

痔切除术后阿片类药物使用

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摘要

背景: 在美国, 每年因痔病就诊的人数超过400万。痔切除术与术后疼痛密切相关。但目前为止, 尚没有关于痔切除术后基于循证证据的阿片类药物处方指南。

目的: 探讨阿片类药物的处方模式, 并明确与痔切除术后阿片类药物续方的相关因素。

设计: 基于数据库回顾分析。

设定: 国防部军事卫生系统数据库 (2006-2014年)。

患者: 参加TRICARE保险, 年龄在18-64岁之间, 接受痔切除术且首次使用阿片类药物的患者。

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主要结局指标: 阿片类药物处方的模式, 预测痔切除术后初次处方结束后两周内的阿片类药物再次处方的相关因素。

结果: 共纳入 6294 例患者。5,536 例 (88.0%) 患者在首次处方中平均使用阿片类药物 5 天, 1,820 例 (32.9%) 患者需阿片类药物续方。基于首次处方情况建立续方的风险模型, 风险范围从首次处方给予 1 日剂量的最高风险 (39.2%), 到首次处方给予 10 日剂量的最低点 (26.1%)。各种社会人口信息和临床特征影响阿片类药物续方的可能性, 包括黑人 (OR 0.75, 95% CI 0.62-0.89), 药物滥用史 (OR 3.26, 95% CI 1.37-7.34) 和阿片类药物处方天数 (4-6 天: OR 0.83, 95% CI 0.72-0.96; 7 天或以上: OR 0.67, 95% CI 0.57-0.78; 对比 1-3 天)。

局限: 由于使用了基于保险索赔的数据, 变量的评估受到一定限制。

结论: 痔切除术后对于阿片类药物处方天数的差异性很大。大约三分之一的患者在术后短期内需要第二次处方。最佳的持续给药时间似乎在 5 至 10 天之间。临床医生可以更有效地使用适当的止痛药物来解除患者的疼痛, 同时最大限度地减少潜在的过度用药风险。视频摘要见 <http://links.lww.com/DCR/B112>。

关键词: 痔; 痔切除术; 麻醉药; 阿片类药物; 术后

引言

滥用阿片类药物给美国的公共健康带来了沉重的负担, 2017 年, 有 7 万多人死于药物过量, 其中超过 67% 与阿片类药物有关^{1,2}。阿片类药物相关的死亡人数每年都在增加, 2016 年到 2017 年之间增长了

12%³。在这场国家危机中, 关于阿片类药物处方的作用引起了越来越多的关注, 然而阿片类药物仍然是术后镇痛的主要手段⁴⁻⁶。尽管阿片类药物在围手术期的护理中发挥着重要的作用, 但缺乏相关的处方指南, 并且术后处方模式存在差异性大的问题^{7,8}。痔病在美国很常见, 大约 4.4% 的美国人有关痔的症状, 每年因痔病就诊的人数超过 400 万^{9,10}。虽然各种非手术方式可用于痔的治疗, 但手术切除仍然是最有效的治疗且复发率最低¹¹⁻¹³。尽管疗效确切, 但痔切除术可导致明显的术后疼痛^{13,14}。由于痔切除术经常在门诊进行, 所以很难确定病人在术后需要阿片类药物的剂量¹⁵。以往的研究表明, 对于许多外科手术, 阿片类药物处方的差异性很大, 临床医生经常存在处方过度的情况^{8,16}。目前, 关于痔切除术后阿片类药物处方的最佳方案知之甚少¹⁵。在此背景下, 我们试图研究痔切除术后阿片类药物处方的模式, 以确定与首次处方后续方的相关因素, 并确定痔切除术后阿片类药物处方的最佳使用天数。我们的目的是提供关于痔切除术后阿片类药物处方的建议。

材料与方法

数据来源与病例选择

本研究使用了军队卫生系统数据库维护的 TRICARE 保险理赔数据。TRICARE 保险覆盖受益人群 900 多万, 其中约 20% 是现役军人, 其余为平民¹⁷。TRICARE 不参与战区内的护理, 也不接受退伍军人管理局的护理。¹⁷关于 TRICARE 数据库的更多细节已经在前面描述过¹⁸⁻²¹。

