

## 临床论著

# 长节段固定治疗成人退变性腰椎侧凸不同近端固定椎患者手术并发症和翻修情况的 Meta 分析

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**【摘要】目的:**分析长节段固定治疗成人退变性腰椎侧凸不同近端固定椎患者的手术并发症和翻修情况。**方法:**于 2018 年 3 月 15 日通过计算机系统检索 Pubmed、Embase、Cochrane、维普、万方数据库、中国知网数据库, 截止时间为 2018 年 3 月 15 日。根据上端内固定椎的不同分为两组: 近端固定到 T10 及以上节段为高位椎 (upper vertebra, UV) 组, 近端固定到 T10 以下节段为低位椎 (lower vertebra, LV) 组。纳入标准:(1)国内外公开发表比较后路长节段不同上端内固定椎治疗成人退变性腰椎侧凸文献;(2)随机或者非随机对照研究;(3)患者年龄≥18岁;(4)随访时间≥1年。提取文献基本信息, 并发症[围手术期及非围手术期术后并发症: 硬脊膜破裂, 深静脉血栓形成, 创口深部感染, 创口浅表感染, 神经系统并发症, 近端邻近节段退变性疾病, 近端交界处后凸畸形 (proximal junctional kyphosis, PJK), 内固定失败, 假关节形成, 总并发症等], 术中出血量和翻修情况 (如 PJK、假关节形成、内固定失败、感染等不同原因导致的翻修情况)。并通过非随机实验方法学指数法 (methodological index for non-randomised studies, MINORS) 评价方法对最终纳入文献进行质量评分, Begg 法评估发表偏倚。通过 STATA 12.0 软件进行 Meta 分析。**结果:**最终纳入 10 篇文献, 中文 2 篇, 英文 8 篇, 共 883 例患者, 其中 UV 组 353 例, LV 组 530 例。所有文献 MINORS 评分为 16~20 分, Begg 法分析无明显发表偏倚。并发症包括围手术期并发症和非围手术期并发症两大类。其中围手术期并发症中, UV 组患者术中出血量显著多于 LV 组, 权重均数差 (weight mean difference, WMD) (95%CI) 为 409.33ml (288.74, 529.92), 而硬脊膜破裂、深静脉血栓形成、创口深部感染、创口浅表感染、神经系统并发症和围手术期总并发症对比无显著性差异 ( $P > 0.05$ )。非围手术期术后并发症中, UV 组近端邻近节段退变性疾病发生率低于 LV 组, 风险比 (relative risk, RR) (95%CI) 为 0.26 (0.11, 0.63),  $P < 0.05$ ; PJK、内固定失败、假关节形成和非围手术期术后总并发症对比无显著性差异 ( $P > 0.05$ ); PJK、假关节形成、内固定失败、感染等原因引起翻修及总翻修率均无统计学差异 ( $P > 0.05$ )。**结论:**长节段固定治疗成人退变性腰椎侧凸近端固定椎向中上胸椎延长可能有利于降低近端邻近节段退变性疾病的发生, 但患者术中出血量更多, 在其他并发症和翻修率方面尚未发现优势。

**【关键词】**退变性腰椎侧凸;长节段固定;近端固定椎;并发症;Meta 分析

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The effect of the proximal instrumented vertebrae on complications and revision rate in long fusion correction of degenerative adult lumbar scoliosis: a Meta analysis/WU Aimin, CHEN Dong, ZHANG Kai, et al//Chinese Journal of Spine and Spinal Cord, 2018, 28(11): 995-1003

**[Abstract]** **Objectives:** To investigate the effect of the proximal instrumented vertebrae on complications and revision rate in long fusion correction of degenerative adult lumbar scoliosis. **Methods:** The databases of Pubmed, Embase, Cochrane library, VIP, Wanfang and CNKI were searched at March 15th, 2018 to identify studies that compared outcome measures of the upper and lower proximal instrumented vertebrae (UV, upper vertebrae to T10 and above region; LV, lower vertebrae to lower than T10 region) in correction of degenerative adult lumbar scoliosis with long fusion. The included criteria were: (1) the studies focusing on comparison

