·临床研究·

疼痛综合管理策略在儿童日间全麻下口腔治疗中应用的随机对照研究

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【摘要】　目的　探讨疼痛综合管理策略在儿童日间全麻下口腔治疗中的应用效果。方法　2020年1月至8月某院接受日间全身麻醉下口腔治疗儿童，年龄3~7周岁，按美国麻醉医师协会（American Society of Anesthesiologists，ASA）分级为Ⅰ~Ⅱ级，治疗牙齿数 ≥ 10颗。120名儿童被随机分配到2组，综合策略组（H组，$n=60$）采用疼痛综合管理策略，包括超前镇痛、疼痛管理指导、微信评估（在术后4、6、24 h通过扫描二维码进行疼痛评估）三项内容；对照组（C组，$n=60$）无超前镇痛及疼痛管理指导，仅进行微信评估疼痛。术后2 h采用表情、下肢、活动、哭闹、可安慰性（face，legs，activity，cry and consolability，FLACC）量表对2组进行疼痛评估。术后4、6、24 h采用父母疼痛测量量表（parents postoperative pain measure，PPPM）对2组进行疼痛评估。结果　与C组相比，H组术后2 h FLACC得分显著降低，差异有统计学意义（$P<0.05$）。H组在术后4、6、24 h三个时间点显著疼痛（PPPM ≥ 6分）发生率均低于C组（$P<0.05$），且PPPM得分较C组显著降低（$P<0.05$）。H组91.7%的家长及时进行疼痛评估，而C组71.6%的家长及时评估疼痛，H组父母依从性更高（$P<0.05$）。结论　疼痛综合管理策略可降低儿童日间全麻下口腔治疗后疼痛的发生率，是安全有效的日间口腔治疗后疼痛管理方法。

【关键词】　儿童；　口腔治疗；　日间全麻；　术后疼痛；　术后疼痛管理；　超前镇痛；疼痛管理指导；　微信评估；　无痛治疗；　舒适化治疗；　随机对照研究

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A holistic approach for postoperative pain management in children receiving dental treatment under general anesthesia: a randomized clinical trial　　LIU Bing¹, WANG Peijuan¹, ZHANG Yaqiu¹, FENG Caihua¹, WANG Jun², ZHANG Hui¹.　1. State Key Laboratory of Military Stomatology & National Clinical Research Center for Oral Disease & Shaanxi Engineering Research Center for Dental Materials and Advanced Manufacture, Department of Anesthesiology, School of Stomatology, Fourth Military Medical University, Xi'an 710032, China;　2. Department of Anesthesiology, Shaanxi Provincial General Hospital of Armed Police, Xi'an 710054, China

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【Abstract】　**Objective**　To investigate the efficacy of a holistic approach for postoperative pain management in children receiving dental treatment under general anesthesia in day-surgery operating room. **Methods**　A total of 120 children, aged 3-7 years, of American Society of Anesthesiologists physical status Ⅰ or Ⅱ, with ≥ 10 treated teeth, receiving comprehensive dental treatment under general anesthesia from January 2020 to August 2020 were enrolled in this trial and randomly allocated into the holistic approach group (group H, $n=60$) and including preemptive analgesia, instructions to parents for pain management and web-based assessment system (assessment pain by scanning the quick re-

微信公众号

sponse code 4, 6, and 24 hours postoperatively) and the control group (group C, $n = 60$) only scanning the quick response code. Pain, face, legs, activity, cry and consolability (FLACC) scale was used to assess the level of pain 2 h postoperatively and the parents postoperative pain measure (PPPM) was used to assess the level of pain 4, 6, and 24 h postoperatively in two groups. **Results**　The FLACC scores of group H 2 h postoperatively were significantly lower than group C ($P < 0.05$). The incidences of significant pain (PPPM scores ≥ 6) 4, 6 and 24 h postoperatively in group H were lower than group C ($P < 0.05$). Altogether, 91.7% of parents in group H and 71.6% in group C assessed the level of pain of children over time. The compliance rate of parents in group H was significantly higher than group C ($P < 0.05$). **Conclusion**　The holistic approach had a positive effect on reducing postoperative pain for children receiving dental treatment under general anesthesia in the day-surgery operating room.

