Determinants of patient satisfaction in light trauma care in hospitals versus in general practitioners

Patient satisfaction in treatment of non-complex fractures and dislocations in hospitals versus in general practitioners: a prospective cohort study

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PROTOCOL TITLE 'Determinants of patient satisfaction in light trauma care in hospitals versus in general practitioners'

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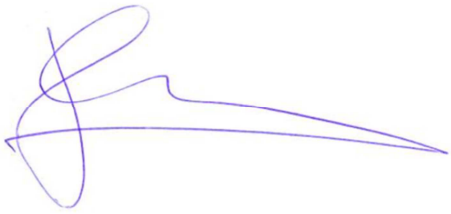
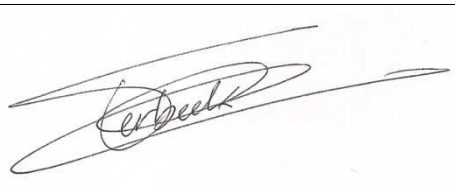
H. Burger, **Associate professor of Epidemiology**		**05-05-2017**
T. Verbeek van Buuren, **Postdoctoral researcher**		**05-05-2017**

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SUMMARY

Rationale: In the Netherlands, diagnostics and treatment of fractures and dislocations are generally organized in the secondary care setting. In contrast, since January 2017 the general practice 'Zorgplein Lemmer' provides equal care for patients with non-complex fractures or dislocations. In this practice, regular X-ray diagnostics are used, which are digitally transmitted to the radiologist. When a non-complex fracture or dislocation is diagnosed, the for this purpose well-trained general practitioner provides the patient with a splint or sling and provides follow-up consults in his practice. While light trauma care is provided in several general practices in the Netherlands and healthcare professionals in both the general practice and the hospital are very satisfied with this provided care, it is unknown what the patient satisfaction level is and which determinants affect this patient satisfaction. Nowadays, substitution of care from the secondary to the primary care setting is stimulated by the government and insurers and in that light we aim to study the patient satisfaction of light trauma care for non-complex fractures or dislocations in the primary care setting in comparison to the secondary care setting. When the general practitioners in our study obtain similar results as the nearby hospitals, light trauma care may be substituted nationwide and beyond.

Objective: To assess patient satisfaction of light trauma care in the primary and secondary care setting. In addition, we aim to study demographic factors, treatment results, time consumption and costs to assess which determinants are responsible for the patient satisfaction.

Study design: Observational cohort study including patients presenting at the X-ray facility in the general practice 'Zorgplein Lemmer' and patients presenting at the X-ray facility of the Antonius Hospital Sneek, with non-complex fractures or dislocations.

Study population: 200 patients (≥12 years old) with fractures or dislocations which are non-complex such that they can be treated in the primary care setting. This sample size will allow us to demonstrate effect sizes of 0.4 (small to medium) or over with 80% (beta 20%) power using a two-sided alpha of 0.05.

Determinants: demographic factors (age, sex, comorbidity), nature of the trauma, treatment setting (in general practice or in the hospital, distance to treatment center), treatment results (functionality scores, complications, general health, quality of life), time consumption and costs.

Main study parameters/endpoints:

Primary:

- Patient satisfaction (questionnaires after 1, 6, and 12 weeks)

Secondary:

- General health (GHQ questionnaire), age, SES (after 1 week)
- Complications (e.g. secondary dislocation and pain scores; questionnaire after 12 weeks)
- Physical function (questionnaire after 12 weeks)
- Time consumption (questionnaires after 1, 6, and 12 weeks)
- Costs (economic evaluation; questionnaire after 12 weeks).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Since this is an observational study using a limited number of questionnaires in patients who receive regular care, there is no risk associated with participating in this study. The burden for participating patients will very low because they will only be asked to fill in a few questionnaires, which take about one and a half hours in total to fill in.