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of outcome measures of the upper and lower proximal instrumented vertebrae in long fusion correction of degenerative adult lumbar scoliosis; (2) randomised or non-randomised controlled studies; (3) age  $\geq 18$  years old; (4) follow up  $\geq 1$  year. The general information, complications[peri-operative and later post-operative complications: dural tear, deep vein thrombosis, deep wound infection, superficial wound infection, neurologic complications, proximal adjacent degenerative diseases, proximal junctional kyphosis (PJK), implant failure, pseudarthrosis and total complications], blood loss and revision rate (different reasons for revision, PJK, pseudarthrosis, implant failure and infection) were extracted. Methodological index for non-randomised studies (MINORS) was used to assess the quality of included studies, and Beggs test was used to assess the publication bias. The Meta analysis was performed by using STATA 12.0. **Results:** Ten articles (2 in Chinese and 8 in English) were enrolled in this meta analysis, with total 883 cases(UV=353 cases; LV=530 cases). The MINORS scores ranged from 16 to 20, no significant publication bias was observed by using Beggs test. The complications included perioperative complications and later post-operative complications. For perioperative complications, the blood loss of UV group was significant more than that of LV group[weight mean difference (WMD): 409.33ml (95%CI: 288.74, 529.92)], however, no significant difference was found in deep vein thrombosis, deep wound infection, superficial wound infection, neurologic complications and total perioperative complications between two groups. For later post-operative complications, the incidence of proximal adjacent degenerative disease in UV group was lower than that in LV group[relative risk(RR): 0.26 (95%CI: 0.11, 0.63)], however, no significant difference was found in PJK, implant failure, pseudarthrosis and total later post-operative complications between two groups. No significant difference was found in the total revision and revision caused by PJK, pseudarthrosis, implant failure and infection. **Conclusions:** Selection of the upper thoracic region as the proximal instrumented vertebrae in the correction of degenerative adult lumbar scoliosis with long fusion may reduce the rate of proximal adjacent degenerative disease, however, present no advantage in terms of blood loss, other complications and revision rate.

**[Key words]** Degenerative lumbar scoliosis; Long fusion; Proximal instrumented vertebra; Complications; Meta analysis

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随着人口老龄化，成人退变性腰椎侧凸发病率越来越高<sup>[1]</sup>。成人退变性腰椎侧凸可导致患者背部疼痛、行走困难及神经根症状等，很多患者最终接受了手术治疗。手术治疗的目的包括减压、重建患者冠状和矢状面平衡<sup>[2,3]</sup>。长节段矫形固定融合术是成人退变性腰椎侧凸常用手术方式，并取得了良好的效果<sup>[4]</sup>。但长节段矫形固定融合术手术创伤较大，且存在一系列手术并发症和较高的翻修率<sup>[5,6]</sup>，相关并发症发生率高达78%<sup>[7]</sup>，翻修率高达50%<sup>[8,9]</sup>。目前关于长节段矫形固定融合术近端固定椎的选择仍存在较大争议，如果选择在下胸椎或者L1-2等位置，可能会发生固定节段近端后凸畸形，最终需要行翻修手术；而延续向上固定可能会增加手术创伤，从而增加其他手术相关并发症等问题<sup>[10]</sup>。不同胸椎固定节段选择对并发症和翻修的影响，特别是对不同类型并发症和不同原因导致的翻修对比结果如何尚不清楚。本研

究基于目前已发表的对比选择不同近端固定椎长节段固定治疗成人退变性腰椎侧凸文献，对并发症和翻修情况进行分析，以期为临床提供参考。

## 1 资料和方法

### 1.1 检索策略

通过计算机系统检索Pubmed、Embase、Cochrane、维普、万方数据库、中国知网数据库。中文关键词包括：成人腰椎侧凸、退行性腰椎侧凸、成人脊柱畸形、长节段固定、长节段融合；英文关键词包括：Adult scoliosis, adult lumbar deformity, degenerative lumbar deformity, proximal fusion level, upper instrumented vertebra, proximal junctional kyphosis, upper instrumented thoracic vertebra。检索时间截止至2018年3月15日。

### 1.2 纳入与排除标准

纳入标准：(1)国内外公开发表比较不同上端

内固定椎[高位椎(upper vertebra,UV)组;近端固定到T10及以上水平节段;低位椎(lower vertebra,LV)组;近端固定到T10以下水平节段]后路长节段固定治疗成人退变性腰椎侧凸的文献;(2)随机或者非随机对照试验;(3)年龄 $\geqslant 18$ 岁;(4)随访时间 $\geqslant 1$ 年。

排除标准:(1)非长节段固定治疗成人腰椎侧凸文献;(2)综述文献;(3)随访时间 $<1$ 年;(4)无并发症和翻修对比数据。

### 1.3 数据提取

两位作者独立提取文献中以下信息数据,包括作者、发表时间、国别、研究类型、对象人群人数、并发症[围手术期及远期并发症:硬脊膜破裂,深静脉血栓形成,创口深部感染,创口浅表感染,近端邻近节段退变性疾病,近端交界处后凸畸形(PJK),假关节形成,总并发症等],术中出血量和翻修情况(如PJK、假关节形成、内固定失败、感染等不同原因导致的翻修情况)。

