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· 专题研究 ·

胆道引流术后荧光腹腔镜手术治疗胆囊结石的临床疗效

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摘要

背景与目的: 腹腔镜胆囊切除术(LC)中经胆道直接注射吲哚菁绿(ICG)行荧光胆管显影,有即刻显影及零肝脏背景荧光的优势,在复杂LC中有更好的效果。本研究旨在探讨经皮经肝胆囊穿刺引流术(PTGBD)或经内镜鼻胆管引流术(ENBD)术后行荧光LC的临床效果。

方法: 选取2019年1月—2021年4月120例行LC的胆囊结石患者的临床资料,在经PTGBD或ENBD术后60例行注射ICG荧光导航的LC(观察组),60例行普通白光LC(对照组)。比较两组患者的肝外胆管显示率及相关临床指标。

结果: 两组患者的术前一般资料差异无统计学意义(均 $P>0.05$)。解剖胆囊三角前,观察组的肝总管、胆总管、胆囊管、胆囊管胆总管汇合部及胆囊颈部显示率明显高于对照组(均 $P<0.05$),但两组的右肝管显示率差异无统计学意义($P>0.05$);解剖胆囊三角后,观察组的肝总管、胆总管及胆囊管胆总管汇合部显示率明显高于对照组(均 $P<0.05$)。与对照组比较,观察组患者手术用时缩短、术中出血量减少,肝下引流管放置率降低,术后住院时间缩短(均 $P<0.05$)。两组的住院费用、并发症发生率差异无统计学意义(均 $P>0.05$)。

结论: 荧光导航LC的运用有利于提高肝外胆管的显示率,降低PTGBD及ENBD术后复杂LC的难度,缩短手术时间及住院时间,减少术中出血量及肝下引流管留置。

关键词

胆囊切除术,腹腔镜;手术导航系统;吲哚花青绿

中图分类号: R657.4

Clinical efficacy of fluorescence-navigated laparoscopic surgery in treatment of cholecystolithiasis after biliary drainage

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Abstract

Background and Aims: Fluorescence cholangiography by intrabiliary indocyanine green (ICG) injection during laparoscopic cholecystectomy (LC) has the advantage of immediate display with zero background liver fluorescence. It is more suitable for complex LC. This study was conducted to investigate the efficacy of fluorescent LC after percutaneous transhepatic gallbladder drainage (PTGBD) or endoscopic nasobiliary drainage (ENBD).

Methods: The clinical data of 120 patients with gallbladder stones undergoing LC from January 2019 to

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April 2021 were selected. Of the patients, 60 cases underwent fluorescence-navigated LC by injection of ICG through the PTGBD tube or ENBD tube (observation group), and 60 cases underwent conventional LC (control group). The display rates of the extrahepatic bile duct structures and the main clinical variables were compared between the two groups.

Results: The preoperative general data showed no significant difference between the two groups of patients (all $P>0.05$). Before dissection of the Calot's triangle, the display rates of the common hepatic duct, the common bile duct, the cystic duct, the junction of cystic duct and common bile duct and the neck of the gallbladder were significantly higher in observation group than those in control group (all $P<0.05$), but there was no significant difference in display rate of the right hepatic duct between the two groups ($P>0.05$); After dissection of the Calot's triangle, the display rates of the common hepatic duct, the common bile duct and the junction of cystic duct and common bile duct were significantly higher in observation group than those in control group (all $P<0.05$). In observation group compared with control group, the operative time, the intraoperative blood loss, the rate of subhepatic drainage tube placement, and length of postoperative hospital stay were all significantly reduced (all $P<0.05$). There was no significant difference in hospitalization cost and incidence rate of postoperative complications between the two groups (all $P>0.05$).

Conclusions: The application of fluorescence-navigated LC is beneficial to improve the display rate of the extrahepatic bile duct structures, decrease the degree of difficulty of complex LC after PTGBD and ENBD, shorten the operative time and postoperative hospital stay, and reduce the intraoperative blood loss and subhepatic drainage tube placement.

