

脛骨骨幹部骨折に対する髄内釘固定とリング型創外固定器による治療の比較 (IMVEX) : 多施設共同ランダム化比較臨床試験

IntraMedullary nailing Versus EXternal ring fixation for the treatment of tibial shaft fractures (IMVEX): a multicentre randomized controlled clinical trial

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Aims:

One of the most common patient-reported complaints following intramedullary nailing (IMN) of tibial shaft fractures is anterior knee pain reported by 10% to 80% of patients. The present study aimed to compare the 12-month Knee injury and Osteoarthritis Outcome Score (KOOS) sport and recreation activities subscale (sport/rec) scores after IMN with external ring fixation (RF) to adult patients with tibial shaft fractures.

Methods:

This study was a pragmatic multicentre randomized, non-blinded trial, with two-group parallel design. Included were adult patients (aged ≥ 18 years) presenting with an acute tibial shaft fracture deemed operable with an intramedullary nail. The primary outcome was the KOOS sport/rec, ranging from 0 (worst score) to 100 (best score) at 12-month follow-up. Secondary outcomes included the Foot and Ankle Outcome Score (FAOS), health-related quality of life assessed by EuroQol five-dimension five-level health questionnaire, and pain scores.

Results:

A total of 67 patients were included in the study. In all, 33 patients were randomized to standard IMN and 34 patients to RF. The mean age of the patients was 47.7 years (SD 19.2; 18 to 84) and 34% were female ($n = 23$). The primary analysis revealed no statistically significant difference in KOOS sport/rec between the IMN and RF groups at the 12-month follow-up (adjusted mean difference -18.1 (95% CI -43.4 to 7.2); favouring RF).

Conclusion:

No statistically significant differences in the KOOS sport/rec were observed between RF and IMN at 12-month follow-up. However, these results should be interpreted with caution, due to high risk of a type II error.

目的:

脛骨骨幹部骨折に対する髄内釘固定 (IMN) 後に患者がもっとも多く報告した合併症の一つは膝前部痛であり、患者の 10~80% で報告された。本研究の目的は、IMN またはリング型創外固定器 (RF) を受けた成人の脛骨骨幹部骨折患者における 12 ヶ月時点の Knee injury and Osteoarthritis Outcome Score (KOOS) の sport and recreation activities サブスケール (sport/rec) スコアを比較することである。

方法:

本研究は、実務的多施設共同ランダム化非盲検並行群間比較試験であった。脛骨骨幹部の新鮮骨折で受診し、髄内釘による手術が可能であると判断された成人患者 (18 歳以上) を対象とした。主要評価項目は術後 12 ヶ月の時点での KOOS sport/rec とし、スコアの範囲は 0 (最低)~100 (最高) であった。副次的評価項目は Foot and Ankle Outcome Score (FAOS)、EuroQol five-dimension five-level health questionnaire (EQ-5D-5L) 評価による健康関連 QOL、疼痛スコアとした。

結果:

67 例を対象とした。全体で 33 例を標準的 IMN、34 例を RF に無作為に割り付けた。患者の平均年齢は 47.7 歳 (標準偏差 19.2, 18~84) であり、女性は 34% (23 例) であった。主要解析では、術後 12 ヶ月の時点での KOOS sport/rec に、IMN 群と RF 群のあいだで統計学的有意差は認められなかった (補正後の差の平均 -18.1 [95%信頼区間 -43.4 ~ 7.2], RF 優位) [線形混合モデル分析]。

結論:

術後 12 ヶ月の時点での KOOS sport/rec に、RF と IMN のあいだで統計学的有意差は認められなかった。しかし、第二種の過誤のリスクが高いため、この結果は慎重に解釈すべきである。

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Table II. Primary and secondary patient-reported outcome measures and between-group comparison.