### 1.4 文献质量评价

由于最终纳入文献均为非随机对照研究,故采用非随机研究方法学指数(methodological index for non-randomised studies,MINORS)评价方法对最终纳入文献进行评分<sup>[11]</sup>,共包括12项内容:(1)明确给出了研究目的;(2)纳入患者的连贯性;(3)预期数据的收集;(4)终点指标能恰当反映研究目的;(5)终点指标评价的客观性;(6)随访时间是否充足;(7)失访率低于5%;(8)是否估算了样本量;(9)对照组的选择是否恰当;(10)对照组是否同步;(11)组间基线是否可比;(12)统计分析是否恰当。每项予以评分:0分代表未报道,1分代表部分报道,2分代表充分报道。

### 1.5 统计分析

数据提取后,采用STATA 12.0软件进行Meta分析。定义 $I^2>30\%$ 或 $P<0.1$ 表示异质性大, $I^2<30\%$ 且 $P>0.1$ 则异质性可以接受<sup>[12]</sup>,可采用固定效应模型,但是分析后发现部分数据如围手术期总并发症发生率、总翻修率等有较大的异质性,敏感性分析无法排除异质性,分析发现固定效应模型同质性好的数据,随机效应模型分析结果和固定效应模型一致,异质性大即 $I^2>30\%$ 或 $P<0.1$ 的数据,随机效应模型分析后结果更加保守,于是采用随机效应模型<sup>[13]</sup>。以Begg法检验发表偏倚。所有并发症和翻修数据均为二分类变量,故采用

风险比(related risk,RR)(95%CI)表示最终结果。 $P<0.05$ 为有统计学差异。

## 2 结果

### 2.1 文献检索结果

根据上述检索,共检索到潜在文章614篇,中英文剔除重复文章后共579篇。通过阅读文题和摘要初步筛选后,剩余45篇予以下载全文复筛,通过全文阅读,发现18篇为非对照研究,4篇为综述,2篇和已纳入文献为相同研究对象,4篇未报告并发症和翻修数据,另外7篇其他原因予以排除,最终纳入10篇文章<sup>[6,8,9,14-20]</sup>,其中中文2篇,英文8篇,详细筛查过程见图1。纳入文献基本特征见表1。Begg法发现所有亚组均 $P>0.1$ ,无明显发表偏倚。

### 2.2 并发症

3篇文章<sup>[6,17,20]</sup>报道了硬脊膜破裂,UV组共4例,LV组共14例;2篇文章<sup>[6,17]</sup>报道了深静脉血栓形成,UV组1例,LV组1例;2篇文章<sup>[6,17]</sup>报道了创口深部感染,UV组共3例,LV组共7例;2篇文章<sup>[6,17]</sup>报道了创口浅表感染,UV组共3例,LV组1例;3篇文章<sup>[8,18,20]</sup>报道了神经系统并发症,UV组共18例,LV组共19例;4篇文章<sup>[6,16,17,20]</sup>报道了围手术期总并发症,UV组共42例,LV组共53例。对比分析发现,两组患者的硬脊膜破裂、深静脉血栓形成、创口深部感染、创口浅表感染、神经系统并发症对比均无统计学差异;围手术期总

