

快速評讀 [臨床隨機試驗 RCT] 結果

文獻：

Routine versus clinically indicated replacement of peripheral intravenous catheters: a randomised controlled equivalence trial.

Rickard CM, Webster J, Wallis MC, Marsh N, McGrail MR, French V, Foster L, Gallagher P, Gowardman JR, Zhang L, McClymont A, Whitby M.

Lancet. 2012 Sep 22;380(9847):1066-74. doi: 10.1016/S0140-6736(12)61082-4.

PMID: 22998716 [PubMed - indexed for MEDLINE]

★Lancet (2011 JCR), IF: 38.278; Medicine, general & Internal 2/155 (1.2%)

步驟 1：研究探討的問題為何？

研究族群 / 問題 (Population/ Problem)：

Patients aged at least 18 years with an intravenous catheter in place and expected treatment of longer than 4 days.

介入措施 (Intervention)：

Routine replacement of peripheral intravenous catheters

比較 (Comparison)：

Clinically indicated replacement of peripheral intravenous catheters

結果 (Outcomes)：

1. The primary outcome was phlebitis during catheterisation or within 48 h after removal.
2. Secondary outcome were catheter-related bloodstream and local infections, all bloodstream infections, catheter tip colonisation, infusion failure, catheter numbers used, therapy duration, mortality, and costs.

步驟 2：研究的品質有多好(內在效度)？

招募(Recruitment) - 受試者是否具有代表性？

評讀結果：■是 □否 □不清楚 說明：[pp1067]

1. Research nurses screened medical and surgical units daily for participants in three university-affiliated, government hospitals in Queensland, Australia (Royal Brisbane and Women's Hospital, Herston; Princess Alexandra Hospital, Woolloongabba; and Gold Coast Hospital, Southport).
2. The ethics committee at each hospital and at Griffith University approved the protocol. We obtained written, informed consent from all participants before enrolment.

分派(Allocation) - 分派方式是否隨機且具隱匿性...？

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評讀結果：■是 □否 □不清楚 說明：[pp1067]
1. Patients were randomly assigned to one of two treatment groups (simple randomisation with 1:1 ratio, no blocking, stratified by hospital). 2. Random allocations were computer-generated on a hand-held device, at the point of each patient's study entry, and thus were concealed to patients, clinical staff, and research staff until this time.
... 每個組別，在研究開始時的情況是否相同？
評讀結果：■是 □否 □不清楚 說明：[pp1068 Table 1, 1069 Table 2 and Results]
1. Equal baseline demographics and clinical characteristics of patients (Table 1) (but do not provide statistical analysis data, such as p-value). 2. Equal Characteristics of peripheral intravenous catheters (such as, Skin integrity, Vein quality, Vein quality, Prescribed treatment...) (Table 2).
維持(Maintenance) - 各組是否給予相同的治療？
評讀結果：■是 □否 □不清楚 說明：See pp1068 Table 1, 1069 Table 2.
... 是否有足夠的追蹤(Follow up)？
評讀結果：■是 □否 □不清楚 說明：See pp1067 Figure 1, 1070 Table 3.
1. Researches did intention-to-treat analysis and per-protocol analysis for primary outcome. 2. Ultimately, only 2537 patients (77%) adhered to the protocol (routine replacement group vs. clinically indicated group: 70% vs. 85%).
評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？
評讀結果：□是 ■否 □不清楚 說明：[pp1067]
1. Patients and clinical staff could not be masked after allocation because of the nature of the intervention. Research nurses were similarly not masked because they had to allocate patients to the treatment group and monitor the integrity of the intervention. 2. Laboratory staff were masked for rating of all microbiological endpoints, and a masked, independent medical rater diagnosed catheter-related infections and all bloodstream infections. 3. Blinded inter-rater reliability checks on a subset of phlebitis assessments.

步驟 3：研究結果及討論

研究結果

All 3283 patients randomised (5907 catheters) were included in our analysis (1593 clinically indicated; 1690 routine replacement). Mean dwell time for catheters in situ on day 3 was 99 h (SD 54) when replaced as clinically indicated and 70 h (13) when routinely replaced. Phlebitis occurred in 114 of 1593 (7%) patients in the clinically indicated group and in 114 of 1690 (7%) patients in the routine replacement group, an absolute risk difference of 0.41% (95% CI -1.33 to 2.15%). Peripheral intravenous catheters can be removed as clinically indicated; this policy will avoid millions of catheter insertions, associated discomfort, and substantial costs in both equipment and staff workload.

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討論(本研究是否可用於臨床?)

■同意 6 人 ■懷疑 7 人 ■不同意 4 人

討論：

1. 常規更換靜脈留置針的政策會加病人痛苦、耗費護理人力，可考慮依本研究研究選 1-2 個病房試行。
2. 臨床上常見的靜脈留置針合併症為 IC cath 與皮膚接觸部位壓迫所造成的傷害(發紅、破皮)，但本研究的 Outcome variable 並未將此納入，且當病人有 indication 時才更換 IC，難以跟病人家屬解釋，易有醫療爭議或糾紛。
3. 台灣氣候較澳洲潮濕，且 on IC 時消毒溶液不同(台灣是 alc BI, 本研究用的是 2% chlorhexidine)，另外，在照護人力比上亦有所不同(靜脈留置針的觀察、固定及照護方式)，是否可以超過 4 天才更換，需要考量。
4. 本研究定期更換導管組，平均更換導管的時間為 70 小時(2.9 天)，有適應症才重新更換組的更換導管的時間為 99 小時(4.1 天)。現行本院政策，若靜脈留置針若無特殊異常，4 天才須重置，與本研究有適應症才需更換的時間相當，暫不建議改變現行政策。