Outcome	Mean (95% CI)		Mean difference (95% CI)	
	IMN	RF	Crude	Adjusted
KOOS Pain				
6 wks	78.9 (73.1 to 84.8)	87.5 (81.8 to 93.1)	-8.5 (-16.7 to -0.4)	-9.4 (-21.1 to 2.3)
3 mths	83.6 (77.6 to 89.6)	91.0 (85.2 to 96.7)	-7.4 (-15.6 to 0.9)	-7.9 (-19.7 to 3.9)
6 mths	88.7 (82.8 to 94.6)	90.9 (85.1 to 96.6)	-2.2 (-10.4 to 6.0)	-2.7 (-14.5 to 9.0)
12 mths	91.1 (85.2 to 97.0)	90.8 (85.1 to 96.5)	0.4 (-7.8 to 8.5)	-0.4 (-12.1 to 11.4)
KOOS Symptoms				
6 wks	73.1 (67.5 to 78.8)	88.6 (83.2 to 93.9)	-15.5 (-23.3 to -7.6)	-14.6 (-26.1 to -3.1)
3 mths	81.3 (75.5 to 87.1)	85.7 (80.2 to 91.2)	-4.4 (-12.4 to 3.5)	-3.3 (-14.8 to 8.2)
6 mths	89.0 (83.3 to 94.6)	89.9 (84.4 to 95.4)	-0.9 (-8.8 to 6.9)	0.1 (-11.3 to 11.6)
12 mths	90.4 (84.8 to 96.1)	90.3 (84.9 to 95.8)	0.1 (-7.7 to 7.9)	1.0 (-10.4 to 12.5)
KOOS ADL				
6 wks	75.6 (69.3 to 81.8)	77.1 (71.7 to 82.4)	-1.5 (-10.2 to 7.2)	-2.3 (-14.2 to 9.5)
3 mths	82.7 (76.3 to 89.1)	84.1 (78.0 to 90.2)	-1.4 (-10.2 to 7.4)	-2.1 (-14.1 to 9.9)
6 mths	90.7 (84.3 to 96.9)	91.1 (84.9 to 97.2)	-0.4 (-9.1 to 8.3)	-1.1 (-13.1 to 10.8)
12 mths	92.4 (86.1 to 98.6)	90.9 (84.9 to 97.0)	1.4 (-7.3 to 10.1)	0.6 (-11.3 to 12.5)
KOOS Sport/Rec				
6 wks	23.2 (10.9 to 35.6)	29.7 (18.1 to 41.4)	-6.5 (-23.5 to 10.6)	-8.8 (-34.1 to 16.4)
3 mths	35.3 (22.7 to 47.9)	45.7 (33.7 to 57.7)	-10.4 (-27.8 to 7.0)	-12.1 (-37.8 to 13.5)
6 mths	55.3 (42.9 to 67.6)	59.7 (47.7 to 71.7)	-4.4 (-21.6 to 12.8)	-6.7 (-32.2 to 18.7)
12 mths	68.4 (56.0 to 80.7)	77.1 (65.2 to 88.9)	-8.7 (-25.8 to 8.4)	-11.4 (-36.8 to 14.0)
KOOS QoL				
6 wks	58.8 (50.7 to 67.0)	81.4 (73.6 to 89.2)	-22.6 (-33.9 to -11.3)	-27.8 (-44.3 to -11.1)
3 mths	62.9 (54.5 to 71.2)	80.2 (72.3 to 88.2)	-17.3 (-28.8 to -5.8)	-22.3 (-39.1 to -5.5)
6 mths	70.9 (62.7 to 79.1)	82.6 (74.7 to 90.6)	-11.7 (-23.1 to -0.3)	-16.4 (-33.1 to 0.3)
12 mths	75.9 (67.7 to 84.0)	82.3 (74.7 to 90.6)	-6.4 (-17.8 to 4.9)	-11.3 (-27.9 to 5.4)
FAOS Pain				
6 wks	71.8 (64.8 to 78.7)	73.9 (67.4 to 80.5)	-2.2 (-11.7 to 7.4)	-6.1 (-21.1 to 8.9)
3 mths	79.5 (72.5 to 86.5)	77.3 (70.7 to 83.9)	2.2 (-7.4 to 11.8)	-1.5 (-16.6 to 13.6)
6 mths	87.0 (80.0 to 93.9)	81.5 (74.8 to 88.2)	5.4 (-4.1 to 15.0)	1.7 (-13.4 to 16.8)
12 mths	88.4 (81.6 to 95.2)	84.5 (77.9 to 91.1)	3.8 (-5.6 to 13.4)	-0.2 (-15.2 to 14.8)
FAOS Symptoms				
6 wks	61.6 (53.6 to 69.6)	55.9 (48.3 to 63.6)	5.7 (-5.3 to 16.8)	1.9 (-15.8 to 19.6)