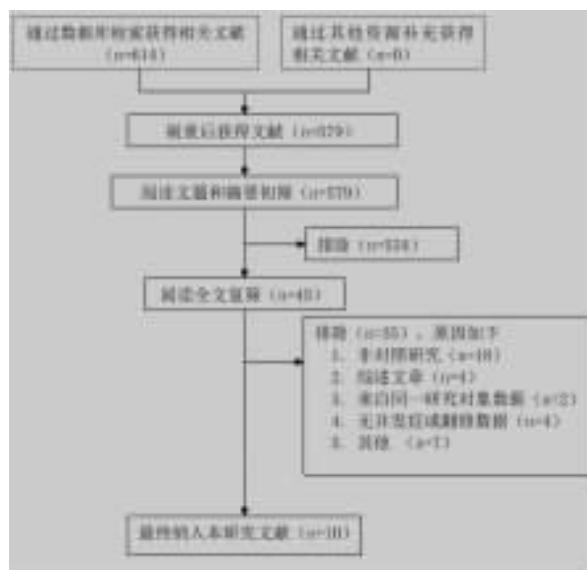


图1 文献检索筛选流程图

Figure 1 Flow chart of selected articles

表1 纳入10篇文献基本信息汇总  
Table 1 Details of the ten included studies

| 作者<br>Author                        | 组别<br>Groups | 年份<br>Year | 例数<br>Number | 性别(男/女)<br>Gender | 平均年龄(岁)<br>Mean age (years) | 随访时间(年)<br>Follow up (years) | MINORS评分<br>MINORS score |
|-------------------------------------|--------------|------------|--------------|-------------------|-----------------------------|------------------------------|--------------------------|
| Cho et al <sup>[14]</sup>           | UV           | 2013       | 22           | —                 | 64.6±7.9                    | 3.4±1.9                      | 18                       |
|                                     | LV           |            | 29           | —                 | 64.6±5.2                    |                              |                          |
| Ha et al <sup>[8]</sup>             | UV           | 2013       | 22           | 5/17              | 64.1±10.7                   | >2                           | 17                       |
|                                     | LV           |            | 67           | 17/50             | 64.2±7.4                    |                              |                          |
| Kim et al <sup>[15]</sup>           | UV           | 2007       | 37           | —                 | 55.4±9.5                    | 4.7±4.4                      | 16                       |
|                                     | LV           |            | 88           |                   | 55.9±8.5                    | 4.5±2.6                      |                          |
| Fujimori et al <sup>[6]</sup>       | UV           | 2014       | 31           | 4/27              | 60±12                       | 3.6±1.6                      | 17                       |
|                                     | LV           |            | 49           | 7/42              | 62±10                       | 3.7±1.6                      |                          |
| O'Shaughnessy et al <sup>[16]</sup> | UV           | 2012       | 20           | —                 | 55.4±9.5                    | 2.8±1.0                      | 20                       |
|                                     | LV           |            | 38           |                   | 55.9±8.5                    | 3.1±1.2                      |                          |
| Yagi et al <sup>[17]</sup>          | UV           | 2013       | 17           | 3/14              | 48.7(33~73)                 | 9.4(5~16)                    | 18                       |
|                                     | LV           |            | 15           | 6/9               | 53.7(33~76)                 | 7.9(5~12)                    |                          |
| Kim et al <sup>[18]</sup>           | UV           | 2014       | 91           | 13/78             | 60.9                        | 2.53                         | 17                       |
|                                     | LV           |            | 107          | 41/66             | 62.0                        | 2.41                         |                          |
| Scheer et al <sup>[9]</sup>         | UV           | 2015       | 81           | 15/66             | 60.3±11.3                   | 2                            | 18                       |
|                                     | LV           |            | 84           | 26/58             | 59.6±11.0                   |                              |                          |
| 章柯杰 <sup>[19]</sup>                 | UV           | 2015       | 15           | 13/17             | 66.4±6.5                    | 1                            | 16                       |
|                                     | LV           |            | 15           |                   | 68.4±5.1                    |                              |                          |
| 徐用亿等 <sup>[20]</sup>                | UV           | 2016       | 17           | 7/10              | 66.2±8.2                    | 2~4                          | 18                       |
|                                     | LV           |            | 38           | 15/23             | 65.8±9.7                    |                              |                          |

注:UV,高位椎;LV,低位椎

Note: UV, Upper vertebra group; LV, Lower vertebra group

并发症对比亦无统计学差异,RR(95%CI)为1.62(0.79,3.34)(图2)。共7篇文章<sup>[6,8,9,16,17,19,20]</sup>报道了术中出血量,不同文章报道的UV组平均出血量为1405.9~4922ml,LV组平均出血量为1014.5~3432ml,对比分析发现UV组患者平均出血量显著多于LV组,WMD(95%CI)为409.33ml(288.74,529.92)(图3)。

共4篇文章<sup>[14,15,19,20]</sup>报道了近端邻近节段退变性疾病,UV组共4例,LV组共35例;共7篇文章<sup>[6,8,9,16,17,19,20]</sup>报道了PJK,UV组共51例,LV组共88例;共2篇文章<sup>[6,17]</sup>报道了内固定失败,UV组共8例,LV组共4例;共2篇文章<sup>[6,17]</sup>报道了假关节形成,UV组共7例,LV组共10例;共4篇文章<sup>[6,17,19,20]</sup>报道了非围手术期术后总并发症,UV组共39例,LV组共75例。非围手术期术后并发症对比发现,UV组近端邻近节段退变性疾病发生率低于LV组,RR(95%CI)为0.26(0.11,0.63)。其他并发症包括PJK、内固定失败和假关节形成均无统计学差异。非围手术期术后总并发症对比也无统计学差异,RR(95%CI)为0.83(0.48,1.43)