2006-2014 年间, 采用国际疾病分类 (ICD) 和现行程序术语 (CPT) 代码 (可根据作者的要求获得) 确定的年龄在 18-64 岁且接受痔

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切除术的患者，排除术前少于6个月或术后少于3个月的患者，以及那些在术前6个月内服用过一次或多次阿片类药物的患者；排除合并括约肌切开术或肛瘘切开术的患者，因为这可能对结果造成影响，这项研究得到了Brigham妇女机构审查委员会的审查和批准。

变量和结果

通过ICD编码收集患者年龄、性别、自述种族、改良查尔森合并症指数、相关伴随疾病包括炎症性肠病、纤维肌痛症或精神疾病、术后常见并发症(包括但不限于出血、感染、术后血肿/皮下积液)等数据。附加的特征，如军衔，军种，和地区也被包括在内。丢失的分类数据被编码为未知。有关阿片类药物处方的信息，包括处方的药品名和处方的天数，可以通过询问药房得知。

阿片类药物被界定为缉毒署分类为阿片类激动剂、部分激动剂和上述阿片类联合的药物。^{22,23} 首次阿片类处方定义为手术(痔切除术)日开具的阿片类药物处方。续方被定义为阿片类药物首次处方结束后的两周内再次开具阿片类药物处方²²。阿片类药物处方的用药天数是以处方开始日至结束日的天数之差。

目标结局是痔切除术后阿片类药物处方的模式包括用药频率和药物，阿片类药物处方续方的预测因素，以及基于续方风险模型的最佳阿片类药物处方天数。

统计分析

采用描述性统计方法对患者特征和阿片类药物处方进行评价。在单变量分析中，对二元变量和分类变量使用卡方检验。采用多元变量logistic回归模型，调整性别、年龄、军衔、种族、受益人类型、查尔森

合并症评分、药物滥用史、术后并发症和阿片类药物处方天数，以确定阿片类药物续方的相关因素。军衔是军官(初级军官、高级军官、准尉)和士兵(初级、高级、军校学员)的二元变量，分别代表社会经济地位的高低。之前使用相同方法的研究表明，较低的军衔与较低的教育水平和收入有关^{23,24}。

为了确定初次处方的最优天数，构建了一个具有平滑样条的广义加性模型(GAM)，以估计每一张阿片类药物处方长度的续方调整风险。之所以选择这种建模方法，是因为它允许获取因变量和自变量之间的非线性关联。模型调整了年龄、性别、种族、军衔、药物滥用史、术后并发症表现和改良查尔森合并症指数。

所有检验双侧 α 值 <0.05 被认为有显著差异，设置95%置信区间，连续变量采用中位数、四分位距(IQR)描述。GAM分析采用SAS统计软件9.4版本(SAS Institute, Cary, NC)，其余的统计分析使用Stata统计软件15.0版本(StataCorp 2017, College Station, TX: StataCorp LLC)。

结果

患者特征

共有6294名接受了痔切除术的患者符合纳入标准(图 1)，5536例(88.0%)患者术后服用了阿片类药物，758例(12.0%)患者没有服用，其中1820例(32.9%)患者需要续方。对不需要续方的患者相比，需要续方的患者更可能是年轻男性、白种人、士兵军衔、伴有术后并发症、药物滥用史、现役受益人状态和处方天数较短(表 1)。

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影响再次服用阿片类药物的因素

在多元变量logistic回归中，以下变量与较低的续方几率显著相关：55-64岁对比18-24岁 (OR 0.63, 95% CI (0.45, 0.89))；处方天数为4-6天 (OR 0.83, 95% CI (0.72, 0.96))和7天以上 (OR 0.67, 95% CI (0.57, 0.78))，对比1-3天；军衔 (OR 0.80, 95% CI (0.69, 0.92))；黑种人 (OR 0.75, 95% CI (0.62, 0.89) 和亚洲人 (OR 0.71, 95% CI (0.56, 0.89))对比白种人。改良查尔森合并症指数大于0 (OR 1.49, 95% CI (1.10, 2.01))；药物滥用史 (OR 3.26, 95% CI (1.37, 7.34))；术后并发症的发生 (OR 2.47, 95% CI (1.89, 3.21)) 与阿片类药物的续方显著相关 (表 2)。

阿片类药物的处方模式

对于痔切除术后患者的首次阿片类药物处方，处方天数的中位时间为5天 (IQR 4, 7)。在这些需要续方的患者中，处方的平均天数为5天 (IQR 3, 6)。羟考酮是首次阿片类药物处方中出现频率最高的药物 (56.1%)，氢可酮是阿片类药物续方中出现比例最高的药物 (43.8%)，羟考酮和氢可酮是处方中出现频率最高的两种药物，分别占到92.1%和81.8%。65%的续方药物与首次处方药物相同 (图 2)。