1. INTRODUCTION AND RATIONALE

In the Netherlands, diagnostics and treatment of bone fractures and dislocations are generally organized in the secondary care setting. When a fracture or dislocation is presumed, most general practitioners refer the patient to an X-ray facility in a nearby hospital. When the fracture or dislocation is confirmed, an emergency care doctor or trauma surgeon generally provides the treatment and follow-up. In contrast, since January 2017 the general practice 'Zorgplein Lemmer' provides equal care for patients with non-complex fractures or dislocations. In this practice, regular X-ray diagnostics are used, which are digitally transmitted to the radiologist. When a non-complex fracture or dislocation (a so-called 'light trauma') is diagnosed, the for this purpose well-trained general practitioners provide the patient with the usual care (e.g. a splint or sling) and provides follow-up consults in his practice. While light trauma care is provided in several general practices in the Netherlands and healthcare professionals in both the general practice and the hospital are very satisfied with this provided care, it is unknown what the patient satisfaction level is and which determinants affect this patient satisfaction. Nowadays, substitution of care from the secondary to the primary care setting is stimulated by the government and insurers and in that light we aim to study the patient satisfaction of light trauma care for non-complex fractures or dislocations in the primary care setting in comparison to the secondary care setting. When the general practitioners in our study obtain similar results as the nearby hospitals, light trauma care may be substituted nationwide and beyond.

2. OBJECTIVES

Primary Objective:

To assess patient satisfaction of light trauma care in the primary and secondary care setting.

Secondary Objective(s):

In addition, we aim to study demographic factors, treatment results, time consumption and costs to assess which determinants are responsible for the patient satisfaction.

3. STUDY DESIGN

This is an observational cohort study including patients presenting at the X-ray facility in the general practice Zorgplein Lemmer and patients presenting at the X-ray facility of the Antonius Hospital Sneek, with an X-ray confirmed diagnosis of a non-complex fracture or dislocation and planned to be treated in either the Zorgplein Lemmer or Antonius Hospital Sneek. Patients aged 11 years or younger, and/or presenting outside ordinary business hours are excluded, due to possible inclusion bias. After inclusion the follow-up questionnaires continue for 12 weeks. The total duration of the study is 18 months.

4. STUDY POPULATION

4.1 Population (base)

The base population consists of patients in the region around Lemmer and Sneek.

4.2 Inclusion criteria

Eligible patients must meet the following inclusion criteria:

1. X-ray confirmed diagnosis of a non-complex fracture or dislocation, which can be treated in the primary care setting according to the treatment protocol.
2. Ability of the patient or assigned representative to understand the content of the patient information/informed consent form.
3. Signed and dated written informed consent. Parents of patients of age 12-17 must provide a signed and dated written informed consent as well.

4.3 Exclusion criteria

1. Age 11 years and younger.
2. Patients presenting outside ordinary business hours.

4.4 Sample size calculation

The sample size calculation has been performed based on the difference in patient satisfaction. There was no literature available concerning patient satisfaction in trauma care in general practices or hospitals. Therefore, we based our sample size calculation on an estimated effect size. With a significance level of 5%, a power of 80% and equal treatment groups, a sample size of 200 patients (100 per group) was calculated. This sample size will allow us to demonstrate effect sizes of 0.4 (small to medium) or over.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

Treatment in the general practice is identical to treatment in the hospital and is equal to the national guidelines. Those are described in the online treatment protocol 'Behandelprotocollen Lichte traumazorg in de eerste lijn'. This study has no impact on speed, choice, location or execution of diagnostics or treatment and thus is an observational study.

5.2 Use of co-intervention

Patients are allowed to ask treatment next to the treatment according to the treatment protocol.

6. METHODS

6.1 Study parameters/endpoints

6.1.1 Main study parameter/endpoint

Patient satisfaction measured using the Patient Satisfaction Questionnaire Short Form (PSQ-18; 12 weeks after treatment).

Marshall GN Hays RD. The Patient Satisfaction Questionnaire Short-Form (PSQ-18). Santa Monica, CA: RAND, 1994.

