Prevention Decline in Older Invasive Cardiac Surgery Patients

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Study question and objective At this stage of developement of the multicomponent is intervention it is unclear whether the intervention is feasible in practice. Therefore the question: Is this multicomponent preadmission intervention feasible in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37825

Source
ToetsingOnline

Brief title
PREDOS

Condition

- Other condition
- Age related factors
- Cardiac therapeutic procedures

Synonym
4 postoperative complications: Temporary confusion (delirium), Bedsores (pressure ulcers), Depression, Infection (surgical wounds, respiratory tract), urinary tract

Health condition

postoperatieve complicaties Delier, Depressie, Decubitus en Infectie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: SIA RAAK Publiek

Intervention

Keyword: Cardiac Surgical Procedures, Frail Elderly, Morbidity & Complication, Prevention & Control

Outcome measures

Primary outcome

Primary outcomes (measured in patients)

- Reasons for non-compliance with non-compliance patients

- The percentage of enrolled patients through the whole intervention

- A record of the number of days between the visit to the POS and the operation

- Satisfaction with the procedure in both groups of patients based on the

definition of satisfaction Quaathoven and Van den Broeck (1990).

A nurse will ask the following questions:

1. What were your expectations regarding preparation for surgery? (open

answer).

2. To what extent did the preparation for surgery meet your expectations?

(rating 1-10).

3. What did you expect from the preoperative screening? (open answer).

4. To what extent did the preoperative screening meet your expectations?

(rating 1-10).

5. What were your expectations of the intervention which helped you prepare

for surgery? (open answer).

6. To what extent did the intervention which helped you prepare for surgery meet your expectations? (rating 1-10)

Secondary outcome

Secondary outcomes (measured in patients)

- Baseline characteristics of the intervention group and control group:

a) Age

b) Gender

c) Education: primary school, secondary school, study (vocational training, higher education)

d) Number of chronic diseases (diabetes, kidney disorder, liver failure, hyper/ hypothyroidism, (pulmonary) hypertension, cardiovascular dysfunction, chronic lung disease, neurologic dysfunction, history of stroke or TIA, stomach problems)

e) ADL aids (glasses, hearing aids, cane, walker, wheelchair, orthopedic shoes)

f) Social status (single, domestic partnership, widowed, married, divorced)

g) Residential status (independent, residential home, retirement home, nursing home)

h) Handicap (deaf, blind, physical disability, mental disorder)

i) BMI (kg/m2)

j) Type of surgery

Secondary outcomes (measured by caregivers)

- A survey of nurses' experiences with implementing the intervention:

1. Did you feel competent to carry out the intervention? Why?

2. What aspects of the intervention did you appreciate? Why?

3. What aspects of het intervention can be improved?

4. What aspects did you miss in the intervention?

5. Was the intervention complementary to the usual care? Why?

6. What was the average duration of POS? How much time was spent onthe intervention? (time in minutes)

7. To what extent was this time too short/too long/just enough? Why?

- An evaluation of the placement of the intervention within the procedures of the organization by managers and planners:

1. What problems did you face during integrating the intervention within the organization?

2. How did you solve these problems?

3. Was it possible to prevent these problems? How?

4. To what extend are you intended to implement the intervention definitive?

5. What are your suggestions to further improve the intervention?

Study description

Background summary

In recent decades, mortality during or shortly after cardiac surgery decreased (Northrup et al, 2004). By contrast, morbidity increased (Ghotkar et al, 2006), mainly because more older, sicker and higher risk patients are presented for cardiac surgery (Litovski et al, 2008; Zangrillo et al, 2006, Northrup et al,