Key words

Cholecystectomy, Laparoscopic; Surgical Navigation Systems; Indocyanine Green

CLC number: R657.4

对于无法实施早期手术的高危急性胆囊炎患者,经皮经肝胆囊穿刺引流术(percutaneous transhepatic gallbladder drainage, PTGBD)是首选的治疗方式之一^[1-2]。目前,治疗胆总管结石合并胆囊结石有多种策略,常用的治疗方案之一是经内镜鼻胆管引流术(endoscopic nasobiliary drainage, ENBD)联合择期腹腔镜胆囊切除术(laparoscopic cholecystectomy, LC)^[3]。然而,PTGBD或ENBD术后择期行LC,因胆囊周围组织粘连严重,腹腔镜胆囊切除术的难度增加,易造成胆汁漏、胆管损伤等手术副损伤^[4-5]。近年来,吲哚菁绿(indocyanine green, ICG)荧光显影技术应用于胆囊切除可增强胆道结构的可视化,降低手术难度^[6-9]。然而,目前鲜有文献描述荧光导航腹腔镜手术在PTGBD或ENBD术后LC中的应用。本研究旨在回顾性比较PTGBD或ENBD术后行荧光LC与普通白光LC的临床应用效果。

1 资料与方法

1.1 一般资料

选取中国医科大学附属盛京医院第二普通外科2019年1月—2021年4月行腹腔镜胆囊切除的患者。纳入标准:(1)诊断为胆囊结石合并急性胆囊炎,病程超过72 h,年龄超过75岁或有严重心、脑、肺、肝、肾等合并症,不宜行急诊LC;(2)超声内镜和腹部彩超检查诊断为胆总管结石合并胆囊结石,胆总管结石直径在15 mm以下。排除标准:(1)无法耐受择期LC手术;(2)合并其他手术,如腹腔镜胆总管切开放石。共有120例患者纳入研究,其中男63例,女57例;平均年龄(62.8 ± 14.3)岁。胆囊结石合并急性胆囊炎60例,均表现为右上腹疼痛,Murphy征阳性,彩超及CT提示胆囊胀大,胆囊壁水肿增厚,胆囊周围积液;胆囊结石合并胆总管结石60例,均具有上腹痛、黄疸及发热的症状,影像学检查诊断为胆囊结石合并胆总管结石。根据手术当天手术室荧光腹腔镜器械的预约及供应情况选择不同的腹腔镜,120例

患者中, 60例行荧光LC(观察组), 60例行普通白光LC(对照组)。两组患者年龄、性别、体质量指数(Body Mass Index, BMI)、开腹史、ASA评分、肝功能Child-Pugh分级、合并症、择期LC时机、术前白细胞计数指标差异均无统计学意义(均 $P>0.05$) (表1)。所有患者术前均签署手术同意书, 研究通过我院医学伦理委员会批准(批件号: 2017PS231K)。

表1 两组患者一般资料比较

Table 1 Comparison of the general data between the two groups of patients

资料	观察组 (n=60)	对照组 (n=60)	$t/Z/\chi^2$	P
年龄(岁, $\bar{x} \pm s$)	61.55±14.75	64.10±13.77	-0.979	0.330
性别[n(%)]				
男	30(50.0)	33(55.0)	0.301	0.583
女	30(50.0)	27(45.0)		
BMI(kg/m ² , $\bar{x} \pm s$)	22.56±2.33	23.15±2.43	-1.361	0.176
开腹史[n(%)]	14(23.3)	19(31.7)	1.045	0.307
ASA评分[n(%)]				
I	27(45.0)	26(43.3)	1.537	0.757
II	18(30.0)	23(38.3)		
III	14(23.3)	10(16.7)		
IV	1(1.7)	1(1.7)		
Child-Pugh分级[n(%)]				
A级	50(83.3)	48(80.0)	0.223	0.637
B级	10(16.7)	12(20.0)		
合并症[n(%)]				
急性胆囊炎	30(50.0)	30(50.0)	1	1
胆总管结石	30(50.0)	30(50.0)		
择期LC时机[d, $M(IQR)$]	10(6.0~87.5)	8.5(5.0~51.0)	0.849	0.396
白细胞计数($10^9/L$, $\bar{x} \pm s$)	6.32±1.96	6.45±2.47	-0.316	0.752

1.2 治疗方法

胆囊结石合并急性胆囊炎患者先行PTGBD, 术后3个月行择期LC。胆囊结石合并胆总管结石患者行内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatography, ERCP)/内镜括约肌切开术(endoscopic lithotomy, EST)后1周内再行LC治疗。(1)PTGBD: 患者取仰卧位, 超声引导下选择体表穿刺点, 术区消毒铺无菌洞巾, 局部麻醉后用尖刀片在皮肤上做一0.2 cm切口, 超声引导下沿切口进针经过肝脏IV或V区、胆囊床至胆囊, 拔除针芯, 抽取胆汁, 造影确认穿刺针位于胆囊内后, 插入导丝于胆囊内成盘曲样, 退出穿刺针