阿片类处方的最佳使用天数

根据首次阿片类处方的不同天数绘制了续方模型比例 (图 3)。根据首次处方量，模型的续方风险为从首次处方给予1日剂量的39.2%高风险到首次处方给予10日剂量的26.1%最低风险。

讨论

在这项研究中，我们调查了6000多名接受了痔切除术的患者，发现年轻、初次处方

开具天数短、士兵军衔 (代表较低的社会经济地位) 和白人是需要续方的重要预测因素。此外，我们还表明，减少术后续方的理想处方天数在5-10天之间。本研究分析了当前阿片类药物处方的模式以及明确了与痔切除术后续方的相关因素，这些有用的信息可以指导痔切除术后阿片类药物处方的使用。

我们在调整后的分析中发现，与白人患者相比，黑人患者续方的可能性明显更低。这与之前的研究结果一致，在阿片类药物的处方习惯中存在种族差异²⁵⁻²⁷。与白人患者相比，黑人患者在很多情况下接受阿片类药物治疗的可能性更小，包括因背痛或头痛、骨折固定术后、肾绞痛这些急诊治疗²⁵⁻²⁷。尽管黑人和白人患者在疼痛治疗上的差异有所改善，但差距仍然存在²⁶。在护理措施方面，TRICARE受益人之间存在着种族差异，尽管这种差异在全国人口中有所减少，但我们的结果表明，种族差异仍是影响痔切除术后阿片类药物处方模式的因素²⁸。先前关于社会经济地位在接受阿片类药物处方中所扮演的角色的文献已经得出不同的结果。例如，Gebauer 等人证明了社会经济水平低的社区与接受阿片类药物治疗背痛的风险增加有关，而Joynt等人表明，与较富裕社区的患者相比，社会经济水平较低的患者接受阿片类药物治疗背痛更少^{29,30}。我们的结果与Gebauer等人的结果更加一致，士兵军衔，作为已被接受的低社会经济地位的代表，与更高的续方率相关。

目前关于痔切除术后阿片类药物处方的文献不多，并且缺乏镇痛的最佳实践指南¹⁵。在一项关于肛周术后阿片类药物使用的单中心研究中，Swarup等人发现13名接受痔切除术的患者中，只有61.5%的患者使用了阿片类药物处方，没有患者需

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要续方³¹。然而，Swarup等人使用的样本量太小，不具有普遍性。一项针对1850名患者的大型研究表明，17.2%的患者在痔切除术后需要续方，但阿片类药物处方率没有报道³²。与这两项研究相比，我们的研究结果显示阿片类药物处方的使用和续方比例更高。

关于阿片类药物处方天数，中位天数为5天，有32.9%的患者需要续方。基于处方开具的天数，模型中需要续方的时间为10天，26.1%的患者需要续方。尽管26.1%仍然代表了续方的高比例，但与首次处方给予1日剂量的高达39.2%的续方模型风险相比，这确实显示出临床续方量的明显减少。这表明，对于痔切除术后患者，最佳的阿片类药物处方天数可能是5-10天²²。为了积极应对阿片类药物引起的危机，州一级已经采取了各种立法行动，来限制阿片类药物的处方。2016年，马萨诸塞州成为第一个通过此类法律的州，将首次阿片类药物处方天数限制在7天³³。此后，又有30多个州采取了类似行动，限定了初次处方的天数(从3天到14天)或吗啡毫克当量(MME)³³。我们的研究结果表明，一些州立法可能对痔切除术患者开具的阿片类药物处方天数过于严格。

需加以解释的是，我们的研究结果存在一定局限性，我们的数据代表了在TRICARE保险范围内的大体健康患者中的特定人群，这可能会限制其普适性。然而，在我们的患者样本中，大多数都不是现役军人，而且之前的工作已经表明，TRICARE人群代表了年龄在18-64岁之间的普通美国人¹⁷。由于使用基于保险理赔的数据，我们也无法解释其他影响痔切除术后疼痛的重要临床因素。例如，我们无法解释已被证明可以显著减少术后阿片类药物使用的辅助镇痛药(局部麻醉剂、神