(图4)。

共3篇文章<sup>[6,16,17]</sup>报道了总并发症,UV组共34例,LV组共58例。两组患者总并发症对比仍无统计学差异,RR(95%CI)为0.89(0.61,1.29)(图5)。

### 2.3 翻修情况

共7篇文章<sup>[6,8,9,15~18]</sup>报道了PJK导致的翻修率,UV组9例,LV组31例;共5篇文章<sup>[6,15~18]</sup>报道了假关节形成导致的翻修率,UV组20例,LV组26例;共4篇文章<sup>[6,9,16,17]</sup>报道了内固定失败导致的翻修率,UV组共8例,LV组共5例;共2篇文章<sup>[6,8]</sup>报道了感染导致的翻修情况,UV组共8例,LV组共13例;共7篇文章<sup>[6,8,9,15~18]</sup>报道了总翻修率,UV组共70例,LV组共143例。对比分析发现,UV组患者因PJK导致的翻修率数值上低于LV组,但仍无统计学意义[RR:0.56(95%CI:0.27,1.14)],假关节形成、内固定失败、感染等原因引起翻修的几率也无统计学差异。总翻修率对比为RR:0.85(95%CI:0.59,1.24),无统计学差异(图6)。

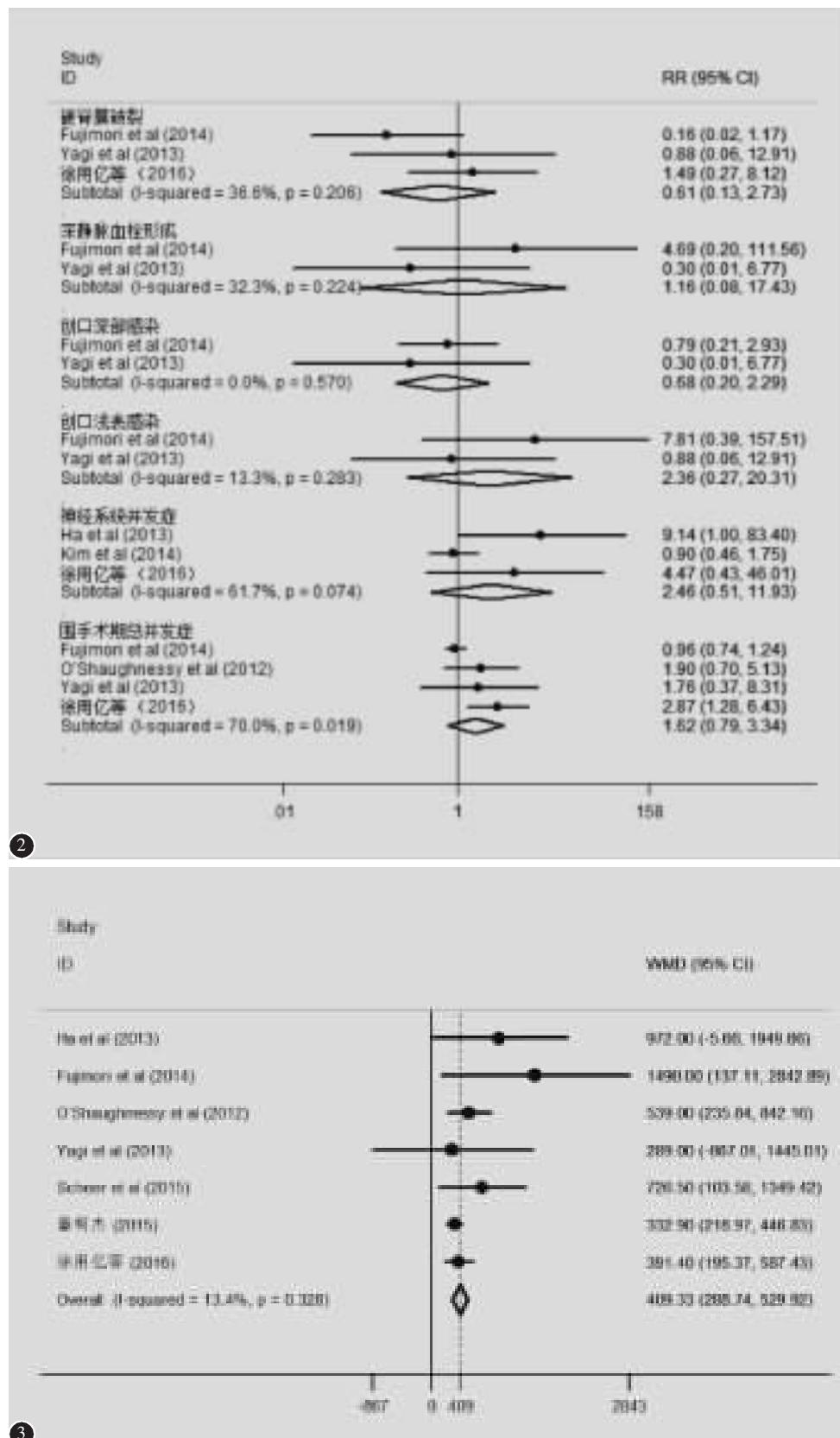


图2 两组患者围手术期相关并发症对比森林图 图3 两组患者术中出血量对比,UV组患者显著多于LV组

**Figure 2** Forest plot of peri-operative complications between two groups **Figure 3** Forest plot of intra-operative blood loss between two groups, The blood loss of UV group is significantly more than the LV group

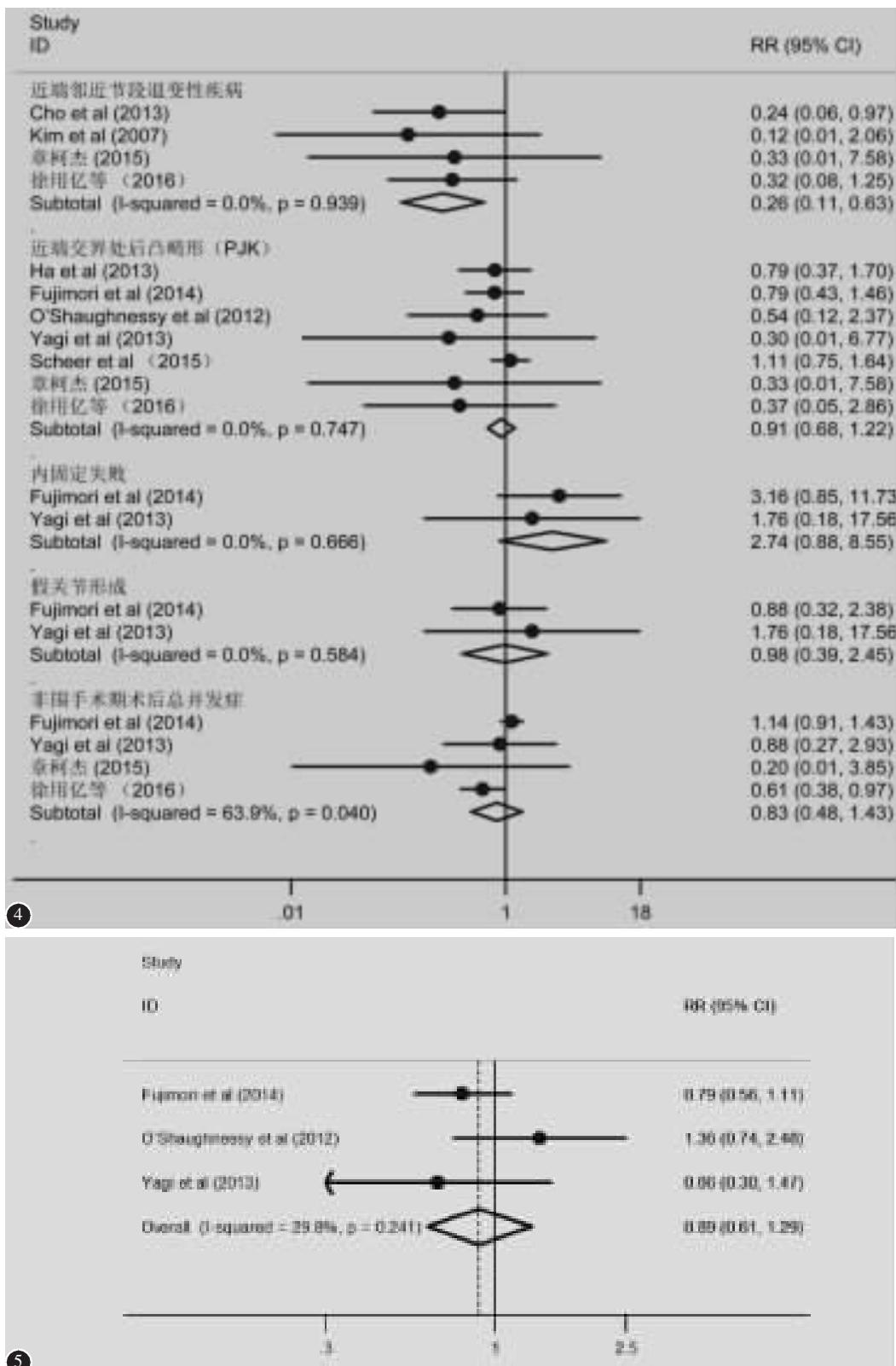


图4 两组患者非围手术期相关并发症对比森林图

**Figure 4** Forest plot of later post-operative complications between two groups    **Figure 5** Forest plot of total complications between two groups