【Key words】　children；　dental treatment；　ambulatory anesthesia；　postoperative pain；　postoperative pain management；　preemptive analgesia；　instructions to parents for pain management；　web-based assessment system；　painless treatment；　comfort therapy；　randomized controlled trial

　　疼痛是日间全麻下儿童口腔治疗术后最常见并发症之一，发生率高达80%[1-2]。疼痛不仅造成儿童哭闹、拒绝进食，也会带来睡眠障碍、行为障碍等一系列问题[3]。儿童日间全麻下口腔治疗后疼痛管理，尤其是离院后疼痛管理，成为棘手问题[4]。大量研究表明，儿童日间手术离院后疼痛管理不善[5-7]。最新PAIN OUT国际儿童疼痛管理记录显示，四分之一的儿童应该接受更多的疼痛治疗[8]。儿童日间手术后疼痛管理的负责人从专业医护人员转换为儿童父母/监护人。镇痛模式、父母对于疼痛的认知和态度、评估和反馈系统等均是影响儿童日间手术后疼痛管理有效开展的重要因素[9]。因此，疼痛管理方案需要综合以上因素。该研究拟采用疼痛综合管理策略，评价其在儿童日间全麻下口腔治疗后疼痛管理中的效果，为促进儿童日间全麻下口腔治疗无痛、舒适，加快治疗后恢复提供参考。

1　资料和方法

1.1　研究对象

　　该前瞻性随机对照研究获得第四军医大学口腔医院伦理委员会批准（IRB-REV-2019060）并在中国临床试验注册中心进行注册（ChiCTR2000029143）。选择2020年1月至8月全麻下口腔治疗儿童120例。纳入标准：①年龄3~7周岁；②美国麻醉医师协会（American Society of Anesthesiologists，ASA）分级Ⅰ~Ⅱ级；③治疗牙齿数≥10颗。

　　排除标准：① 有严重全身系统性疾病，日间全麻无法确保安全；② 有对乙酰氨基酚过敏史和出血性疾病史；③ 拔牙数＞5颗。采用计算机随机数法，将纳入患者随机分为2组：综合策略组（H组）和对照组（C组），每组60例。

1.2　麻醉过程

　　所有患儿无术前用药。患儿在父母陪伴下入室。吸入8%七氟醚和40%笑气，患儿入睡后开通静脉通路，静脉给予芬太尼2~3 μg/kg、丙泊酚2~2.5 mg/kg和顺式阿曲库铵0.1~0.12 mg/kg进行诱导，经鼻气管插管。麻醉中采用2.5%~3%的七氟醚进行维持，维持心率、SpO_2、无创血压、呼吸频率和呼吸末二氧化碳等体征平稳。口腔根管治疗、拔牙术等有创操作前使用阿替卡因肾上腺素注射液（Produits Dentaires Pierre Rolland，法国）进行局部麻醉。治疗结束前20 min静注昂丹司琼（Glaxo Operations UK Limited，英国）2 mg以减少术后恶心呕吐（postoperative nausea and vomiting，PONV）。达到拔管标准后拔除气管导管，转移至麻醉后恢复室进行观察。

1.3　疼痛管理策略

　　H组采用疼痛综合管理策略，包括超前镇痛、疼痛管理指导、微信评估指导镇痛三项内容。超前镇痛：诱导插管后给予对乙酰氨基酚栓剂（湖北东信药业有限公司，中国）150 mg；疼痛管理指导：离院前对父母进行疼痛管理知识培训，内容包含

疼痛危害、评估时间点、给药注意事项、非药物疼痛管理等相关内容;微信评估指导镇痛:将疼痛评估表置于微信问卷星中,家长在3个规定时间点T_1(术后4 h)、T_2(术后6 h)、T_3(术后24 h)通过扫描二维码进行疼痛评估。家长根据疼痛得分判断是否给药,所给药物统一为对乙酰氨基酚栓剂(150 mg)。

