Traumatic Splenic Injury and Management "Quality of Life and Clinical Outcomes of Treatment for Splenic Injury after Trauma" Retrospective study

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The primary objective of this project is to demonstrate the equivalence of treatment of traumatic splenic injury with splenic artery embolization (SAE) compared to splenectomy and non-operative management (NOM) in terms of quality of life measured...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries NEC
Study type	Observational invasive

Summary

ID

NL-OMON42351

Source
ToetsingOnline

Brief title
SPLENIQ study

Condition

- Injuries NEC
- Therapeutic procedures and supportive care NEC

Synonym
Splenic injury, splenic laceration

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Project Trauma TopZorg van ZonMw

Intervention

Keyword: Embolization, Quality of life, Spleen, Trauma

Outcome measures

Primary outcome

(I) RETROSPECTIVE

PRIMARY

Quality of life is assessed with the generic 26-item World Health Organization

Quality of Life-Bref (WHOQOL-Bref) [14]. This measure assesses four domains

(Physical health, Psychological health, Social relationships, and Environment)

and a general facet *Overall QOL and general health*.

The short-form (12) health survey is a shorter version of the SF-36, which is

used to evaluate individual patients health status, researching the

cost-effectiveness of a treatment and monitoring and comparing disease burden.

Secondary outcome

(I) RETROSPECTIVE

SECONDARY

Furthermore the three treatments will be compared in terms of clinical

outcomes, recovery related outcomes and cost outcomes. Also imaging outcomes

will be investigated in the SAE group, thereby identifying morphological

(versus immunological) aspects of the spleen after endovascular treatment.

The following endpoints apply to each of the outcomes:

- Clinical: complications during and/or after treatment; failure rate (technical, clinical); any re-intervention or additional therapy

- Recovery related: hospital stay (days)

- Imaging: how does the spleen morphologically look like, in patients who underwent embolization treatment of the splenic artery in case of traumatic splenic injury? Splenic morpholical characteristics such as: volume; necrosis; splenosis; calcifications; chronic infarction morphology

Reference data from the manuals of the associated questionnaires will serve as a control group. Results of the comparison between our retrospective group and the reference data will be used for the design of the prospective study.

Study description

Background summary

Morbidity and mortality are the most commonly used outcome parameters in the literature on trauma care. However, most patients will survive their trauma and depending on the severity of the trauma, they will be limited in daily life, both physically and mentally. Multiple studies has shown psychological complaints and decreased quality of life (QOL) in severely injured patients. [1-3] These factors have a major social and economic impact because it often involves young patients, who frequently become unsuitable to return to work, to reintegrate back into society or to retrieve their previous activity level. Despite that QOL is an important factor, it is still not widely used in trauma care studies.

In splenic injury after blunt abdominal trauma much is known about morbidity and mortality, but still very little in terms of QOL. The spleen is one of the most frequently injured organ after blunt abdominal trauma. [4] Internal bleeding caused by abdominal organ injury is one of the main causes of death after trauma, and a missed splenic rupture is the most common cause of

preventable death in trauma patients. [5,6]
Presently, the standard of care in hemodynamically stable patients is nonoperative management (NOM) involving close observation of the patient, with success rates up to 90%. [4] Angiography and splenic artery embolization (SAE) can be used as a supplement to NOM when necessary. The success rate of SAE ranges from 73% to 100% with an overall success rate of NOM combined with SAE from 86% to 100% (most studies reporting success rates greater than 90%). [7]
There is still much unknown about splenic function after SAE, but there seems to be a link between splenic volume and immunologic status of the patient. Preservation of splenic function is one of the biggest advantages of NOM and SAE. Avoiding post-splenectomy complications such as sepsis and thrombocytosis and potentially preventing a lifetime risk of invasive infections. [8,9] In other words, avoiding factors with major impact on quality of life.
In all three therapies (NOM, SAE and surgery) minor and major complications may occur. Patients treated with SAE have a risk of developing splenic infarction, abscesses or cysts, with distal embolization having a significantly higher association with major complications compared to proximal embolization. [10]
A recent study suggests that there are prognostic factors for failure of NOM in the treatment of adults with blunt splenic injury. Strong evidence exists for: age of 40 years or above, Injury Severity Score (ISS) of 25 or greater and American Association for the Surgery of Trauma (AAST) splenic injury grade of 3 or greater. [11] Failure of therapy leads to more interventions, longer hospital stay and higher mortality; resulting in decreased QOL and increased costs.