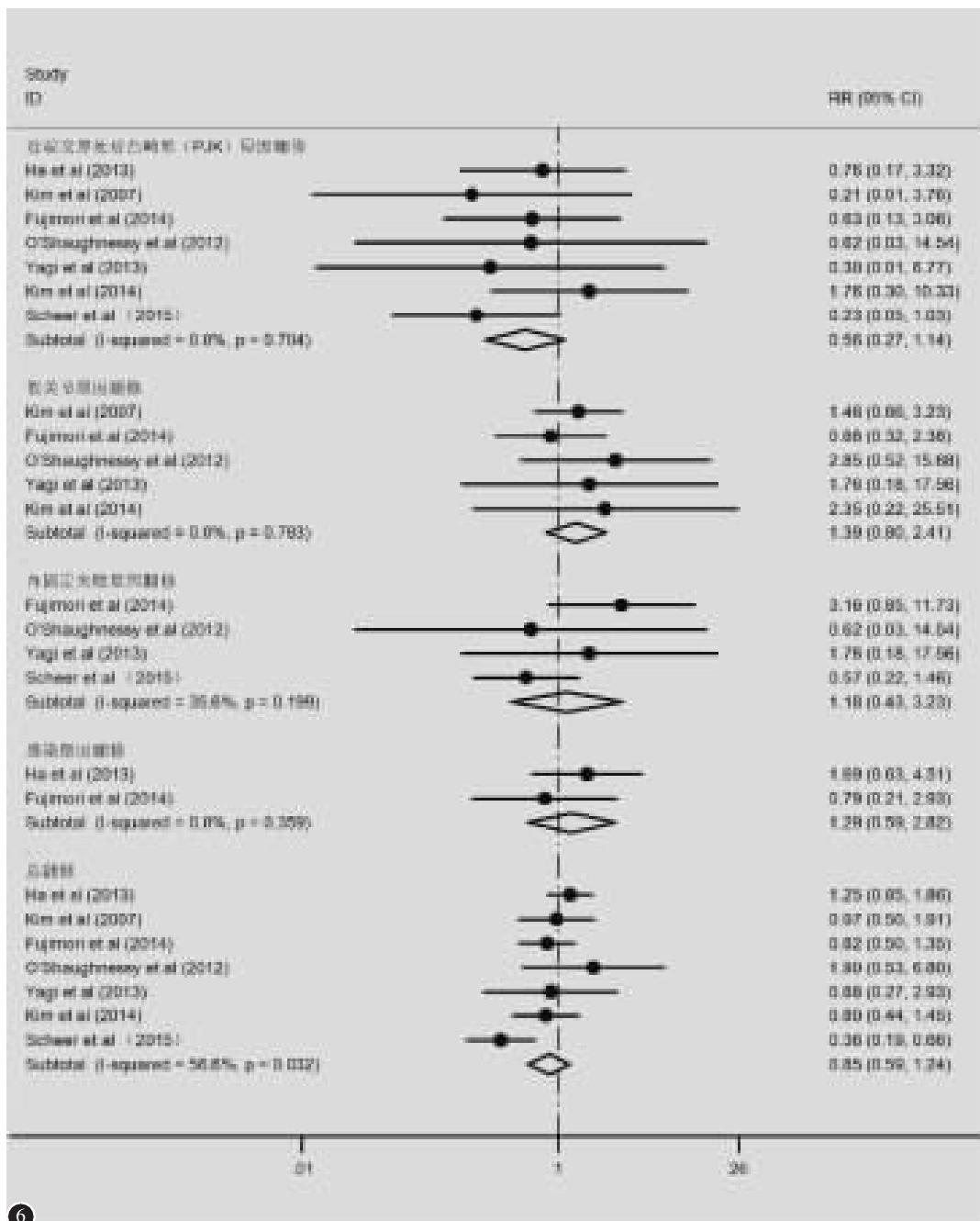


图 6 不同原因造成的翻修和总翻修对比分析森林图

**Figure 6** Forest plot of the total revision and different causes for revision between two groups

### 3 讨论

退变性脊柱侧凸常见于老年患者<sup>[21,22]</sup>, 症状可表现为腰痛, 伴或不伴双下肢放射痛, 影像学上可表现为冠状或者矢状面失衡, 部分节段椎管狭窄或者椎间孔狭窄等<sup>[23-26]</sup>。此类患者常常需要长节段固定矫形融合术, 重建冠状和矢状平衡<sup>[27-29]</sup>。但长节段固定近端固定椎的选择一直存在较大争议<sup>[10]</sup>。因长节段固定节段越多会造成患者更长的