　　C组无超前镇痛及疼痛管理指导,在T_1、T_2、T_3时间点扫描二维码进行疼痛评估。未要求家长根据评估结果给患儿使用镇痛药物。

1.4　疼痛评估工具

　　采用表情、下肢、活动、哭闹、可安慰性(face, legs, activity, cry and consolability, FLACC)量表评估患儿术后2 h疼痛程度[10]。FLACC量表包括表情、下肢、活动、哭闹和可安慰性五个类别。每个类别的分数为0~2分,总分0~10分,分数越高,疼痛程度越强。术后2 h由经过培训的护士进行FLACC量表评分。如果FLACC > 7分,两组均可考虑给予强效镇痛药。

　　术后父母疼痛测量(parents postoperative pain measure, PPPM)量表用于评估离院回家后疼痛[11]。PPPM量表由15个相关问题组成,其对于父母进行疼痛评估具有良好的特异性和敏感性。家长根据孩子的行为判断,回答"是"得1分,回答"否"得0分。总分为15分,当得分≥6分时认为是显著疼痛,需要给予镇痛药。

1.5　统计学分析

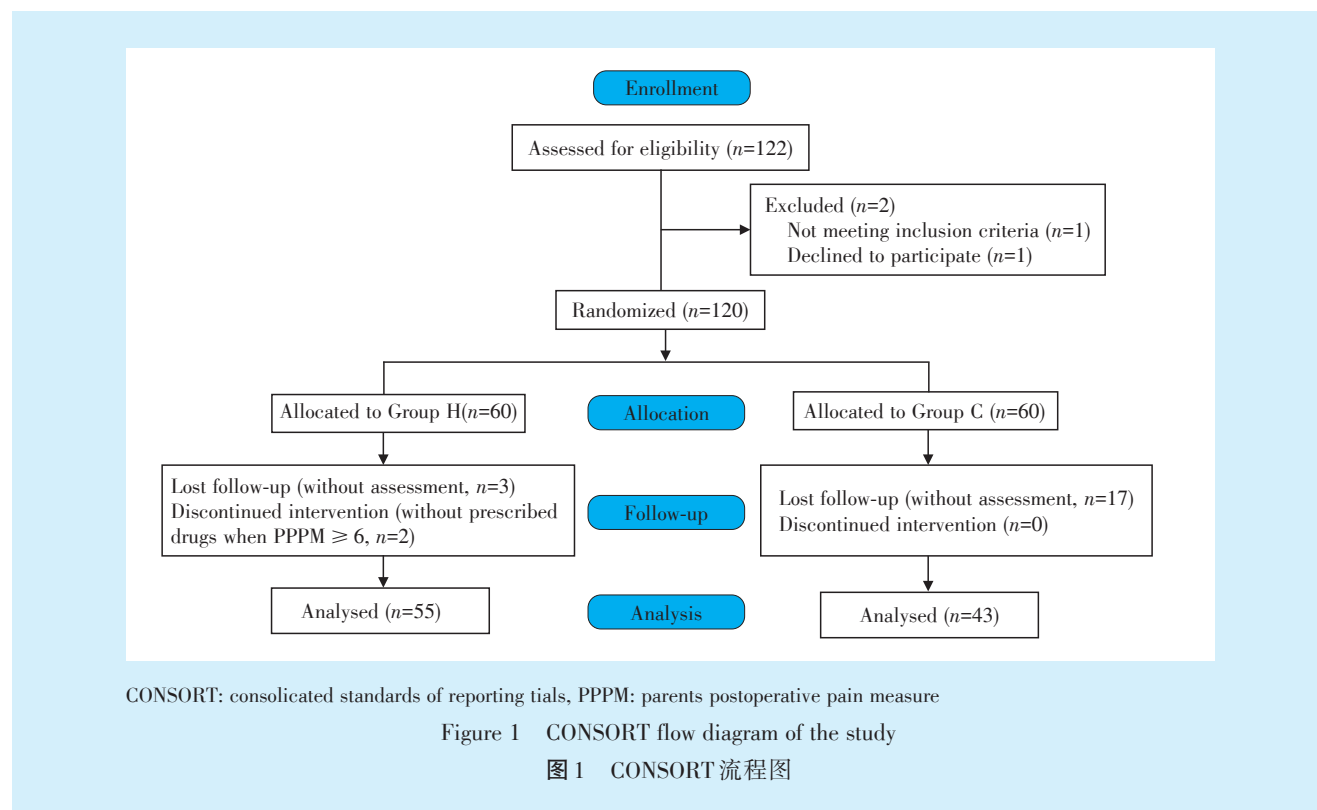　　主要研究结果为术后2 h FLACC量表评分、T_1时间点PPPM量表评分。次要研究结果为T_2、T_3时间点PPPM量表评分、父母依从性。

