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两种引流方式在单侧膝关节置换术后的前瞻性临床对比研究 *

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摘要 目的:分析和比较单侧膝关节置换使用氨甲环酸术后两种不同引流方式(不夹管,夹管 6 小时后持续开放)对于手术的影响(出血量;并发症;康复锻炼等)。方法:根据纳入及排除标准,随机的将 2015 年 6 月 -2017 年 6 月在我院行单侧人工全膝关节置换的共计 52 例患者分为两组(不夹管组;夹管 6 小时后持续开放组)进行研究。每组各 26 例患者。分别观察和比较两组患者的各项术后资料:总引流量,总输血量,总失血量,小腿周径增幅,并发症等。同时对两组患者的膝关节功能进行评估和比较。结果:两组患者在年龄、性别组成、等一般临床资料的比较中未见显著差异($P>0.05$)。不夹管组的总失血量,总引流量,隐性失血量,输血量等指标显著高于夹管 6 小时组($P<0.05$)。术后两组患者在血栓,感染等并发症及小腿周径增幅等方面未见显著差异($P>0.05$)。结论:单侧膝关节置换术后早期进行夹管能够有效的减少总失血量、引流量等指标,更有利于患者术后的早期康复,而且不增加并发症的发生。

关键词: 全膝关节置换;氨甲苯酸;临床疗效;骨性关节炎

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Clinical Effects of Primary Total Knee Arthroplasty with Different Drainage Ways*

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ABSTRACT Objective: The aim of this study was to evaluate the clinical effects in patients who had undergone primary total knee arthroplasty (TKA) with 2 different closed negative pressure drainage (not clip pipe; clip to remain open after 6 hours). **Methods:** A total of 52 patients (52 knees) underwent primary TKA in our hospital from 2015.06 to 2017.06 was conducted. They were randomly divided into two groups (don't clip pipe group, clip pipe 6 h). Comparing three groups of patients with postoperative total flow rate and amount of allogeneic blood transfusion, total blood loss and hidden blood loss, postoperative week diameter growth of leg, incision infection rate, incidence of thrombosis and the function of knee joint after December (HSS score) evaluate the situation. **Results:** There were no significant difference in the baseline characteristics including age, gender, height, weight and time of operation between the two groups ($P>0.05$). However, total blood loss, hidden blood loss, blood transfusion in study group were higher than that in control group ($P<0.05$). Multiple comparison between groups of patients, postoperative 1 d, 3 d weeks diameter growth of leg, postoperative incidence of thrombosis, incision infection rate and postoperative HSS score 12 months were no significant statistical difference ($P>0.05$). **Conclusion:** Early continuous negative pressure drainage after clip pipe (6 h) can significantly reduce the amount of blood loss and the blood transfusion rate, and do not increase the obvious adverse consequences.

Key words: Total knee arthroplasty; Ammonia mesylate; Clinical effects; Osteoarthritis

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前言

随着工作及生活方式的改变、生活水平的提高以及人们对生活标准要求的提升,因膝关节骨性关节炎及其它关节疾病

而行关节置换术的数量显著增加^[1,2]。特别是各种材料及手术方式的不断完善,人工全髋关节置换术的效果也已得到了大家的公认,已成为目前骨科手术中的经典手术治疗方法^[3,4]。但该类手术中的出血问题一直未得到有效解决^[5,6]。已有相关文献报

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道,膝关节置换术后的失血一般可到达 1000 mL 以上,不但会因出血对患者造成负面影响,而且当引流不畅时,还会在关节腔内形成血肿并容易引发感染等严重问题^[7]。因此,在很长一段时间内,膝关节置换术后应用负压引流已成为一种常规^[8]。但有学者认为^[9],负压吸引会导致出血量进一步增加,并对感染、血栓等不产生正面预防作用。因此建议在膝关节置换术后不放置负压引流管,以便患者能够更早进行康复和功能训练^[10,11]。本次研究,拟在相关文献的基础上,对 52 例患者采用前瞻性分析的方法,比较人工膝关节置换术后是否放置引流管的差异,以为临床工作提供相关理论基础和参考。

