Can a New IV Securement Device Reduce Accidental Catheter Removal?

A fictional two-center randomized superiority trial

Structured abstract

Background

Accidental removal of a peripheral intravenous catheter interrupts treatment and can require reinsertion. Additional securement is a plausible intervention, but its effects must be evaluated for a defined outcome and population. This manuscript is an original fictional teaching scenario, not published medical evidence.

Objective

To compare the proportion of clinically stable adult general-ward patients with any accidental dislodgement of their index peripheral IV catheter by day 7 between a hypothetical additional securement patch plus usual dressing and usual securement alone.

Design and setting

Two-center, two-arm, parallel, 1:1 randomized superiority trial at Larkmoor General and Saint Ives Valley Hospital, both invented hospitals. Hospital-stratified computer-generated allocation used concealed variable blocks and central release after baseline assessment. Patients and staff were not blinded; treating staff documented events without blinding.

Participants and interventions

228 adults were screened: 14 were ineligible and 14 declined. 200 clinically stable adults aged 18 years or older with newly inserted peripheral IV catheters were randomized and analyzed, 100 per arm. Follow-up continued for seven days or until earlier planned catheter removal; endpoint status was known for all 200 participants.

Results

The primary endpoint occurred in 4/100 patients (4%) with the hypothetical patch and 18/100 (18%) with usual securement. The absolute device-minus-control difference was -14 percentage points (95% Newcombe confidence interval -23.0 to -5.4 percentage points); two-sided Fisher exact p=0.002568276974149181. The prespecified primary superiority criterion was met in this simulation. Exploratory skin irritation occurred in 4/100 versus 3/100; no safety comparison was established.

Conclusion

Within these fictional data, accidental dislodgement was less frequent with the hypothetical patch. Unblinded measurement, a selected population, two centers and short observation limit interpretation. No real product benefit, mortality, infection, workload or cost effect is established.

Introduction and trial design

Clinical question

Among clinically stable adult general-ward patients with a newly inserted peripheral IV catheter, does an additional hypothetical securement patch, alongside the usual dressing, reduce accidental removal of that catheter compared with usual securement alone? The question concerns accidental dislodgement, not all causes of catheter failure.

Rationale

Securement may influence catheter movement. A difference in accidental dislodgement would not by itself establish an effect on infection, survival, workload or cost. Those outcomes require their own definitions, measurements and suitable study designs. This scenario is deliberately restricted to a single catheter-related primary outcome.

Design and setting

This was a two-center, two-arm, parallel-group randomized superiority trial with 1:1 assignment. Larkmoor General enrolled 110 participants and Saint Ives Valley Hospital enrolled 90; both institutions and this trial are fictional. A seven-day observation window was selected for this teaching scenario. There is no external trial registration or published protocol.

Eligibility

Eligible participants were clinically stable adults aged 18 years or older, cared for on general wards, with a newly inserted peripheral IV catheter. Exclusion criteria were ICU admission, severe adhesive allergy, active skin injury at the insertion site, or inability to document the primary endpoint. The selected population does not represent children, critically ill patients or home-care settings.

Intervention and comparator

The device group received an additional hypothetical securement patch plus the usual dressing. The control group received usual securement alone. There is no real manufacturer, device approval or commercial product in this scenario. Usual dressing care otherwise continued in both groups; detailed dressing-change schedules were not specified.

Observation period

Participants were observed for seven days or until earlier planned removal of the index catheter. An earlier planned removal was not an accidental dislodgement. Patient-level endpoint status over the observed catheter period was known for all 200 patients; this does not imply that every patient had seven full days of catheter exposure.

Methods and prespecified analysis

Randomization and allocation concealment

A computer-generated sequence was stratified by hospital, using variable block sizes concealed from enrolling staff. Central allocation was released only after eligibility and baseline information were recorded. Larkmoor allocated 55 patients to each arm and Saint Ives Valley allocated 45 to each arm. No envelope-based allocation was used.

Blinding and measurement

The patch was visible. Patients and clinical staff were not blinded, and the same unblinded staff documented catheter events. Knowledge of assignment could change handling of catheters, observation or classification of events. No blinded independent endpoint adjudication was specified.

Endpoints

The single predeclared primary endpoint was the patient-level occurrence of any accidental dislodgement of the index peripheral IV catheter by day 7 or earlier planned removal. Accidental dislodgement meant unintended catheter removal or displacement requiring replacement or loss of usable access; each patient counted at most once. Skin irritation at the securement site was a secondary exploratory endpoint. Other adverse-event categories were not reported; unreported does not mean zero events.

Hypotheses and success rule

H0: the groups have equal proportions with accidental dislodgement. H1: the proportions differ, with fewer dislodgements expected in the device group. The prespecified primary superiority criterion required both a lower device-group proportion and a two-sided Fisher exact p-value below alpha=0.05. There was one confirmatory primary comparison and no multiplicity adjustment; the secondary endpoint was exploratory and not tested.