2004; Kilger et al, 2001). This leads to more postoperative complications and a potential decrease in quality of life (Litovski et al, 2008; Pätilä et al, 2006, Stoica et al, 2002).
Nearly 60% of cardiac surgical procedures done in patients aged 65 years and older (Northrup et al, 2004, Prismant, 2010). Patients aged 65 and older do not have equal risk of negative postoperative outcomes. While non-vulnerable older people, compared to the population of all ages, have no increased risk of postoperative complications (Zangrillo et al, 2006; Norkiene et al, 2007), frail elderly have a higher risk of experiencing post-operative complications (Scott et al, 2005). Highly prevalent complications after cardiac surgery include delirium, depression, pressure ulcer and infections. Incidences reported in the literature include among others: for delirium, 11.9% to 43.1% (Katznelson et al, 2010, Rudolph et al, 2010), for depression, 15% - 18% (Tully et al, 2010; Hellgren & Stahle 2005), for pressure ulcer 13% - 18% (Feuchtinger et al, 2007; Sewchuk et al, 2006) and infection 1.3% - 2.4% (Kanafani et al 2009; Filsoufi et al, 2009).

Intervention
For developing the multicomponent complex intervention, we followed the guidelines for developing and evaluating complex interventions of the new Medical Research Council (Graig et al, 2008a. On the basis of a systematic review for effective preventive interventions; an etiological study on links between preadmission patients characteristics and the occurrence of postoperative complications; a prognostic study where 4 prediction models are developed for predicting the risk of occurrence of postoperative complications; interviews among patients to the hospital and needs during the admission period and a survey among 450 nurses to their views on postoperative complications, a multicomponent intevention is developed to prevent the occurence postoperative delirium, depression, decubitus and infection cardiac surgery in patients of 65 years and older. In addition, the intervention is reviewed by experts in the areas of delirium, depression, pressure ulcers, infection and anesthesiology. It is also reviewed by practice experts (doctors and nurses) in three hospitals participating in this survey.
The intervention will be performed by the POS-nurse during a visit of the patient to the pre-op screening consultation (POS-office hours) in the preadmission phase. The intervention begins with a general part for all patients aged 65 and over, which also include selecting patients with an increased risk for post-operative delirium, depression, pressure ulcers and/or infection. If a patient is screened positive on increased risk, a specific intervention follows.

Study objective

Study question and objective
At this stage of developement of the multicomponent is intervention it is unclear whether the intervention is feasible in practice. Therefore the question: Is this multicomponent preadmission intervention feasible in practice

and is there effectiveness te be expected?
Assuming that:
1. Not all elderly patients are equally at risk for the occurrence of postoperative care-related complications, and
2. some of this risk can be reduced in the preadmission period (Kendel et al, 2010; Roth et al, 2006),
is the purpose of this feasibility study of the PREDOS project to test the multicomponent intervention to improve the preadmission physical, social and psychological condition of the patient, to prevent one or more of the postoperative complications.

Study design

In piloting and feasibility testing questions to ask yourself include: Have you done enough piloting and feasibility work to be confident that the intervention can be delivered as intended? Can you make safe assumptions about effect sizes and variability, and rates of recruitment and retention in the main evaluation study?
In this feasibility study, the multicomponent intervention will be tested for feasibility in patients, nurses and doctors. The (multicomponent) intervention will take place in the period before hospitalization. The (multicomponent) intervention seeks to reduce delirium, depression, pressure sores and infections in the postoperative phase.

Design
The feasibility study consists of an observational study of patients scheduled for cardiac surgery at UMC Utrecht, St. Antonius Hospital in Nieuwegein and the Isala Clinics in Zwolle in the period December 2011 - May 2012. Using the developed prediction models in this pilot study the group of older patients (65 years and older) vulnerable patients will be selected. For this purpose during the preadmission screening (POS) data will collected. Immediately during the visit of the patient's nurse at the POS is clear how vulnarable the patient is to the experience delirium, depression, pressure sores and / or infection after surgery during hospitalization. The POS nurse can then invite the patient to participate in the study. Patients have three choices:
1) participate and undergo the preadmission intervention;
2) participate, but only permission to use data (no intervention) and;
3) failed to cooperate with the investigation.