手术切口, 手术时间延长, 出血增多, 创伤较大<sup>[30]</sup>。但是固定节段太少, 尤其是低于 T10 的固定方式, 很多术者担心邻椎退变加速, 发生 PJK 概率变大, 从而导致患者需要翻修手术<sup>[31]</sup>。

《Spine》于 2006 年发表了关于近端椎选择的讨论, 邀请了 Suk 教授和 Mardjetko 教授进行了辩论<sup>[10]</sup>, 通过权衡利弊, 他们最后总结认为近端的融合节段选择包括以下几点原则:(1)近端椎选择应

该在稳定区,冠状位上距离垂直轴小于2cm,如果条件允许,近端椎选择应矫正冠状平衡,使上终板和邻近椎间盘呈一水平面;(2)近端椎选择应使脊柱重建矢状平衡并承担力学转化区功能;(3)近端椎的邻近节段椎间盘或者关节突关节需无明显退变或仅轻度退变;(4)近端椎应选择在无旋转椎体(或中立位椎体);(5)近端椎邻近节段应在所有方向都是稳定的,后方附件结构应是完整的。

退变性脊柱侧凸固定后其PJK的发生受到广泛关注。Ming等<sup>[31]</sup>报道PJK的发生率高达32.2%,约6.7%患者需要行翻修手术,他们认为近端向上固定到中上胸椎可减少PJK的发生和翻修手术。Kim等<sup>[18]</sup>报道长节段固定融合治疗198例退变性腰椎侧凸患者,其中UV组3/91例因PJK行翻修手术,而LV组仅2/107例行翻修手术,反而UV组翻修多1例。本研究纳入的10篇文献中共7篇报告了PJK造成翻修的原因,虽然结果发现UV组因PJK导致翻修率比LV组PJK导致的翻修率在数值上更低,但两组无统计学差异。UV组因为长节段固定融合,其假关节形成导致翻修的概率有高于LV组趋势,但也无统计学差异。总体上,两组患者的总翻修率无显著性差异。

本研究尚未发现两组患者PJK发生率有显著性差异,但UV组患者近端邻近节段退变性疾病的发生率显著低于LV组。近端退变不一定需要翻修手术,而且目前纳入研究随访时间多数低于5年,很多患者可能还没退变到需要手术的程度。

UV组患者的围手术期并发症比LV组稍多,但仍无统计学差异。术中出血量分析,UV组明显多于LV组。Fu等<sup>[30]</sup>一项Meta分析发现,UV患者手术时间更长,术中出血更多,手术创伤大于LV患者。因此可能会造成UV组患者相对高的围手术期并发症。徐用亿等<sup>[20]</sup>报道1例长期吸烟患者行长节段融合固定,围手术期发生严重肺部感染而死亡。因此对于一些长期吸烟、年龄大、体质差、对手术耐受性差等患者,延长到中上胸椎的长节段固定融合术一定要谨慎选择。

其他并发症包括硬脊膜破裂、深静脉血栓形成、创口深部感染、创口浅表感染、神经系统损伤等,两组患者无显著性差异。硬脊膜破裂可通过术中仔细操作、小心减压分离等方法预防,硬脊膜破

裂如果术后发生脑脊液漏,一般保守治疗也可恢复<sup>[32]</sup>;长节段固定手术时间一般较长,术后卧床时间也相对较长,容易发生深静脉血栓形成,术中、术后予以间歇性气压泵可起到一定预防作用<sup>[33]</sup>。创口感染这一并发症的发现需要术后仔细观察,早发现、早治疗,尽量避免需要二次手术治疗。

本研究也存在一些不足之处:(1)纳入的文献均是非随机对照研究,存在选择偏倚;(2)纳入文章的病例数均比较少,这和本疾病的自身特性有关,而且PJK导致翻修等发生率本来就比较低,因此,纳入病例不足可能是PJK等指标尚未出现显著性差异的一个原因;(3)不同研究的随访时间有一定差异,也会导致翻修等发生率存在一定异质性。未来需要更高质量的、大样本、多中心研究更加科学地评估和研究。

总之,目前文献显示长节段固定治疗成人退变性腰椎侧凸患者近端固定椎向中上胸椎延长有利于降低近端邻近节段退变性疾病的发生,但其他并发症和翻修率无显著性差异,而术中出血量更多。

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