Statistical methods and sample size

All 200 randomized patients were analyzed in their assigned groups, with 100 per arm and no missing primary endpoint status. The primary 2x2 comparison used a two-sided Fisher exact test, summing fixed-margin table probabilities no greater than the observed table probability. The device-minus-control risk difference was accompanied by a 95% Newcombe hybrid-score interval without continuity correction. No a priori sample-size or prospective power calculation was provided. A sample of 200 must not automatically be described as adequately powered.

Participant flow

Of 228 screened patients, 14 were ineligible and 14 declined, leaving 200 randomized: 100 device and 100 control. All 200 contributed a known primary endpoint status. No post-randomization exclusions were specified. Baseline characteristics and outcome counts are given in Tables 1 and 2 on physical PDF page 4.

Results

Analysis population

All 200 randomized participants were analyzed in their assigned groups (100 per arm). No primary endpoint status was missing. Site recruitment was 110 at Larkmoor General (55/55) and 90 at Saint Ives Valley Hospital (45/45).

Table 1. Baseline characteristics

Characteristic	Hypothetical patch	Usual securement
Randomized and analyzed	100	100
Age, mean (SD), years	56 (14)	55 (15)
Women, n/N (%)	52/100 (52%)	50/100 (50%)
Diabetes, n/N (%)	29/100 (29%)	31/100 (31%)
Larkmoor General, n	55	55
Saint Ives Valley Hospital, n	45	45

Table 2. Primary and exploratory outcomes

Outcome	Hypothetical patch	Usual securement
Accidental dislodgement (primary)	4/100 (4%)	18/100 (18%)
No primary dislodgement	96/100 (96%)	82/100 (82%)
Skin irritation (exploratory)	4/100 (4%)	3/100 (3%)

Primary comparison

Device minus control: -14 percentage points; 95% Newcombe CI -23.0 to -5.4 percentage points. Two-sided Fisher exact p=0.002568276974149181 (rounded p=0.00257). With a lower device-group proportion and $p<0.05$, the prespecified primary superiority criterion was met in this simulation.

Reading the statistics

The p-value is evidence against the no-difference hypothesis under the test assumptions; it is not the probability that the device works. The confidence interval expresses a plausible range for the size of the difference under the model. The negative signs indicate fewer device-group events. A 14-per-100 absolute difference concerns dislodgement only; clinical importance still depends on context.

Secondary result and baseline context

Skin irritation was exploratory and was not tested for superiority, noninferiority or equivalence. The counts 4/100 and 3/100 establish neither equal safety nor a safety benefit. Baseline age, sex and diabetes summaries describe the groups; they do not prove absence of all baseline imbalance or confounding.

Discussion, limitations and declarations

Principal finding

The fictional data show fewer accidental dislodgements with the hypothetical patch: 4 of 100 versus 18 of 100. The prespecified criterion was met for this one endpoint in this simulation. This is a teaching example of an analysis, not evidence that an actual medical device is effective.

Strengths for this question

Random assignment, concealed central allocation after baseline and complete primary endpoint status support a fair comparison of the measured endpoint in this scenario. A defined patient-level endpoint, stated denominators and a prespecified test make the result interpretable. These features do not remove all possible bias.

Methodological limitations

Patients and staff knew assignment and staff recorded outcomes without blinding. Performance and ascertainment bias remain plausible, even with randomization. Only two invented hospitals, selected stable adult ward patients, and seven days or earlier planned catheter removal limit applicability. Exposure duration need not be identical across patients. No prospective power rationale was supplied, so adequacy of planned power cannot be assessed.

What is and is not supported

The comparison supports an interpretation of fewer accidental dislodgements in these synthetic data only. It does not establish mortality, infection, workload or cost effects; those outcomes were not measured here. Exploratory skin irritation counts do not establish comparative safety. Other adverse-event categories were unreported, not confirmed absent. No conclusion applies automatically to ICU patients, children, longer catheter dwell, other securement devices or real clinical care.

Practical response

If asked whether the device prevents infections, an appropriate answer is: this fictional study measured accidental dislodgement, not infection; no infection claim can be drawn. If asked about power, explain that power is the planned probability of detecting a specified true effect under assumptions; this manuscript supplies no prospective calculation.

Conclusion

Within this fictional trial, the measured primary outcome favored the hypothetical patch, with substantial qualifications about unblinded measurement and limited scope. Statistical significance is not a universal measure of clinical importance, freedom from bias or product value.

Declarations

Created for MedTechLens educational demonstration. There are no real participants, named real authors, participating real hospitals, journal publication, DOI, trial registration, claimed ethics approval or commercial device endorsement. No real study funding or conflicts are asserted. The source manuscript and accompanying model report are curated teaching materials, not an independently generated AI analysis. No supplementary dataset is available.