6.1.2 Secondary study parameters/endpoints

1. Patient satisfaction measured using the PSQ-18 (1 and 6 weeks after treatment).
   Marshall GN Hays RD. The Patient Satisfaction Questionnaire Short-Form (PSQ-18). Santa Monica, CA: RAND, 1994.
2. Complications of treatment and pain scores (12 weeks after treatment).
3. Physical functioning according to the 12-item World Health Organisation (WHO) Disability Assessment Schedule II (12 weeks after treatment).
   World Health Organization Disability Assessment Schedule II (WHO-DAS II) WHO, Geneva (2000) www.who.int/icidh/whodas/whodasversions/12int.pdf
4. Limitations in functions of upper extremities (if applicable) according to the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (12 weeks after treatment).
   Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder, and hand). Am J Ind Med, 29 (1996), pp. 602–608
5. General health status according to the 12-item General Health Questionnaire (GHQ-12; 12 weeks after treatment).
   Goldberg, D. P. (1972). The Detection of Psychiatric Illness by Questionnaire. Maudsley Monograph No. 21. Oxford University Press: Oxford.
6. Quality of life using the EQ5D questionnaire (12 weeks after treatment).
   Euroqol Group (1990) Euroqol—a new facility for the measurement of health-related quality of life. Health Policy 16:199–208
7. Time consumption (waiting time, treatment time, travelling time and distance; 1, 6, and 12 weeks after treatment).
8. Costs (12 weeks after treatment).

6.1.3 Other study parameters

Baseline data: age, gender, social economic status, location and severety of the trauma (1 week after treatment).

6.2 Randomization, blinding and treatment allocation

This is an observational cohort study, so randomization and blinding are not applicable.

6.3 Study procedures

Hospital

Light trauma care (treatment of non-complex fractures and bone dislocations) is generally provided by emergency care doctors, under supervision of (trauma) surgeons. When a radiologist diagnoses a non-complex fracture or dislocation, the emergency care doctors clinically assess the patients, as well as evaluate the X-ray diagnosis. When the emergency care doctor agrees with the diagnosis he composes a treatment plan. When needed, he may assess a trauma surgeon for supervision. The treatment plan is presented to the patient and after approval the emergency care doctor treats the patient. The trauma surgeon provides follow-up consults in his outpatients' clinic. Treatment, follow-up consults, all procedures and management are provided according to the standard of surgical care in the Antonius Hospital Sneek.

General practice

Zorgplein Lemmer is a general practice where regular general medical care is provided by three general practitioners, supported by nurse practitioners, nurses, and doctor's assistants. The Antonius Hospital Sneek equipped this general practice with a regular X-ray facility, which is operated by a radiographer who is employed by the hospital. Digital images are digitally transmitted to in the Antonius Hospital Sneek, where they are assessed by a radiologist. When a non-complex fracture or dislocation is diagnosed, one of the for this purpose well-trained general practitioners is asked to clinically assess the patient, as well as to evaluate the X-ray diagnosis. When the general practitioner agrees with the diagnosis and no contraindications for treatment in the general practice (e.g. severe divergent bone position, suspicion of damage to nerves, vessels or tendons) are indicated, the general practitioner composes a treatment plan according to the treatment protocol. When needed, the general practitioner telephonically assesses a trauma surgeon from the Antonius Hospital Sneek, who is able to assess the X-ray as well. The treatment plan is presented to the patient and after approval the general practitioner treats the patient. This general practitioner also provides follow-up consults in his practice. Treatment, follow-up consults, all procedures and management is provided according to the hospital's standard of care.

Any other treatment not specifically described in this investigation is performed according to the standard of surgical care in the Antonius Hospital Sneek.

Inclusion of participants

The assessment of eligibility will be performed by participating general practitioners near Lemmer, who will approach each potential study patient and inquire about their interest and eligibility in participating in this study. Both the Zorgplein Lemmer as well as the Antonius Hospital Sneek will be informed and trained about the importance of recruiting consecutive patients. If the patient wishes to participate, a legally eligible member of the research team or staff will go through the informed consent process, explaining the purpose of the study, procedures, risk/benefits, alternatives to participation and data protection. Each patient choosing to participate will sign and date an informed consent form. Parents of participants of age 12-17 years old at the date of informed consent must provide a signed and dated written informed consent as well. A copy of the signed informed consent form(s) will be placed into the patient's medical record and the investigator site file and one copy will be handed over to the patient. All patients with written informed consent will be allocated to a unique patient study number. The date of informed consent and the recruitment information is entered in the study database. All patients who commence treatment within the study are considered as enrolled and all enrolled patients should be followed up within the study, except if their study participation is prematurely terminated. All patients recruited in the Zorgplein Lemmer or Antonius Hospital Sneek are automatically allocated to the Zorgplein Lemmer and Antonius Hospital Sneek analysis group, respectively.