　　使用比率和平均值描述和比较两组人口统计学特征和基线数据。组间年龄、身高和体重等连续变量的差异采用t检验。分类变量的差异,包括性别和ASA分级,采用卡方检验。PPPM量表得分的差异采用Manne-Whitney U检验。PPPM量表得分随时间的组间差异采用重复测量方差分析。

　　采用SPSS19.0进行统计学分析,$P < 0.05$为差异有统计学意义。

2　结　果

2.1　两组患儿的基本情况

　　本研究纳入120例儿童,22例因未完成随访,予以剔除,最终98例纳入研究分析,图1为该研究CONSORT流程图。两组患儿基本情况比较,差异无统计学意义($P > 0.05$),见表1。

CONSORT: consolicated standards of reporting tials, PPPM: parents postoperative pain measure

Figure 1　CONSORT flow diagram of the study

图1　CONSORT流程图

2.2　两组患儿术后不同时间点疼痛评分

　　术后2 h,H组儿童FLACC得分为0分、1~3分、4~7分的占比分别为7.27%、72.73%、20.00%;C组儿童FLACC得分为0分、1~3分、4~7分的占

表1　两组患儿基本情况比较

Table 1　Demographic characteristics of children in the two groups

Items		Group H ($n=55$)	Group C ($n=43$)	χ^2/t	P
Male∶female		32∶23(58.18%)	26∶17(60.47%)	0.05	0.819
Age/months		51.00 ± 10.06	50.09 ± 12.34	0.98	0.689
Weight/kg		16.64 ± 2.50	17.02 ± 3.16	0.26	0.497
ASA-PS1/ASA-PS2		53/2	42/1	0.05	0.828
Anesthesia-related data	Fentanyl/μg	33.95 ± 4.80	35.72 ± 6.87	4.33	0.136
	Propofol/mg	50.84 ± 7.43	50.51 ± 7.80	0.05	0.835
	Cisatracurium/mg	1.67 ± 0.25	1.68 ± 0.42	1.73	0.974
	Duration of anesthesia/min	146.64 ± 31.17	140.53 ± 30.22	0.35	0.332
Dental treatment-related data	Teeth treated(n)	16.04 ± 2.73	16.47 ± 2.67	0.04	0.438
	Number of teeth extracted ⩾ 3(%)	12(21.81%)	8(18.60%)	0.15	0.695
	Local anesthetic/mL	0.96 ± 0.36	1.08 ± 0.46	2.92	0.134

ASA-PS: American Society of Anesthesiologists-Physical Status. Group H: preemptive analgesia, instructions to parents and web-based assessment system; group C: only web-based assessment system. FLACC: face, legs, activity, cry and consolability; PPPM: parents postoperative pain measure

比分别为0、62.79%、37.21%。与C组相比，H组得分显著降低，差异有统计学意义（ $P=0.032$ ）。

与C组相比，H组在术后4 h（ $P=0.017$ ）、6 h（ $P=0.019$ ）、24 h（ $P=0.002$ ）时间点显著疼痛（PPPM ⩾ 6分）发生率均显著降低（表2）。