经阻滞、非阿片类药物/非处方药)的使用情况，因为TRICARE只收集处理过的理赔³⁴⁻³⁶。此外，我们不能调整术后护理指导的依从性(坐浴、避免便秘)，或特定的手术技术，这些都可能成为混杂因素^{14,15}。我们也没有关于每个处方中所提供的药片或吗啡毫克当量的总剂量的信息，处方中所提供的用药说明，或每个处方中未用完的阿片类药物的百分比(之前的研究表明这个数字很高)^{16,31}。然而，以天为单位的处方时间仍然是一个重要的度量标准，因为大多数关于首次使用阿片类药物处方的州立法规定了处方天数的限制³³。8年的研究时间相对较长，但发生在阿片类药物限制立法出台之前，敏感性分析显示诊断年份并不影响我们的结果。最后，我们的研究没有解决术后阿片类药物处方与随后持续使用之间的潜在关联，这是临床医生在开具阿片类药物处方时需要考虑的另一个重要指标。尽管存在这些局限性，但这仍是一项大型研究，考虑了来自全国各地的患者队列，在不同的临床和地区背景下接受治疗，具有足够的变异允许我们对痔切除术后的最佳阿片类药物处方实践进行方法上的严格建模。

痔切除术后阿片类药物处方的剂量和使用天数有很大的差异。在确定术后阿片类药物处方的最佳天数和影响阿片类药物续方需求的因素方面，我们提供的数据可以被临床医生在不同的临床环境中灵活使用，在更有效地解除患者疼痛的同时，最大程度地减少用药过度的可能性。

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表 1. 患者特征及单因素分析

变量	总数 (n=5536)	没有续方 (n=3716)	续方 (n=1820)	p 值
性别				0.001
女性	2772 (50.1%)	1917 (51.6%)	855 (47.0%)	
男性	2755 (49.8%)	1799 (48.4%)	965 (53.0%)	
年龄				<0.001
18-24	212 (3.8%)	127 (3.4%)	85 (4.7%)	
25-34	1031 (18.6%)	624 (16.8%)	407 (22.4%)	
35-44	1533 (27.7%)	1017 (27.4%)	516 (28.4%)	
45-54	1612 (29.1%)	1104 (29.7%)	508 (27.9%)	
55-64	1148 (20.7%)	844 (22.7%)	304 (16.7%)	
服务部门				0.97
空军	1675 (30.3%)	1119 (30.1%)	556 (30.5%)	
陆军	2207 (39.9%)	1490 (40.1%)	717 (39.4%)	
海岸警卫队	125 (2.3%)	81 (2.2%)	44 (2.4%)	
海军陆战队	421 (19.6%)	284 (7.6%)	137 (7.5%)	
海军	1086 (19.6%)	726 (19.5%)	360 (19.8%)	
其它	22 (0.4%)	16 (0.4%)	6 (0.3%)	
军衔				0.001
士兵	4277 (77.3%)	2823 (76.0%)	1454 (79.9%)	
军官	1259 (22.7%)	893 (24.0%)	366 (20.1%)	
种族/民族				<0.001
白种人	2822 (51.0%)	1824 (49.1%)	998 (54.8%)	
黑种人	768 (13.9%)	538 (14.5%)	230 (12.6%)	
拉美裔	262 (4.7%)	174 (4.7%)	88 (4.8%)	
亚裔	424 (7.7%)	310 (8.3%)	114 (6.3%)	
本地/其它	249 (4.5)	162 (4.4%)	87 (4.8%)	
未知	1010 (18.2%)	707 (19.0%)	303 (16.6%)	
患者所在地区				0.12
中西部	590 (10.7%)	382 (10.3%)	208 (11.4%)	
东北部	247 (4.5%)	168 (4.5%)	79 (4.3%)	
南部	3161 (57.1%)	2112 (56.8%)	1049 (57.6%)	
西部	1488 (26.9%)	1013 (27.3%)	475 (26.1%)	
未知	50 (0.9%)	41 (1.1%)	9 (0.5%)	
婚姻状况				0.16
已婚	4793 (86.6%)	3234 (87.0%)	1559 (85.7%)	