There is a growing demand for a (national) guideline or protocol for clinical decision-making in traumatic splenic injuries. For that reason it is important to determine the optimal selection criteria for the appropriate management strategy. This can only be achieved by looking at the entire process surrounding a trauma patient.

The first aim of this project is to determine/compare the quality of life (QOL) and clinical outcome of patients after therapy (NOM, SAE, splenectomy) for traumatic splenic injury. First, this will be done with a retrospective group of patients and the results hereof will be extracted into the prospective part of the study.
The second aim is (I) to examine therapy-related complications, (II) to establish the necessity of additional therapies, (III) the assessment of splenic function related to splenic morphology (MR imaging) after treatment, and (IV) to find the prognostic factors for failure of non-operative management (NOM) in patients with splenic injuries.

Finally, with the acquired data from this study a patient-oriented protocol will be provided for the management of traumatic splenic injury.

Study objective

The primary objective of this project is to demonstrate the equivalence of treatment of traumatic splenic injury with splenic artery embolization (SAE) compared to splenectomy and non-operative management (NOM) in terms of quality of life measured by WHOQOL-Bref and quality of life short-form-12 questionnaire.

Furthermore, the three treatments will be compared in terms of clinical outcomes, recovery related outcomes, quality of life outcomes and cost outcomes. Also imaging outcomes will be investigated in the SAE group, thereby identifying morphological (versus immunological) aspects of the spleen after endovascular treatment.

Finally, with the acquired data from this study a patient-oriented protocol will be provided for the management of traumatic splenic injury.

Specific questions:
1. Is SAE superior to splenectomy in terms of quality of life outcome after treatment?
2. How do NOM, SAE and splenectomy compare in terms of complications during treatment, need for re-intervention and hospital stay (days)?
3. How does SAE affect imaging outcomes (splenic morpholical characteristics such as volume, necrosis, splenosis, calcifications or chronic infarction morphology) 1 month and 1 year after embolization?
4. Can we design a patient-oriented protocol for the treatment of traumatic splenic injury?
5. Is there a difference between proximal versus distal SAE? (immunologic/imaging)
6. What are the prognostic factors for failure of NOM?

Study design

A combination of a retrospective and a prospective multicentre cohort study will be conducted comparing non-operative management (NOM), splenic artery embolization (SAE) and splenectomy in patients with splenic injury after blunt abdominal trauma. This protocol is designed for the retrospective part of the study. This is supplemented with a systematic review of the literature that will be written according to the PRISMA criteria [13].
The literature search will consist of a staged process in order to retrieve all relevant articles. First, an extensive literature search will be done using PubMed, Cochrane, and PsycINFO and the publication date between January 2005 until the date of the search. The reference lists will be canned to identify relevant articles that did not appear during the literature search. This search will result in an overview of the latest opinions with insight in state-of-the-art management of traumatic spleen injury.
The total duration of the project is 48 months.

Study burden and risks

Questionnaires quality of life (all patients):
If patients have an Internet connection, they will fill in the questionnaires online. This will take approximately 15-30 minutes. If patients do not have an Internet connection, they will receive the questionnaires by post. This will possibly take more time.

MRI scan of the abdomen (only patients who have been treated with embolization of the splenic artery):
Patients will be called for a voluntary one-time MRI abdomen in the St. Elisabeth Hospital in Tilburg. Undergoing an MRI scan of the abdomen could be uncomfortable and may cause some physical and psychological discomfort. There are no known harmful or biological effects. Prior to the scan, contraindications for MRI will be excluded. Doing an MRI scan is necessary for this study to assess the spleen morphology after embolization of the splenic artery.
The MRI examination will take approximately 45 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
- With splenic injury after blunt abdominal trauma
- Currently 18 years or older
- For MRI: treated with splenic artery embolization (approximately 30 patients)
Retrospective: January 2005 to now

Exclusion criteria

- Insufficient knowledge of the Dutch language.
- Patients who died during or after treatment are (of course) excluded for questionnaires and MRI, not for clinical outcomes.;Exclusion for MRI only:
- Patients treated with SAE: patients who do not want to or are not able to undergo an MRI abdomen (for example pregnant women or other contraindications for MRI).
! Patients excluded for MRI still need to fill out the questionnaires. Also, their clinical outcomes will be processed in the database.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2016
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL54339.028.15