1 资料与方法

1.1 一般资料

本次研究的研究对象为 2015 年 6 月 -2017 年 6 月的共计 52 例患者。所有纳入患者经严格的纳入及排除标准^[12]筛选后按照随机数字表进行随机分组。每组 26 名。所有患者中,男性为 21 例,女性 31 例;年龄最小为 49 岁,最大为 78 岁(63± 8.7岁)。

纳入标准为:^① 患者有明确的膝关节疼痛症状,且结合临床及影像学资料明确诊断为骨性关节炎;^② 患者均已接受系统的保守治疗,且治疗效果不佳,有手术适应症者;^③ 患者拟行初次单侧膝关节置换。

排除标准为:^① 患者有严重的膝关节创伤及手术史;^② 膝关节已由于各种原因出现严重畸形者(内外翻畸形 15° 及 / 或屈曲畸形 20°);^③ 患者合并有明确的白血病、败血症等全身性疾病;^④ 术后患者依从性较差者。

1.2 实验方法

所有纳入患者均在术前完善各项检查,包括双膝负重正侧位,下肢全长片及双髌骨轴位片。根据影像学结果,提前对假体的大小,截骨的长短及下肢力线方向做出预估。手术常规采用全身麻醉,常规消毒铺单后,快速滴完氨甲苯酸上止血带,使用前方直切口,按照常规路径,逐层切开各组织及关节囊直至暴露关节面。咬除骨赘后使用截骨器对胫骨进行截骨。试模安装完毕后,按照流程对股骨进行处理。使用脉冲冲洗器对关节面进行彻底冲洗。然后注射已配好的鸡尾酒(布比卡因 + 甲强龙

+ 鸡尾酒)。干纱布彻底擦净关节腔后,注入水泥,安装假体。待水泥完全固化后,再次探查确保无水泥存留。放置负压引流管并进行固定。可吸收线逐层缝合关节囊及韧带、深筋膜。普通丝线逐层缝合切口。无菌辅料包扎。并使用弹力绷带进行适当包扎。负压引流管均采用“贝诺斯”医疗的“外科手术引流导管套装”。不夹管组术后即进行负压吸引。夹管组在关闭负压吸引 6 小时候打开通道,进行吸引。

1.3 术后处理

术后两组患者常规给予一级护理,均在术后 3 小时候给予静脉滴注氨甲苯酸。弹力绷带包扎时间为常规一周时间。术前及术后按照常规应用抗生素预防感染。在术后第 2 日即可在康复医师的指导下进行下肢的功能锻炼。主要包括膝关节主动及被动屈曲,股四头肌等长收缩,直腿抬高及踝关节主动屈伸等训练。无意外情况时,在术后 48 h 后给予拔除负压引流管,一般不超过 72 h。3 天给予常规换药一次。并记录切口情况,如无意外,术后 14 天给予拆线。

1.4 观察指标

主要观察指标如下:^① 手术持续时间术中出血量;^② 患者术前及术后第 3 天、第 7 天的血常规;^③ 患者的总负压引流量;^④ 患者术前、术后第 1、3、7 天的 VAS 评分;^⑤ 患者术后的小腿肿胀程度及增幅;^⑥ 两组患者的切口情况及其他并发症问题;^⑦ 两组患者的总失血量以及显性、隐性失血量和输血情况。隐性失血量根据 Gross 方程计算^[13,14]而来。各指标根据相关计算公式和方程计算得出。

1.5 统计学方法

应用 SPSS 17.0 软件对数据进行分析。计量资料的比较采用独立样本 t 检验;计数资料采用 χ^2 检验, $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 患者一般资料比较

两组患者(各 26 例)的一般性资料进行比较,结果显示:两组患者在年龄、性别组成、身高、术前 Hct(%)等指标中并无统计学意义(表 1)。

表 1 两组患者临床资料的比较($\bar{x} \pm s$)

Table 1 Comparison of the clinical data between two groups($\bar{x} \pm s$)

Group	Age (years)	Gender (male : female)	Height (cm)	Weight (kg)
Control group	62.47± 6.89	8:20	1.64± 0.08	61.52± 9.36
Study group	63.92± 6.56	7:17	1.63± 0.06	63.27± 8.64
T or χ^2	0.543	0.067	0.630	0.296
P	0.614	0.795	0.524	0.815