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未婚	743 (13.4%)	482 (13.0%)	261 (14.3%)	
受益人类型				<0.001
现役	1731 (31.3%)	1088 (29.3%)	643 (35.3%)	
现役家属	1100 (19.9%)	716 (19.3%)	384 (21.1%)	
退役家属	1270 (22.9%)	927 (24.9%)	343 (18.8%)	
退役	1348 (24.3%)	928 (25.0%)	420 (23.1%)	
其它	87 (1.6%)	57 (1.5%)	30 (1.6%)	
查尔森评分				0.1
0	5337 (96.4%)	3593 (96.7%)	1744 (95.8%)	
1 或以上	199 (3.6%)	123 (3.3%)	76 (4.2%)	
药物滥用史	22 (0.4%)	9 (0.02%)	13 (0.7%)	0.009
炎症性肠病史	85 (1.5%)	55 (1.5%)	30 (1.6%)	0.63
纤维肌痛史	443 (8.0%)	283 (7.6%)	160 (8.8%)	0.13
阿片类药物处方天数				<0.001
1-3 天	1320 (23.8%)	826 (22.2%)	494 (27.1%)	
4-6 天	2647 (47.8%)	1770 (47.6%)	877 (48.2%)	
7 天以上	1569 (28.3%)	1120 (30.1%)	449 (24.7%)	
术后并发症	239 (4.3%)	112 (3.0%)	127 (7.0%)	<0.001

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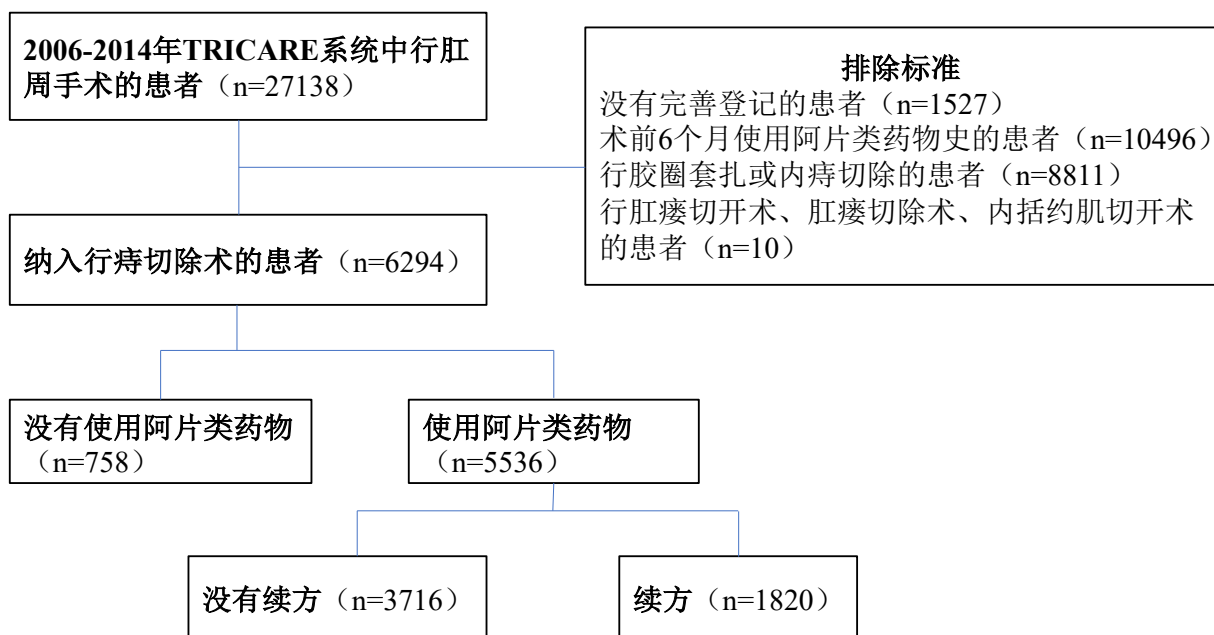
表 2. 阿片类药物处方续方的多因素分析