外套, 将引流管沿着导丝插入胆囊内4 cm, 再于造影下确认引流管于胆囊内成襻, 固定引流管, 连接引流袋。(2)ERCP/EST: 术前口服利多卡因胶浆, 取左侧卧位。十二指肠镜进镜后, 逆行胆总管插管造影, 若证实为胆总管结石, 以弓形刀行EST, 并用取石网篮取石。结石较大取石困难者可试行大球囊扩张联合机械碎石器碎石后取石。留置ENBD管引流进行减黄处理。(3)荧光导航LC: 全麻下建立CO₂气腹, 压力维持在12~14 mmHg(1 mmHg=0.133 kPa)。取头高脚低左倾位, 按三孔法放置Trocar, 送入腹腔镜(苏州国科美润达医疗技术有限公司, 苏械注准20172222339)。左手以把持制钳抓住胆囊体部向患者右上方牵拉, 暴露胆囊三角。随后经PTGBD引流管缓慢持续注射10 mL(0.025 mg/mL) ICG(25 mg, 丹东医创药业有限公司, 国药准字H20055881)溶液, 在腹腔镜荧光模式下可观察到胆囊、胆囊管、胆总管和肝总管依次显示荧光信号(图1), 若荧光强度较低, 可再次注入10 mL ICG溶液。以同样方法经ENBD引流管注射ICG, 术中可见胆总管、肝总管、胆囊管和胆囊依次显影(图2)。随后通过荧光图像明确肝总管、胆囊管和胆总管三管关系及毗邻组织, 钝性解剖胆囊三角, 顺行或逆行切除法切除胆囊, 拔除PTGBD引流管, 胆囊通过脐部穿刺孔取出。ENBD管术后第1天拔除。(4)普通白光LC: 行传统LC手术, 不使用荧光胆道显影。

1.3 观察指标

观察并记录两组患者的肝外胆管显影情况、手术用时(从切开皮肤到缝合完毕)、术中出血量、肝下引流管放置率、术后住院时间、住院费用、并发症类型、并发症发生率、并发症治疗情况。术后通过门诊、电话回访(回访日期截至2021年8月)了解患者结石复发等情况。

1.4 统计学处理

采用SPSS 25.0统计软件进行分析。符合正态分布的计量资料以均数±标准差($\bar{x} \pm s$)表示, 组间比较采用 t 检验; 符合偏态分布的计量资料以中位数(四分位数间距) $[M(IQR)]$ 表示, 组间比较采用Mann-Whitney U 检验。计数资料以例数(百分比) $[n(%)]$ 表示, 组间比较采用 χ^2 检验。 $P<0.05$ 为差异有统计学意义。

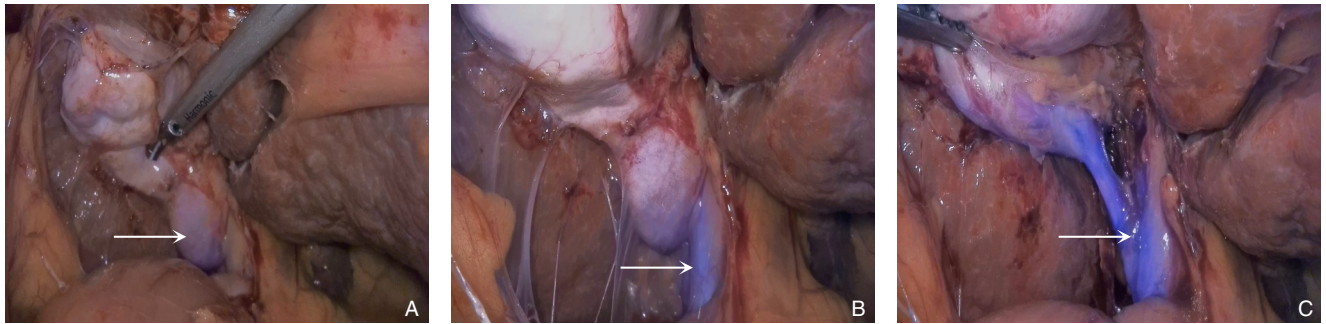


图1 经PTGBD管注射ICG行荧光LC A: 经PTGBD管注射ICG, 胆囊(白色箭头)立即显影; B: 注射2 s后胆总管(白色箭头)显影; C: 夹闭胆囊管前, 确认胆囊管与胆总管汇合部(白色箭头)