Intervention

Multicomponent intervention

Based on a systematic review to workable prevention interventions, an etiological study of relationships between preadmission patient characteristics and the occurrence of postoperative complications, a prognostic study in which

four prediction models were developed for predicting the risk of occurrence of postoperative complications, interviews with patients to needs during their hospitalization and a survey among nurses about their views on postoperative complications, preadmission interventions where designed to prevent the occurrence of delirium, depression, pressure ulcers and infection in the phase after the cardiac surgery in patients aged 65 years and older.

1. Interventions generally applicable to all patients during the preadmission screening (POS)

• Provide standard information to the patient at three levels:
1) The procedure (critical path);
2) What patients will experience or notice;
3) What the patient him or her self can and should do.
(This reinforces the self-management of the patient.)
• Provide information about nutrition and emphasize that a proper nutritional status is necessary for surgery. Use the malnutrition screening
cardiac surgery score (A screening tool without the predictor 'patient weight, especially developed for this patient group).
Assign the patient to a dietitian if an unintended weight loss is seen (usually caused by loss of appetite due to illness).
• Support the single patient or the patient with a social environment which is not (yet) ready for her or him to support the patient during the hospital admission. (This reinforces the self-management of the patient.) If applicable, announce that a temporary guest spot for the partner can be requested.

2. Test patients for being at risk for postoperative delirium, depression, pressure ulcers and infection.

In a prognostic study prediction models have been developed to apply in the phase prior to
the hospitalization for an individual patient's risk of postoperative occurrence of
a complication. Based on these models below scorecards are derived, which are listed below.
With each scorecard the risk of one of the four postoperative complications can be assesed.

• During the preadmission screening consultation ask the questions to predict the risk
on delirium, depression, pressure sores and infections.

* If a patient has a risk on postoperative delirium of 35% or more, the patient

has
an increased risk of experiencing a delirium.
(It is estimated that about 1 out of 10 patients after 65 years and older
is at risk of having a delirium after cardiac surgery).

Delirium Risk Score Card during Preadmission Screening
(Consultation) Points
- Previously experienced a
delirium 1
- Diagnosis of
Alzheimer
1
- Stroke and / or a history of a
TIA 1
- Uses a cane or
walker
1
- Does support from family / friends (mantle-care) as
living alone or no active support
partner 1
- Is a
religious
1
-
Single
1
- Use a
benzodiazepine
1
Total (increased risk of delirium is 4 or higher)

* If a patient has a risk on postoperative depression of 22% or more, the
patient has
an increased risk of experiencing a depression.
(It is estimated that approximately 1 out of 9 patients of 65 years and older
after
is at risk of experiencing a depression after cardiac surgery).

Depression Risk Score Card during Preadmission Screening
(Consultation) Points
- Use a
benzodiazepine
1
- Deaf or hard of hearing a
very
1

- Physical
limit(s)*
1
- Is religious and has mainly contact with fellow
believers 1
- Use a
diuretic
1
Total (increased risk of depression is 3 or higher)

*) In the survey was asked whether the patient was disabled. The response categories were: 'deaf', 'blind', 'physical disability' and 'mental handicap'.

* If a patient has a risk on postoperative pressure ulcer of 20% or more, the patient has
an increased risk of experiencing pressure ulcer.
It is estimated that approximately 2 out of 25 patients of 65 years and older are
at risk of experiencing pressure ulcers).

Pressure Ulcer Risk Score Card during Preadmission Screening
(Consultation) Points
- Logistic EuroSCORE higher than 20%
risk 4
- History of
tricuspidalusinsufficiency
1
- Diabetes Type
1
2
- Physical
limit(s)*
1
Total (increased risk of pressure ulcers is 2 or higher)

*) In the survey was asked whether the patient was disabled. The response categories were: 'deaf', 'blind', 'physical disability' and 'mental handicap'.

* If a patient has a risk on postoperative infection of more than 15%, the patient has
an increased risk of experiencing an infection.
It is estimated that approximately 2 out of 13 patients of 65 years and older are
at risk of experiencing an infection).