变量	OR 值	95% CI	p 值
性别			
男性	参考值		
女性	0.83	(0.68, 1.00)	0.052
年龄			
18-24	参考值		
25-34	1.05	(0.77, 1.43)	0.76
35-44	0.88	(0.65, 1.19)	0.4
45-54	0.81	(0.59, 1.12)	0.21
55-64	0.63	(0.45, 0.89)	0.009
军衔			
士兵	参考值		
军官	0.8	(0.69, 0.92)	0.002
种族/民族			
白种人	参考值		
黑种人	0.75	(0.62, 0.89)	0.001
拉美裔	0.84	(0.64, 1.10)	0.2
亚裔	0.71	(0.56, 0.89)	0.004
本地/其它	0.98	(0.74, 1.29)	0.87
未知	0.94	(0.78, 1.13)	0.51
受益人类型			
现役	参考值		
现役家属	1.01	(0.82, 1.26)	0.9
退役家属	0.82	(0.64, 1.06)	0.13
退役	0.88	(0.72, 1.07)	0.2
其它	1.09	(0.66, 1.79)	0.74
查尔森评分			
0	参考值		
1 分以上	1.49	(1.10, 2.01)	0.009
阿片类药物处方天数			
1-3 天	参考值		
4-6 天	0.83	(0.72, 0.96)	0.01
7 天以上	0.67	(0.57, 0.78)	<0.001
术后并发症	2.47	(1.89, 3.21)	<0.001
药物滥用史	3.26	(1.37, 7.34)	0.007

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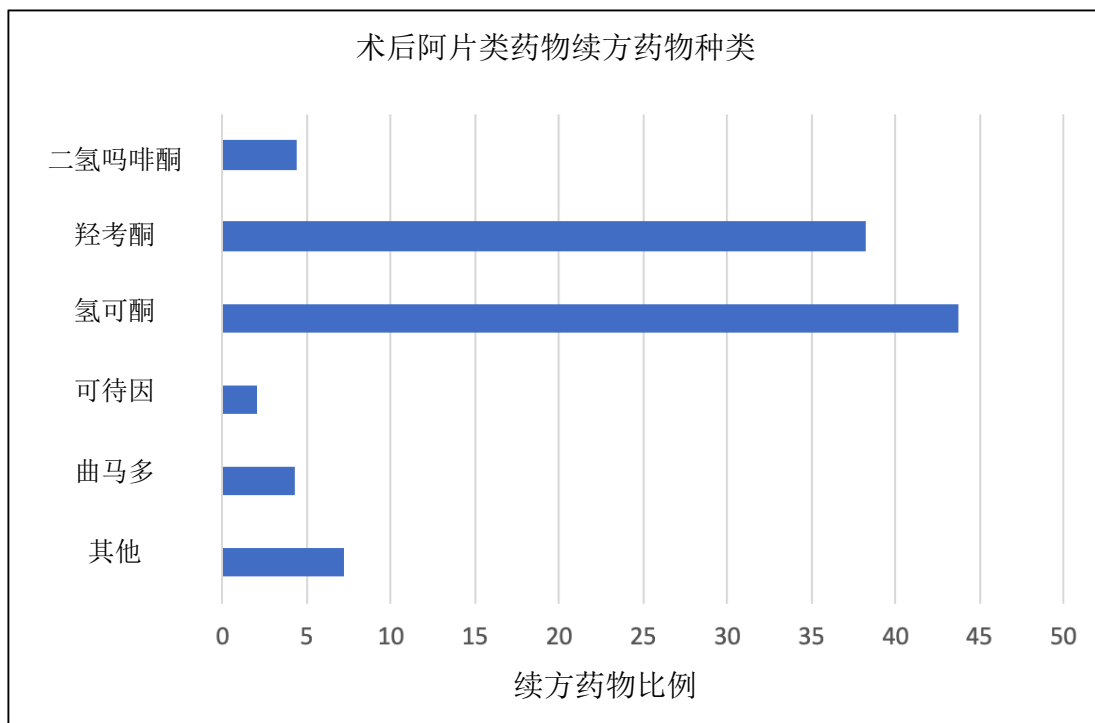
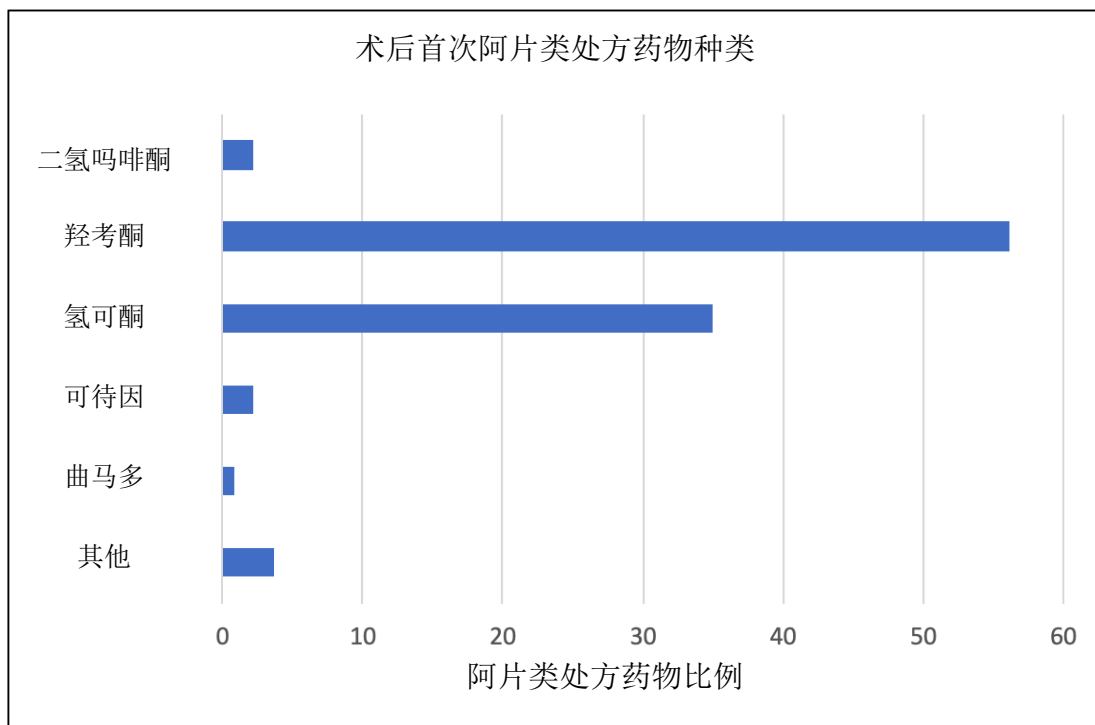
图 1. 患者筛选示意图