2.2 患者术前基本情况比较

两组患者的血液指标(血红蛋白、红细胞压积)及患者的疼痛评分(VAS 评分)进行统计和比较,结果显示两组患者在上述指标的比较中未发现显著性差异(表 2)。

2.3 患者术中及术后基本情况比较

分别对两组的术中出血量,术后的总引流量,术后 3 天的 Hct,VAS 评分, 总失血量及隐性失血量等指标进行统计和比

较。实验结果显示,两组患者的术中出血量并无统计学差异,实验组的 Hct 明显高于对照组,两组总引流量,失血量和隐性失血量的比较中,都发现有显著统计学意义(表 3)。

2.4 并发症的比较

两组患者在发热,切口愈合,输血人数及小腿周径增幅等方面进行比较。研究结果发现实验组术后 3 天内的发热患者的数量明显高于对照组,但在 5-7 天内两组无统计学意义。两组

患者切口出现红肿、延迟愈合等问题的数量并无统计学差异，且经处理后均在出院前愈合。在输血指标的比较中，实验组的输血患者数量显著少于对照组，两者具有统计学差异；在术后

1天，实验组的小腿肿胀增幅高于对照组，但两组之间并无统计学差异(表4)。

表2 术前患者观察指标比较($\bar{x} \pm s$)
Table 2 Comparison of the results between two groups before operation($\bar{x} \pm s$)

Group	Hb (g/L)	HCT (%)	VAS
Control group	128.80± 11.62	40.24± 2.31	6.53± 1.78
Study group	130.10± 13.31	39.72± 3.01	6.49± 1.82
t	0.474	1.12	0.586
P	0.638	0.31	0.604

Note: Hb, hemoglobin; HCT, hematocrit; VAS, visual analogue scores.

表3 术后患者观察指标比较($\bar{x} \pm s$)
Table 3 Comparison of the results between two groups after operation($\bar{x} \pm s$)

Group	Blood loss (operation)(mL)	HCT (%) (3d)	Total lead flow (mL)	VAS (3d)	Total blood loss (mL)	Invisible tal blood loss (mL)
Control group	94.55± 23.72	28.26± 3.52	530.52± 59.77	3.62± 1.81	996.52± 138.32	480.48± 87.23
Study group	99.27± 28.74	34.21± 3.79	356.89± 47.34	3.77± 0.97	805.71± 114.21	390.45± 68.74
P	>0.05	<0.05	<0.05	>0.05	<0.05	<0.05

Note: Hb, hemoglobin; HCT, hematocrit; VAS, visual analogue scores.

表4 患者术后并发症的比较(人)
Table 4 Comparison of the complications between two groups after operation

Group	Fever(1-3d)	Fever(5-7d)	Incision	Blood transfusion	Increase circumferential diameter of calf (cm)
Control group	9	2	7	6	8.26± 2.52
Study group	16	3	8	2	8.61± 2.17
P	<0.05	>0.05	>0.05	<0.05	>0.05

3 讨论

随着社会的发展及老龄化的到来，膝关节疾病已经成为当代的常见疾病^[15]。尤其是骨性关节炎为主要病因的关节疾病所带来的疼痛给广大患者带来了沉重的精神及肉体负担^[16]。对于终末期骨性关节炎，行人工膝关节置换术已成为常规的经典手术术式^[17]。其主要的目的是为了解除因关节疾病导致的活动或静止性疼痛并有效的改善关节的功能。特别是随着科学的发展，尤其是材料学和外科手术术式的发展，人工髋关节置换术的整体治疗效果和治愈率已有了显著的提高^[18]。但目前仍不可避免的是，人工全膝关节手术仍然需要进行充分的暴露和软组织的广泛剥离，特别是此手术需行截骨处理^[19]。因此会带来较为严重的出血及由此引发的各种并发症(贫血，多器官衰竭，切口愈合不良等)。据相关统计，在人工全膝关节术后其出血量最高可达到近2000 mL，全膝关节术后的大量渗血可导致严重的关节疼痛，肢体肿胀，不但影响术后的关节功能锻炼，降低治疗效果，还容易引发深静脉血栓等重要问题^[20]，并可作为细菌培养的温床大大提高了细菌感染的可能。尽管人们已使用各类止血药，止血凝胶等方式及改善手术方式的方法来改善出血的问