Infection Risk Score Card during Preadmission Screening
(Consultation) Points
- Tricuspidalusinsufficientie a history
of 5
- Uses three
benzodiazepines
3
- Uses steroid
(s)
5
- Uses a cane or
walker
4
- Uses a
wheelchair
7
- Mainly a sedentary profession had during a working
life 1
Total (increased risk of pressure ulcers is 2 or higher)

These scorecards can be used manually. As indicated earlier, there are (more detailed) models that can be used with the computer. These can also be used at the POS, while using a computer. The scorecards are derived from these models. The tresholds are for the (more accurate) models. The cut-off point at the bottom of the scorecard are derived from these thesholds.

3. Preventive measures for patients with an increased risk of postoperative Delirium:

• Inform the patient and her or his family to watch for symptoms of delirium together with the nurses and doctors and, if necessary, to notify nurses. (Self-management of the patient and her or his family contribute to successfully gothrough the postoperative phase in the hospital.) The patient may notice an incipient delirium to herself that she or he is an increase experience of forgetfulness, slowly in a kind of haze live, feel fear and sometimes excited. When the delirium continues, the patient lives in a haze (a nightmare) itself with seeing, hearing or feeling strange things. (Patients with delirium presents is a combination of cognitive problems, varying levels of consciousness, changes in sleep-wake pattern, alternating restlessness (often accompanied with fear and excitement), hallucinations (dreamlike perception of things not occur in reality) and other abnormalities in the perception.) See also the Guide for patients and their families who suffer with delirium. (http://www.argo-rug.nl/html/Handreiking_Delier.php).
• In the context of combating malnutrition / dehydration ask the patient what

she or he likes to eat and drink and advise the patient to tell the nurse what this favorite food and drink is and try them to make it 24 hours a day available for the patient. In consultation with the nurses, the family can also care for it. Furthermore, nurses and family regularly offer something to the patient.
• Discuss with the patient that immobility for longer than necessary is not good for the patient. Discuss with the patient having a good position in bed and doing active or passive motion exercises.
• In order to control problems with sleeping, ask the patients for its sleeping habits. Discuss with the patient and family to correspond as much as possible these habits with the routine in the hospital and discuss this with the nurses. Ensure that a proper distinction between day and night is clear to the patient by e.g. change for the night and counter many stimuli.
• Make sure the patient uses her or his aids (glasses, hearing aid, walking stick, etc.) and discuss the importance of to use these aids especially during the admittance period in the hospital. Discuss with the family to ensure that the patient has these aids at hand and actually use in the hospital.
• Discuss with the patient to have clock and / or a calendar for its own, so they can to orient themselves.
• Emphasize during the preadmission screening (consultation) the importance of that the patient should like to have information on the surgery and anesthesia. The patient him of herself must have an idea of how to deal with the complications such as delirium. (Patients aged 65 years and older who are mentally well prepared for the hospital admission with cardiac surgery are much less likely to develop a complication after surgery and when it occurs it is less complicated.)
• Discuss with the patient her of his wishes and possibilities for daily visits from family and friends of the patient. Discuss with family the importance of the presence of a trusted person postoperatively. Explain the occurrence of delirium in relation to disorientation. Ask the family to see if they possibly overnight can be requested to be contacted if something happens to the patient (such as delirium).

The ward:
• Report that the patient in question is amenable to the postoperative increase of delirium and that this is a serious potential barrier to the postoperative recovery. Indicate that these patients should be screened for delirium (e.g. DOS) postoperatively (3x per 24h) and when positive on the screening or suspected apart from the screening, to send in for diagnosis and treatment (Haloperidol). and to identify and treat any physical cause (infection, specific low blood levels, constipation, urinary retention).