表2　两组患儿术后不同时间点疼痛FLACC、PPPM量表评分

Table 2　Pain scores assessed by FLACC and PPPM at different time points in the two groups　　 n (%)

	Score	Group H ($n=55$)	Group C ($n=43$)	χ^2	P
FLACC score	0	4(7.27)	0(0)		
	1-3	40(72.73)	27(62.79)	6.90	0.032
	4-7	11(20.00)	16(37.21)		
PPPM score⩾6	T_1	13(23.64)	20(46.51)	5.65	0.017
	T_2	11(20.00)	18(41.86)	5.54	0.019
	T_3	3(5.45)	12(27.91)	9.38	0.002

T_1: 4 h postoperatively; T_2: 6 h postoperatively; T_3: 24 h postoperatively. Group H: preemptive analgesia, instructions to parents and web-based assessment system; group C: only web-based assessment system. FLACC: face, legs, activity, cry and consolability; PPPM: parents postoperative pain measure

2.3　两组患儿离院后不同时间点PPPM量表得分

两组患儿离院后不同时间点PPPM量表得分，两组之间没有显著的组别×时间交互作用（ $F=1.896$ ， $P=0.169$ ），H组儿童PPPM得分明显低于C组（ $F=4.50$ ， $P=0.036$ ）。随着时间的推移，两组的PPPM得分均呈下降趋势（ $F=38.74$ ， $P<0.001$ ）（图2）。
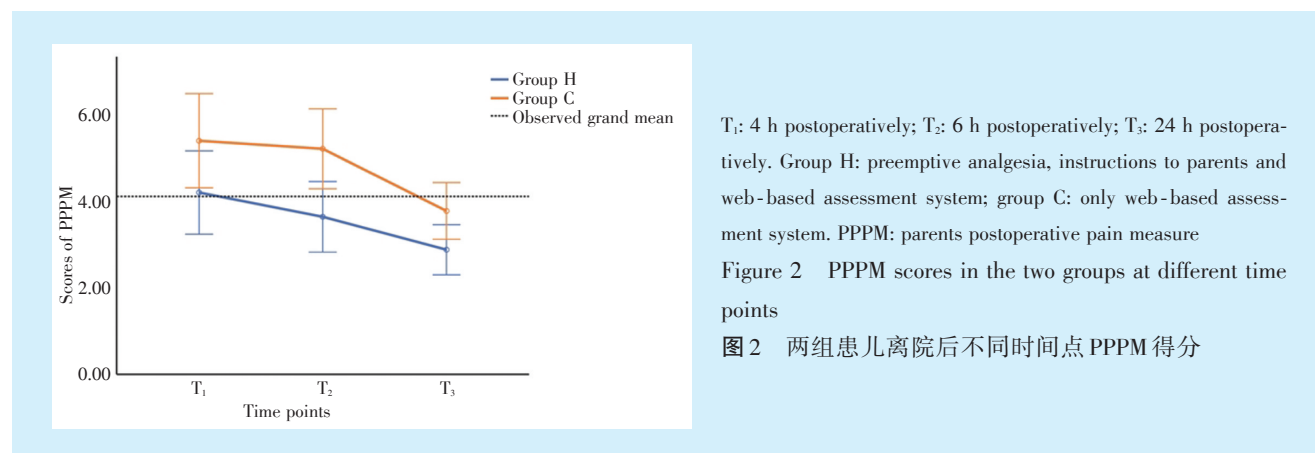
T_1: 4 h postoperatively; T_2: 6 h postoperatively; T_3: 24 h postoperatively. Group H: preemptive analgesia, instructions to parents and web-based assessment system; group C: only web-based assessment system. PPPM: parents postoperative pain measure

