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Research

Standard restrictive sternal precautions and modified sternal precautions had similar effects in people after cardiac surgery via median sternotomy ('SMART' Trial): a randomised trial

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KEY WORDS

Randomized controlled trial
Cardiac surgery
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Sternal precautions
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ABSTRACT

Question: In people who have undergone cardiac surgery via median sternotomy, does modifying usual sternal precautions to make them less restrictive improve physical function, pain, kinesiophobia and health-related quality of life? **Design**: Two-centre, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants**: Seventy-two adults who had undergone cardiac surgery via a median sternotomy were included. **Intervention**: Participants were randomly allocated to one of two groups at 4 (SD 1) days after surgery. The control group received the usual advice to restrict their upper limb use for 4 to 6 weeks (ie, restrictive sternal precautions). The experimental group received advice to use pain and discomfort as the safe limits for their upper limb use during daily activities (ie, less restrictive precautions) for the same period. Both groups received postoperative individualised education in hospital and via weekly telephone calls for 6 weeks. **Outcome measures**: The primary outcome was physical function assessed by the Short Physical Performance Battery. Secondary outcomes included upper limb function, pain, kinesophobia, and health-related quality of life. Outcomes were measured before hospital discharge and at 4 and 12 weeks postoperatively. Adherence to sternal precautions was recorded. **Results**: There were no statistically significant differences in physical function between the groups at 4 weeks (MD 1.0, 95% CI −0.2 to 2.3) and 12 weeks (MD 0.4, 95% CI −0.9 to 1.6) postoperatively. There were no statistically significant between-group differences in secondary outcomes. **Conclusion**: Modified (ie, less restrictive) sternal precautions for people following cardiac surgery had similar effects on physical recovery, pain and health-related quality of life as usual restrictive sternal precautions. Similar outcomes can be anticipated regardless of whether people following cardiac surgery are managed with traditional or modified sternal precautions. **Trial registration**: Australian and New Zealand Clinical Trials Registry ANZCTRN12615000968572. **[Katijjahbe MA, Granger CL, Denehy L, Royse A, Royse C, Bates R, Logie S, Nur Ayub MA, Clarke S, El-Ansary D (2018) Standard restrictive sternal precautions and modified sternal precautions had similar effects in people after cardiac surgery via median sternotomy ('SMART' Trial): a randomised trial. *Journal of Physiotherapy* XX: XX–XX]**

Introduction

Cardiac surgery via median sternotomy is performed in over a million cases per year worldwide.[1] It is the procedure of choice for patients with multiple vessel disease and comorbidities because it provides the best clinical outcomes.[2] Sternal complications following median sternotomy may include infection, non-union and instability. The incidence of sternal complications has remained relatively unchanged for the last two decades and is reported to be between 1 and 8% worldwide.[3–5] These complications are associated with significant patient morbidity, prolonged hospital stay and contribute to increasing healthcare costs.[5,6]

In an attempt to reduce or prevent sternal complications, current practice involves the routine prescription of sternal precautions immediately after surgery. These precautions place restrictions on the use of the upper limbs immediately following surgery for 6 to 12 weeks, depending on the institution.[4,7] Patients are encouraged to not use their upper limbs during everyday tasks such as bed transfers or lifting objects.[4,8,9] The rationale for these

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restrictions is to promote solid osteosynthesis and bone healing by minimising the forces and the amount of micromotion between the sternal edges, which can promote progression to non-union and/or infection.[4,7]

Few studies have investigated the rationale for clinical implementation of sternal precautions. A comprehensive search in Medline, PubMed and CINAHL revealed no systematic reviews on the topic; instead, the evidence for these restrictions was scarce and based on limited cadaver studies.[4,7] Those studies reported that this rationale is based on historical practice, expert opinion, and extrapolation from bone fracture healing research (eg, radius).[4,7]

Healthcare professionals, including surgeons, nurses and physiotherapists, routinely advise patients to follow sternal precautions following median sternotomy. However, a recent study demonstrated minimal micromotion of the sternal edges (< 2 mm as measured by real-time ultrasound) during tasks such as cough, sit to stand, and bilateral and unilateral upper limb elevation.[10] These findings challenge the rationale for the restrictions.[10] The rationale for the restrictions is further undermined by the fact that health professionals also actively encourage patients to perform upper limb and trunk exercises following cardiac surgery as part of their postoperative care to promote recovery and return of function.[4,7,11] The prescription of such exercises alongside sternal precautions poses a clinical dilemma, as they contradict each other.[4,7] Furthermore, physical activity and upper limb exercises reduce sternal pain[12] and may be imperative for healing and remodelling of bone, which responds to loading.[4,13] It has been postulated that sternal precautions may be unnecessarily restrictive, thereby compromising the ability of patients to mobilise and delaying functional recovery.[4,13]

To date, no robust randomised controlled studies have compared a program of usual standard precautions to one that encourages less-restrictive use of the upper limbs and trunk in the cardiac surgery population.