Figure 1 Fluorescence-navigated LC after ICG injection through PTGBD tube A: Immediate display of the gallbladder (white arrow) after ICG injection through the PTGBD tube; B: Display of the common bile duct (white arrow) 2 s after injection; C: Identification the junction between the cystic duct and the common bile duct (white arrow) before occlusion of the cystic duct

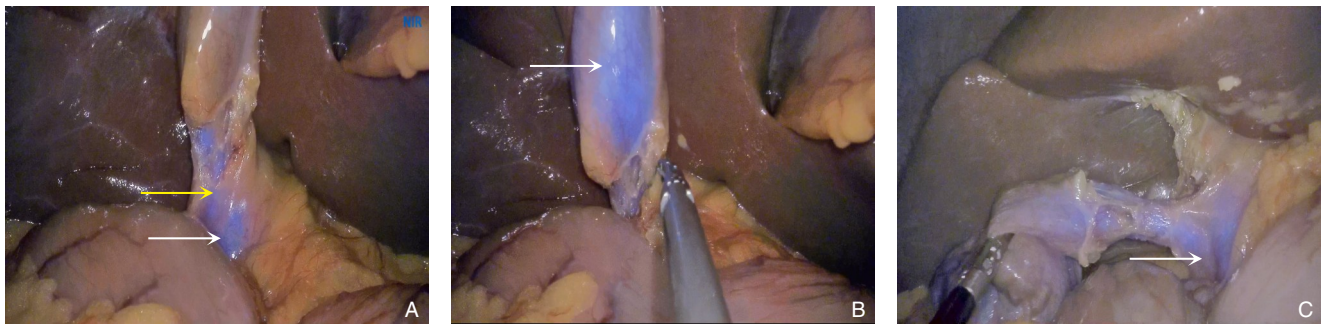


图2 经ENBD管注射ICG行荧光LC A: 经ENBD引流管注射ICG, 肝总管(白色箭头)和胆囊管(黄色箭头)立即显影; B: 注射2 s后, 胆囊(白色箭头)显影; C: 夹闭胆囊管前, 确认胆囊管与肝总管汇合部(白色箭头)

Figure 2 Fluorescence-navigated LC after ICG injection through ENBD tube A: Display of the hepatic duct (white arrow) and cystic duct (yellow arrow) immediately after ICG injection through the ENBD tube; B: Display of the gallbladder (white arrow) 2 s after injection; C: Identification of the junction between the cystic duct and the common bile duct (white arrow) before occlusion of the cystic duct

2 结果

2.1 两组患者肝外胆管显示率比较

解剖胆囊三角前, 观察组的肝总管、胆总管、胆囊管、胆囊管胆总管汇合部及胆囊颈部显示率明显高于对照组(均 $P < 0.05$), 但两组的右肝管显示率差异无统计学意义($P > 0.05$); 解剖胆囊三角后, 观察组的肝总管、胆总管及胆囊管胆总管汇合部显示率明显高于对照组(均 $P < 0.05$)(表2)。

2.2 两组患者围手术期指标比较

120例患者均顺利行腹腔镜胆囊切除术。与对

照组比较, 观察组患者手术用时更短、术中出血量更少, 肝下引流管放置率更低, 术后住院时间更短($P < 0.05$)。而观察组与对照组的住院费用差异无统计学意义($P > 0.05$)。在对照组中, 1例发生术后腹腔积液, 经对症治疗后积液减少出院。观察组与对照组的并发症发生率差异无统计学意义($P > 0.05$)(表3)。120例患者均获得随访, 随访时间为3~24个月, 中位随访时间为3个月。两组患者均无因术后并发症再次入院治疗。

表2 两组患者肝外胆管显示率比较[n (%)]

Table 2 Comparison of the display rates of the extrahepatic bile duct structures between two groups of patients [n (%)]

胆管结构显示	解剖胆囊三角前			解剖胆囊三角后		
	观察组(n=60)	对照组(n=60)	P	观察组(n=60)	对照组(n=60)	P
胆囊管	35(58.3)	23(38.3)	0.028	59(98.3)	58(96.7)	1.000 ¹⁾
右肝管	3(5.0)	2(3.3)	1.000 ¹⁾	9(15.0)	4(6.7)	0.142
肝总管	17(28.3)	6(10.0)	0.011	32(53.3)	17(28.3)	0.005
胆总管	48(80.0)	29(48.3)	<0.001	52(86.7)	32(53.3)	<0.001
胆囊管胆总管汇合部	27(45.0)	11(18.3)	0.002	43(71.7)	25(41.7)	0.001
胆囊颈部	29(48.3)	16(26.7)	0.014	51(85.0)	49(81.7)	0.624