题，但效果一直并不理想^[21]。

为了能将渗血尽快的排出体外，人们逐渐探索出了负压引流技术。通过闭式负压引流技术，可以将关节腔内的渗血尽快的排出体外，有效避免血肿的产生并加速切口愈合的效率。显著提高患者术后的功能锻炼效果。并且由于减少了“积血”的出现，作为细菌培养基的减少也在一定程度上有效的降低了术后感染的可能。尽管有学者认为^[22]，进行负压吸引后会导致显性出血量显著增加，从而直接导致患者术后输血概率的增加及输血风险和并发症的增加。但随即有患者通过实验证实^[23]，行负压吸引后，患者的总失血量并无显著增加，但可以有效的降低出血所导致的各种问题。因此，目前人工关节置换术后行闭式负压吸引已得到大家的公认。

为了避免显性出血量增大及输血量增加的问题，人们也在不断探索进行引流方式的改善。其中最主要的就是对引流闭管的时间进行控制^[24]。特别是有研究发现，在全髋关节术后，患者出血量是有一定规律的，在术后4 h内已达到总失血量的一半以上^[25]。人们逐渐提出，是否可以在引流的早期进行闭管，待渗血到一定程度后再将积血引流的概念。这种引流方式的优势在于，在早期由于形成负压，可以利用压力对关节腔形成压迫止

血作用,减少显性及隐性出血。在后期通过负压吸引,又可以将血肿排除,减少感染及并发症的可能。但对于夹管的时间,间隔的时间等一直存在较大的争议^[26]。在一篇前瞻性实验中^[27],人们发现,夹管4小时后再开放引流组的患者与术后持续引流组患者相比其引流量有显著的差异。并且在血红蛋白等血液指标中也发现了类似的结果。他们认为夹闭4小时可以有效的减少出血和输血量并能够显著降低各项费用和并发症的发生。而另外一篇meta分析中指出^[28],对于各项前期的夹闭时间的实验显示,当夹闭时间在4小时以下时,并不能显著的减少出血量和输血的概率。此外,还有很多医生尝试采用间隔夹闭的方法,即间隙性的关闭一段时间再打开引流一段时间^[29]。此外,还有学者尝试,采用改变负压引流压力的方法来降低术后的出血量,他们将负压引流组分为低负压引流组和高负压引流组两大类。但结果是两组患者在总引流量中并无显著性差异^[30]。从而提示负压的时间而不是负压的大小和引流相关。

同样必须要注意的是,尽管放置引流管与引流液的引出与人工膝关节术后的临床疗效密切相关。但并不是说,引流的时间越长越好。因为随着时间的进行,由于出血的减少,作为异物存在的引流管反而会加大感染的可能。已有相关研究证实^[31],引流管的放置时间与感染的发生率呈正相关。

在本次实验中,我们通过随机分组,将两组患者分为两组。实验组采取术后6小时内夹闭,6小时后松开再进行负压吸引的方式。而对照组则采用常规术后即开始引流的方式。实验结果显示,两组患者经不同的引流方式后,两组患者在术后3天疼痛评分,并发症,切口愈合,小腿周径增幅等方面并无统计学差异。但夹管6小时组在总引流量,显性及隐性失血量,输血概率等方面均显著优于对照组。从而提示,在夹管6小时后再进行负压吸引对于人工全膝关节置换患者有很好的治疗效果,且并不增加相关并发症的风险,可以在临床中进一步推荐使用。

当然,本实验还有较多的局限和问题。例如,受到样本数目的限制,本次实验未能完全做到将肢体限于同侧。同时,尽管主刀医生固定为同一高年资主任,但由于助手不同,手术完成程度仍略有异常。同时,各夹管时间未能做到完全的准则。但无论如何,膝关节置换术后夹管6小时候放置引流管更有利于术后的早期康复,并减少患者围手术期输血率,同时并不增加患者的并发症风险,在临床中可以进一步进行推广。

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