Figure 2　PPPM scores in the two groups at different time points

图2　两组患儿离院后不同时间点PPPM得分

2.4　两组患儿术后并发症及依从性

两组患儿术后无严重并发症。H组91.7%的家长按推荐时间及时进行疼痛评估,有13例儿童在T_1时间点发生显著疼痛(PPPM ≥ 6分),其中11例(84.6%)接受了镇痛药。C组71.6%家长按推荐时间及时进行疼痛评估,H组的依从性更高(χ^2 = 8.01,P = 0.005)。

3　讨　论

随着日间手术逐年增多,疼痛管理是儿童日间全麻下口腔治疗后面临的主要问题。既往研究表明,儿童因素、父母因素、评估系统、用药方案是日间手术后疼痛管理面临的主要障碍[12]。60%儿童因为药物味道无法接受而拒绝服药[13]。父母在离院后疼痛管理中扮演越来越重要的角色。然而,对于大多数父母而言,这是一项复杂的工作。为了有效地进行疼痛管理,父母必须完成一系列任务,包括理解疼痛管理的重要性、及时且准确评估孩子的疼痛、给予安全有效的镇痛药物等[14]。部分研究通过对父母进行培训、鼓励父母记录疼痛管理日记、给予父母疼痛管理相关信息表等方式提高父母疼痛管理能力,均有一定的效果[15-17]。一项研究采用电子提醒系统,通过提示父母及时进行疼痛评估给药,可降低疼痛发生率[18]。

本研究结果表明疼痛综合管理策略对于儿童日间术后疼痛管理是安全有效的方法。疼痛综合管理策略是整合以往文献中对于儿童术后疼痛管理的方法而提出,综合策略包括超前镇痛、疼痛管理指导、微信评估指导镇痛。超前镇痛是指在伤害性刺激作用于机体之前进行镇痛干预,防止中枢对痛觉的敏化,预防术后疼痛[13]。对乙酰氨基酚通过抑制前列腺素等的合成和释放,提高痛阈而起到镇痛作用,在多项研究中被证明对于轻中度疼痛是安全有效镇痛药物,且提前用药效果更好[19-21]。H组在诱导插管后即刻给予对乙酰氨基酚栓剂,术后2 h FLACC评分在两组存在统计学差异,表明可有效减轻手术后短期内疼痛。离院前对父母进行疼痛管理指导,包括疼痛危害、评估时间点、给药注意事项、非药物疼痛管理等相关内容,有效提升父母疼痛管理能力,同时提高父母在离院后评估及给药的依从性。在规定时间点通过微信扫描二维码进行评估,保证了离院后父母可以准确判断儿童疼痛程度。疼痛综合管理策略通过超前镇痛、疼痛管理指导、微信评估指导镇痛形成术后疼痛管理的关键链条,实现持续管理。

PPPM量表是专门为儿童手术离院后疼痛评估设计。研究表明,儿童术后更倾向于依赖父母,且通过安静、退缩等行为表达疼痛[22]。PPPM量表与儿童,尤其学龄前儿童的疼痛相关性很高,因此,该研究选择此量表进行离院后疼痛评估。

该研究结果尚不能适用所有类别的手术。首先,该研究中儿童均接受口腔治疗,以轻度至中度疼痛为主,对于疼痛程度高的术式,需根据手术内容调整镇痛药物。其次,本研究中选用药物为栓剂,虽然可以避免儿童对口服药物的抗拒,但仍有个别儿童无法接受此类给药方式拒绝用药。未来,疼痛综合管理策略在超前镇痛、疼痛管理指导、微信评估指导镇痛的基础上,根据手术方式调整镇痛药,开展对更多术式的研究,对于不同手术后疼痛管理进一步探索。

综上所述,本研究是一项前瞻性随机对照研究,探讨了疼痛综合管理策略在儿童日间全麻下口腔治疗中的应用,发现疼痛综合管理策略是改善儿童术后疼痛的有效方法。该策略不仅降低术后2 h疼痛的发生率,而且通过提升父母对儿童疼痛管理能力及依从性,有效降低了离院回家后疼痛发生率,是安全有效的日间手术后疼痛管理方法。

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