3 mths	67.1 (59.0 to 75.3)	64.4 (56.6 to 72.1)	2.7 (-8.5 to 14.0)	-1.0 (-18.9 to 16.9)
6 mths	78.6 (70.6 to 86.7)	70.4 (62.7 to 78.2)	8.1 (-3.1 to 19.2)	4.1 (-13.8 to 22.0)
12 mths	84.5 (76.5 to 92.5)	76.9 (69.2 to 84.6)	7.6 (-3.4 to 18.7)	3.5 (-14.3 to 21.3)
FAOS ADL				
6 wks	74.8 (68.7 to 80.8)	69.8 (64.1 to 75.5)	4.9 (-3.3 to 13.3)	2.9 (-9.3 to 15.1)
3 mths	83.3 (77.2 to 89.4)	78.5 (72.7 to 84.2)	4.8 (-3.5 to 13.2)	3.1 (-9.2 to 15.4)
6 mths	88.5 (82.5 to 94.5)	85.8 (80.0 to 91.6)	2.8 (-5.5 to 11.1)	1.0 (-11.3 to 13.3)
12 mths	92.4 (86.4 to 98.3)	88.5 (82.8 to 94.2)	3.9 (-4.4 to 12.1)	1.9 (-10.3 to 14.2)
FAOS Sport/Rec				
6 wks	24.1 (12.4 to 35.8)	19.7 (8.8 to 30.6)	4.3 (-11.6 to 20.3)	-1.5 (-22.9 to 19.9)
3 mths	44.2 (32.5 to 56.0)	34.7 (23.7 to 45.7)	9.4 (-6.7 to 25.5)	3.5 (-18.2 to 25.2)
6 mths	64.1 (52.5 to 75.7)	49.7 (38.6 to 60.8)	14.4 (-1.6 to 30.5)	8.0 (-13.6 to 29.7)
12 mths	70.4 (58.9 to 81.8)	69.6 (58.6 to 80.6)	0.8 (-15.1 to 16.6)	-6.3 (-27.8 to 15.2)
FAOS QoL				
6 wks	48.3 (39.9 to 56.7)	48.9 (41.0 to 56.9)	-0.6 (-12.2 to 10.9)	-2.9 (-21.0 to 15.1)
3 mths	59.1 (50.6 to 67.6)	58.2 (50.2 to 66.2)	0.9 (-10.8 to 12.6)	-1.4 (-19.6 to 16.8)
6 mths	69.7 (61.3 to 78.2)	67.1 (59.0 to 75.2)	2.7 (-9.0 to 14.4)	0.3 (-17.8 to 18.5)
12 mths	76.3 (68.0 to 84.6)	71.4 (63.4 to 79.4)	4.9 (-6.7 to 16.5)	2.3 (-15.9 to 20.4)
EQ-5D-5L index				
6 wks	0.630 (0.577 to 0.683)	0.549 (0.500 to 0.601)	0.081 (0.007 to 0.155)	0.068 (-0.059 to 0.197)
3 mths	0.679 (0.624 to 0.734)	0.673 (0.621 to 0.726)	0.006 (-0.070 to 0.082)	-0.008 (-0.137 to 0.122)
6 mths	0.769 (0.715 to 0.824)	0.746 (0.693 to 0.798)	0.024 (-0.052 to 0.099)	0.010 (-0.119 to 0.140)
12 mths	0.784 (0.731 to 0.838)	0.772 (0.721 to 0.824)	0.012 (-0.063 to 0.087)	-0.003 (-0.132 to 0.125)

Continued

Table II. Continued

Outcome	Mean (95% CI)		Mean difference (95% CI)	
	IMN	RF	Crude	Adjusted
EQ-VAS				
6 wks	61.9 (56.1 to 67.7)	62.4 (56.8 to 68.0)	-0.5 (-8.5 to 7.6)	-1.0 (-13.9 to 12.1)
3 mths	68.0 (62.0 to 74.0)	68.3 (62.6 to 74.0)	-0.3 (-8.6 to 8.0)	-0.7 (-13.9 to 12.6)
6 mths	76.8 (70.9 to 82.7)	77.7 (72.0 to 83.4)	-0.8 (-9.0 to 7.4)	-1.4 (-14.6 to 11.9)
12 mths	78.0 (72.1 to 83.8)	78.0 (72.3 to 83.6)	-0.0 (-8.1 to 8.1)	-0.7 (-12.5 to 13.9)

ADL, activities of daily living; FAOS, Foot and Ankle Outcome Score; IMN, intramedullary nailing; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, quality of life; RF, external ring fixation; VAS, visual analogue scale.