生率。

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(收稿日期 2024 - 10 - 13)