注:1)连续性校正 χ^2 检验Note: 1) Continuity-adjusted χ^2 test

表3 两组患者围手术期指标比较

Table 3 Comparison of the perioperative variables between the two groups of patients

指标	观察组(n=60)	对照组(n=60)	t/Z/ χ^2	P
手术时间(min, $\bar{x} \pm s$)	68.4±23.4	80.6±30.9	-2.429	0.017
术中出血量[mL, M(IQR)]	10(5~20)	20(10~20)	-2.215	0.027
放置引流[n(%)]	27(45.0)	48(80.0)	15.680	<0.001
术后住院时间(d, $\bar{x} \pm s$)	2.6±1.7	3.6±1.4	-3.430	0.001
住院费用[元, M(IQR)]	41 307.5(22 820.3~540 79.3)	40 991.7(26 813.4~606 61.4)	-1.076	0.282
并发症[n(%)]	0(0.0)	1(1.7)	—	0.496 ¹⁾

注:1)Fisher精确检验

Note: 1) Fisher's exact test

3 讨论

ICG 近红外荧光显像技术可以帮助医师术中实时观察胆道显影效果, 进而提高手术的安全性和有效性, 达到精准治疗的目的^[10-11]。荧光腹腔镜在术中可一键切换白光、荧光及融合荧光模式, 不需要额外的操作及设备。与术中造影和超声相比, 这项技术具有安全无辐射、省时、实时导航、价格低廉等优点, 甚至在胆管结构可视化方面可媲美磁共振胰胆管成像(MRCP)^[6, 12-13]。

ICG 在荧光胆道显影中最常见的使用方法为经外周静脉注射^[14-15]。但 ICG 需经肝脏代谢分泌到胆汁中, 因此术中胆道显影时肝脏也会产生强烈的荧光信号, 高强度的肝脏背景信号会干扰术者对胆道解剖结构的辨认^[16-17]。笔者在之前的临床研究中尝试通过延长给药时间以得到低信噪比的荧光图像, 发现术前 7 h 经静脉注射 2.5 mg ICG 可以获得较好的术中肝外胆道荧光显影效果^[18]。但过长的术前给药时间增加医护工作人员的劳动量且不利于急诊手术, 而术中经胆道直接注射药物的方

式可实现肝外胆管结构即刻显影及肝脏零背景信号^[19-20]。本研究采用了经 PTGBD 管或 ENBD 管直接注射 ICG 的方法, 获得了较好的荧光显影图像, 避免了肝脏代谢能力差异对胆管显影造成的影响。此外与经胆囊穿刺注射 ICG 的给药途径相比, 经胆道引流管注射可避免 ICG 经胆囊穿刺点溢出造成的术区视野污染。

术者对胆管结构的错误判断易致医源性胆道损伤(bile duct injury, BDI), 且 90% 以上的 BDI 需通过胆肠吻合术修补, 对患者的身心健康及经济条件造成了极大的负担^[21-22]。准确识别并解剖胆囊三角是避免 BDI 发生的最重要措施。Dip 等^[8]的临床试验表明, 荧光胆道显影能将胆管结构的检出率提升 3 倍以上。杜金柱等^[23]对 90 例行 LC 的患者资料分析发现: 第一次观察即可识别荧光腹腔镜组 88.8% 的胆管解剖位置, 胆管识别率显著高于对照组。本文中佐证了以上观点, 荧光腹腔镜下肝总管、胆总管及胆囊管与胆总管汇合部的显示率在胆囊三角解剖前后均显著高于普通腹腔镜下的显示率, 而解剖胆囊三角前观察组的胆囊管显

示率优于对照组。荧光胆管显影精准显示肝外胆管解剖结构,便于术者更快更确切地处理胆囊,免去因胆囊萎缩和胆囊三角纤维化而反复评估确认围肝门结构的犹豫。但两组解剖后的胆囊管显示率、解剖后胆囊颈部显示率、解剖前后右肝管显示率差异不显著,考虑为胆囊管需在术中夹闭,所以两组的大部分胆囊管或胆囊颈部结构在胆囊三角解剖后都得以确认,而左右肝管汇合点较高,脂肪组织堆积多,荧光难于穿透,两组右肝管结构均不易辨认。总的来说,荧光胆道显影能提升LC术中胆道结构的显示率,尤其是解剖胆囊三角前的肝外胆管识别率。