4. Preventive measures for patients with an increased risk of postoperative depression:

• Learn relaxation breathing to the patient that she or he can do before an

during hospitalization.
(Relaxing excercizes gives the patient a tool to control stress and anxiety.)
• Advise the patient relaxing music (MP3 player or similar) to carry and it also prepared prior to the hospitalization. (Relaxing gives the patient a tool to control stress and anxiety.)
• Discuss with the patient her of his wishes and possibilities for daily visits from friends.
• Inform the patient and her or his family to watch for symptoms of complications together with the nurses and doctors, and inform the nurse if necessary. (Self-management of the patient and his or her relatives help the successful completion of the postoperative phase.) The patient may notice an incipient depression herself that she or he feel depressed, feels no more fun , can not concentrate well and has sometimes no appetite. (Patients with delirium present with a depressed mood, loss of interest or positivity or any enthusiasm, sometimes with guilt, low self-worth, disturbed sleep patterns, lack of appetite, low energy and low concentration.)

The ward:
• Report that the patient in question is amenable to postoperative increase of depression and that this is a potential barrier to postoperative recovery. Emphasize that the patient also should be screened for depression (with a screening tool used by the ward). And with positive screening for depression or a suspicion of, the practitioner will be informed and asked for treatment.

5. Preventive measures for patients with an increased risk of postoperative pressure ulcers:

• Inform the patient and his or his family together with the nurses and doctors to watch for signs of pressure ulcer stage 1 (no timely change of location and appearance of non blanchable redness at the mooring) and notify the nurses if necessary. (Self-management of the patient and her or is family contributes to successful completion of the postoperative phase.)

The ward:
• Report that the patient in question is vulnarable to experience postoperative pressure ulcers and that this is a serious potential barrier to the postoperative recovery. Also indicate that this patient should be given priority to pressure ulcer prevention, even if seriously ill after surgery and that funds and materials for this patient to be deployed. At the moment the patient is removed from the ICU or operating room use a pressure reducing mattress directly, so the patient does not have to be tilt again. Place the heels free as long as the patient is not mobile. Change lie position every 3 to 4 ours if necessary. Report that for this patient postoperatively (3x per 24h) the risk categories should be scored and the accompanied risk prevention measures must be taken (such as indicated in the CBO pressure ulcer guideline).

6. Preventive measures, for patients an increased risk of postoperative infection:

• Provide standard information that the patient may experience pain and that pain treatment is available and adequate pain treatment is necessary for recovery after surgery. (Adequate pain therapy helps the patient was less tense and taking better care for her- or himself (self-management.)
• Teach the patient breathing exercises, and report that the patient if necessary together with the physiotherapist will do these exercises after the operation. (Breathing exercises help avoiding a pneumonia caused by a lung infection)
• Inform the patient and her or his family to watch together with the nurses and doctors for signs of a complication and if necessary to inform the nursing on time. (Self-management of the patient and her or his family contribute to the successful completion of the postoperative phase.) The patient may notice an initial infection to her- or himself by that she or he is in pain (the surgical wounds, respiratory tract, bladder), feel very uncomfortable or very ill and is not mobile. (The most common infection in elderly cardiac surgery patients are infections of surgical wounds, the bronchi and lungs and bladder.)
• Instruct the patient not to touch the wound with his or her hands and not wash the wound with soap, but just to shower it off with tap water and to pat it dry afterwards.

The ward:
• Report that the patient in question is susceptible to an infection postoperatively and that an infection is a serious potential barrier to the postoperative recovery. Indicate that proper nutrition and the existing decontimination policy (0.12% chlorhexidine gluconate (CHX)) has an effect in preventing infections.

Study burden and risks

- The intervention itself: One to half hour screening, information and motivational interview during preadmission screening (first visit).
- At discharge a few questions about satisfaction with the procedure

Contacts

Public
Universitair Medisch Centrum Utrecht

Bolognalaan 101
3584 CJ Utrecht

NL
Scientific
Universitair Medisch Centrum Utrecht

Bolognalaan 101
3584 CJ Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Scheduled for cardiac surgery, 65 years or older and minimum waiting time between the preoperative screening and the hospitalization of 1 day, and Dutch speaking.

Exclusion criteria

Psychiatric illness, heart and lung transplantations, intraoperative death, preoperative infection or intubation, allergic for chlorhexidine and legal incapacity.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38065.075.11