Therefore, the research question for this randomised controlled trial was:

> In people who have undergone cardiac surgery via median sternotomy, does modifying usual sternal precautions to make them less restrictive improve physical function, pain, kinesiophobia and health-related quality of life?

Method

Design

This was a prospective, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. It was conducted at two hospitals in Melbourne, Australia. The trial compared usual advice to restrict upper limb use (ie, restrictive sternal precautions) with advice to use pain and discomfort as the safe limits for upper limb use during daily activities (ie, less restrictive precautions) in people who had undergone median sternotomy. Participants were randomised to the trial after surgery, once they had met the eligibility criteria, given informed consent, and completed baseline measurement testing. Randomisation was conducted by an independent person offsite using a computer-generated, randomly ordered list of 72 allocations with a 1:1 allocation ratio. The allocations were concealed in sealed, numbered, double-layered, opaque envelopes. In order to minimise placebo and Hawthorne effects, participants enrolling in the study were only advised that they would be randomised to one of two sets of sternal precautions, without being given detail of the two sets.

Later, when the randomly allocated precautions were being explained to the participants, the alternative precautions were not discussed. The treating physiotherapists and nursing staff were not blinded to group allocation. The outcome assessor was located offsite, and only attended to assess all outcomes while remaining blinded to each participant's allocated intervention. To preserve blinding of the assessor, details of sternal management were not documented in the medical records and the treating physiotherapist avoided delivering the intervention to participants on the ward during a set daily time period when the blinded outcome assessor was present. If a participant's allocation became unblinded to the outcome assessor, this was recorded. Members of the research team involved in data management were blinded to treatment allocation. Outcomes were measured immediately before randomisation and at 4 and 12 weeks after surgery.

The trial was reported in accordance with the CONSORT guidelines for clinical trials of non-pharmacologic treatment[14] and the intervention was reported in accordance with the TIDieR checklist for reporting of interventions.[15] The full protocol for this trial has been published.[16]

Participants, therapists and centres

Patients at the two sites were eligible to participate if they were: aged ≥ 18 years, able to provide informed consent, and undergoing cardiac valve surgery, coronary artery bypass graft surgery, or a combination of both via median sternotomy. Usual care at the recruitment sites is that patients underoing cardiac surgery via a median sternotomy have sternal closure achieved using a series of single stainless steel wires placed through the manubrium and around the lateral edge of the body of the sternum. Patients were excluded if they had insufficient English comprehension to complete the questionnaires or lived outside of the Melbourne metropolitan area (ie, 52 km radius) precluding their ability to return to the hospital for follow-up testing.

One physiotherapist at each participating hospital was responsible for providing the intervention for both groups. Both physiotherapists were senior clinicians with > 5 years of clinical experience in cardiac surgery. Each site was a metropolitan hospital that performs ≥ 500 cardiac surgeries via median sternotomy annually.

Interventions

Each participant was randomly allocated their sternal precautions on Day 4 (± 1 day) after surgery. Each participant received standardised verbal and printed sternal precautions by the treating physiotherapist. These precautions were delivered during a single 15-minute session in an enclosed room on the ward prior to discharge from the hospital. Telephone follow-up was conducted weekly for 6 weeks, to encourage patients to continue with their allocated precautions.

The experimental group was provided with instructions to encourage the use of upper limbs within the limits of pain or discomfort. This included being permitted to use the arms during transfers and other tasks within the limits of pain and discomfort, as well as encouragement to perform upper limb exercise three times daily within the limits of pain and discomfort. The verbal instructions explained to participants in the experimental group are listed in Box 1. The printed instructions given to participants in the experimental group are presented in Figure 1.

Box 1. Precautions explained to participants in the experimental group.

- Use pain and discomfort to guide use of the arms
- Avoid pushing or pulling with one arm
- Keep both arms close to the body during lifting
- Use of the arms for other tasks is permitted but keep them close to the body
- Avoid stretching both arms backwards at the same time
- When coughing, support sternum with a cushion or the arms in a self-hugging position
- When getting out of bed, roll onto side, ease legs over the edge of the bed, and carefully use the arms to help you sit up from lying position

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