对于全身状态差和胆囊炎症严重的患者,术者行早期胆囊切除时往往操作困难,手术并发症发生率增加,患者不能从早期手术中获益,因此,常行PTGBD以减轻胆囊及周围组织的充血和水肿并阻止胆囊炎进一步发展^[2]。但与非急性胆囊炎患者相比,PTGBD术后择期手术的风险较高^[24-25]。此外,内镜下取胆总管结石加LC时,由于炎症反应的影响,LC手术难度大,易造成中转开腹及胆管意外损伤^[26-27]。而荧光胆道显像技术能增强胆道结构的可视化,这对困难LC具有重要的临床意义。多项研究^[28-30]显示荧光胆道显影能降低困难LC的难度,缩短手术时长、住院时间,降低中转开腹率、并发症发生率。本研究通过对比发现,经PTGBD管和ENBD管注射ICG行荧光胆管显影能有效缩短手术时间,降低肝下引流放置率及缩短术后平均住院日。可能与荧光胆管显影下肝外胆管识别率增加有关,胆管结构的准确判别增加术者的信心,术者对手术更有把握,术中分离解剖操作更少,患者创伤更小,恢复更快。观察组LC术中胆囊床呈现一条清晰的分界线,胆囊呈现强烈荧光而肝脏无荧光信号,沿着此界线处理胆囊床时不会造成出血。分离胆囊三角炎症粘连时,清晰的胆管解剖使得操作更精确灵活,避免出血的发生。新技术开展成功与否,实施费用是重要的考量因素,而本研究表明荧光胆管显影技术不会给患者带来额外的费用。两组并发症发生率比较差异无统计学意义,这可能与研究例数少有关,尚需扩充病例数进一步研究。

综上所述,荧光胆道显影对困难LC安全可行,疗效确切,可以增强胆管结构显示率,降低手术难度,提高手术精准性,缩短手术时间、术

后住院时间、减少术中出血量及肝下引流管留置率,具有推广价值。

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本刊对来稿中统计学处理的有关要求

1. 统计研究设计: 应交代统计研究设计的名称和主要做法。如调查设计(分为前瞻性、回顾性或横断面调查研究); 实验设计(应交代具体的设计类型, 如自身配对设计、成组设计、交叉设计、正交设计等); 临床试验设计(应交代属于第几期临床试验, 采用了何种盲法措施等)。主要做法应围绕4个基本原则(随机、对照、重复、均衡)概要说明, 尤其要交代如何控制重要非试验因素的干扰和影响。

2. 资料的表达与描述: 用 $\bar{x} \pm s$ 表达近似服从正态分布的定量资料, 用 $M(QR)$ 表达呈偏态分布的定量资料; 用统计表时, 要合理安排纵横标目, 并将数据的含义表达清楚; 用统计图时, 所用统计图的类型应与资料性质相匹配, 并使数轴上刻度值的标法符合数学原则; 用相对数时, 分母不宜小于20, 要注意区分百分率与百分比。

3. 统计分析方法的选择: 对于定量资料, 应根据所采用的设计类型、资料所具备的条件和分析目的, 选用合适的统计分析方法, 不应盲目套用 t 检验和单因素方差分析; 对于定性资料, 应根据所采用的设计类型、定性变量的性质和频数所具备条件以分析目的, 选用合适的统计分析方法, 不应盲目套用 χ^2 检验。对于回归分析, 应结合专业知识和散布图, 选用合适的回归类型, 不应盲目套用简单直线回归分析, 对具有重复实验数据的回归分析资料, 不应简单化处理; 对于多因素、多指标资料, 要在一元分析的基础上, 尽可能运用多元统计分析方法, 以便对因素之间的交互作用和多指标之间的内在联系进行全面、合理地解释和评价。

4. 统计结果的解释和表达: 当 $P < 0.05$ (或 $P < 0.01$) 时, 应说明对比组之间的差异有统计学意义, 而不应说对比组之间具有显著性(或非常显著性)的差别; 应写明所用统计分析方法的具体名称(如: 成组设计资料的 t 检验、两因素析因设计资料的方差分析、多个均数之间两两比较的 q 检验等), 统计量的具体值(如 $t=3.45$, $\chi^2=4.68$, $F=6.79$ 等)应尽可能给出具体的 P 值(如 $P=0.0238$); 当涉及到总体参数(如总体均数、总体率等)时, 在给出显著性检验结果的同时, 再给出95%置信区间。

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