6.4 Withdrawal of individual subjects

Patients are allowed to withdrawal at any moment without consequences for their treatment plan or follow-up consultations.

6.5 Follow-up of subjects withdrawn from treatment

Patients are allowed to withdrawal at any moment without consequences for their treatment plan or follow-up consultations.

7. SAFETY REPORTING

7.1 Section 10 WMO event

In accordance to section 10, subsection 1, of the WMO, the investigator will inform the subjects and the reviewing accredited METC if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited METC, except insofar as suspension would jeopardize the subjects' health. The investigator will take care that all subjects are kept informed.

8. STATISTICAL ANALYSIS

All statistical tests will be performed blinded for treatment allocation.

8.1 Primary analysis

The primary analysis will be conducted using data from all enrolled patients. The reported patient satisfaction at 12 weeks after treatment will be reported at the patient level along with the 95% CIs according to both treatment groups. In addition, univariable and multivariable regression models will be used whereby the outcome will be the patient satisfaction related to the treatment.

8.2 Secondary analyses

Secondary analyses will be conducted using data from all enrolled patients. Initially, univariable statistical tests (eg, $\chi 2$ test or Fisher's exact test for categorical variables; t test or Wilcoxon rank-sum test for continuous variables) will be used to evaluate differences in outcome scores between the two treatment groups. Subsequently, data will be analyzed using multivariable regression models to estimate differences in mean patient satisfaction scores using possible predictors (eg, complications, pain scores, physical functioning, EQ-5D, time consumption) between both treatment groups.

8.3 Cost-effectiveness

The proposed cost–utility analysis will use decision modeling and sensitivity analysis techniques to ensure the robustness of the study's conclusions. Cost-effectiveness will be assessed using the incremental cost-effectiveness ratio, which is determined by calculating the difference in costs divided by the difference in QALYs between both treatment groups.

9. ETHICAL CONSIDERATIONS

9.1 Regulation statement

The study will be executed according to law (WMO). All data will be processed and saved anonymously.

9.2 Recruitment and consent

Patients have sufficient time (approximately several hours between the moment of referral by the general practitioner, the moment when the assessment of eligibility is performed by participating general practitioners near Lemmer, who will approach each potential study patient and inquire about their interest and eligibility in participating in this study and the moment of X-ray diagnostics and composing a treatment plan) to ask questions and to consider participation. Patient information, website and informed consent forms are easy-to-read. Patients are allowed to withdrawal at any moment without consequences for their treatment plan or follow-up consultations.

9.3 Benefits and risks assessment, group relatedness

This is an observational cohort study consisting of questionnaires, thus there are hardly any risks associated with participation in this study. The burden of patients is considered as low because the study only consists of questionnaires (in total about 1.5 hours).

9.4 Compensation for injury

Because all interventions in this study (the questionnaires) are non-invasive, there is no obligatory insurance for a liability insurance.

9.5 Incentives

Participants have no (extra) costs by participating in this study. There is no compensation for participation in this study.

10. ADMINISTRATIVE ASPECTS AND PUBLICATION

10.1 Handling and storage of data and documents

All data is processed anonymously. All participants are coded and blinded.

10.2 Annual progress report

At their request, the METC may receive an annual report stating inclusion of participants, questionnaires completed, and adverse events.

10.3 End of study report

Researchers will inform the METC about the end of the study within 8 weeks after the last inclusion. The end of the study is defined as the last inclusion. When the study is terminated beforehand, the researchers will inform the METC.

Within a year after the end of the study the researchers will report the results of the study to the METC.

10.4 Public disclosure and publication policy

Publication(s) about this study will never contain personal data of individual participants.