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图 2. 阿片类药物种类

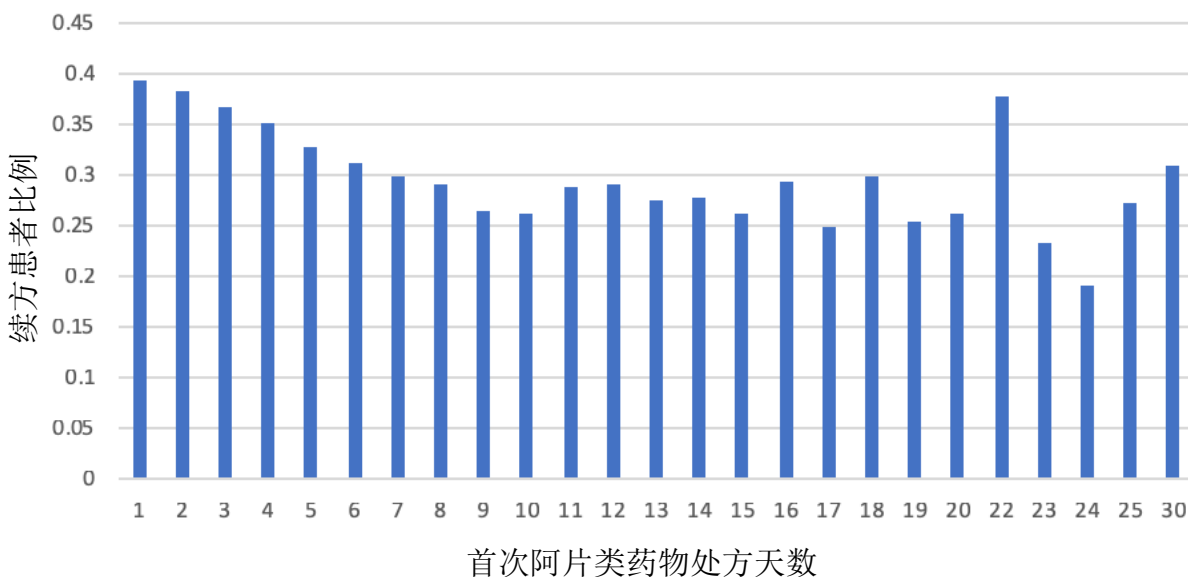


毫克吗啡当量换算因子：氢吗啡酮=4；羟考酮=1.5；氢可酮=1；可待因=0.15；曲马多=0.1

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图 3. 基于术后首次阿片类药物处方天数的续方模型比例



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