BMJ Open

Potential benefit in information providing and influence on patient anxiety and satisfaction by means of preoperative explanatory videos in total extraperitoneal inguinal hernioplasty: study protocol of a multicentre, double-blinded, randomised parallel-group controlled trial

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To cite: Lunger F, Frank F, Peros G, *et al*. Potential benefit in information providing and influence on patient anxiety and satisfaction by means of preoperative explanatory videos in total extraperitoneal inguinal hernioplasty: study protocol of a multicentre, double-blinded, randomised parallel-group controlled trial. *BMJ Open* 2021;**11**:e043702. doi:10.1136/bmjopen-2020-043702

► Prepublication history and supplemental material for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-043702).

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Received 11 August 2020
Revised 21 December 2020
Accepted 12 January 2021

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ABSTRACT

Introduction The use of electronic media in informed consent giving has become increasingly important in recent years. Due to the easy access to information via electronical media, patients are primed in a heterogeneous manner concerning expectations and wishes regarding surgical interventions. Inherent to its nature elective interventions are critically questioned as there is time for information gathering and reflection. In this study, we set out to investigate the effect of an educational video as a supporting element in the process of informed consent giving for one the most frequently performed interventions in general surgery, namely inguinal hernia repair.

Methods and analysis In a multicentre setup, eligible patients for primary inguinal hernia repair will be randomly assigned to one of three groups. All three groups will have a preoperative informed consent discussion with a physician in which they will eventually sign the informed consent sheet if participation is desired. Eventually, all three groups will get an online link. For two groups, the link will lead to a video with audiovisual information (an inguinal hernia video for the intervention group and a mock video for the control group). The intervention video provides basic principles of endoscopic extraperitoneal hernia repair. The second video is similar in length and design and displays general aspects of day surgery in the two study centres. All the three study groups will be provided with a copy of the informed consent form as it is standard by now. The third group's link will lead to the digital version of the informed consent brochure. Primary outcomes will consist of (1) score in a multiple choice test assessing gain of knowledge regarding hernia repair, (2) difference in the State-Trait Anxiety Inventory and (3) patient satisfaction questionnaire Individual Clinician Feedback (ICF, Picker Institute, Germany) as assessed 1–2 days after the first consultation. The study design guarantees double blinding, there will be no unblinding at any point. All patients will receive the same, quality and number of medical consultations as well as in the same surgical treatment. (Minor differences in the total extraperitoneal technique of the surgical treatment due to anatomical or pathophysiological differences are independent of the group allocation). Except for the additional videos, there will be no difference in in the information provided and the treatment prior, during or after the hernia repair.

Ethics and dissemination We plan to publish the study in a peer-reviewed journal. The proposed research project has been reviewed by the Cantonal Ethics Committee (BASEC-No 2020–01548). In accordance with national legal regulations in Switzerland stated by the Human Research Act, the proposed project was declared exempt from approval requirement.

Trial registration number NCT04494087; Pre-results.

Strengths and limitations of this study

- ► First multicentre double-blinded randomised controlled trial to investigate the impact of additional visual media on patient education during the process of informed consent in inguinal hernia repair.
- ► The secondary outcomes of this study will provide insight on the effect of counselling on anxiety, patient satisfaction and the development of chronic groin pain.
- ► The primary limitation of this study is its explicit focus on inguinal hernia, possibly limiting general applicability of the results.

INTRODUCTION

The use of electronic media in informed consent giving has become increasingly important in recent years as an increase amount of articles as well as reviews show.[1 2] Surgical procedures are becoming more complex as medicine advances. Common knowledge of complications on one hand and therapeutic alternatives on the other are constantly increasing. This is opposed by a healthcare system that has to operate in a cost-optimised manner in order to meet the demands of performance and financial expenditure. Time restraints often limit detailed patient health care provider conversations. In turn, it is often difficult for patients to follow the information provided during a surgical consultation,[3–7] possibly compromising the ability to make a truly informed decision.

In addition to the postulated better transfer of knowledge through an additional educational video, the reduction of anxiety before surgery will be determined with a questionnaire (State-Trait Anxiety Inventory, STAI).[8] Some positive effects of such an educational video in terms of knowledge advantage over a control group has already been shown.[9–11] In the field of thoracic surgery, patients with lung resections provided with an educational video showed a reduction in anxiety with respect to the forthcoming intervention and at the same time a subjectively increased feeling of a rise in knowledge.[12] Zieren *et al*[13] were able to show a reduction of the bureaucratic effort by video-assisted patient education in inguinal hernia operations, which in turn suggests a potentially positive effect on health costs. Although the effect on expenses is not in our primary interest, a follow-up study on economic effects is conceivable.

In the field of paediatric surgery, Book *et al* showed in a controlled randomised study a reduction of anxiety and an increase in knowledge in parents of paediatric patients who had undergone surgery on hernias. However, an increase in subjective patient satisfaction could not be shown.[14]

Due to the high risk of moderate an severe chronic postoperative inguinal pain of (estimated at about 10%–12%[15]), groin hernia repair is hardly comparable with many other standardised surgical interventions. Therefore, we want to study if patients informed with an explanatory video understand these interventional risks better and do react differently regarding the amount of pain killers taken and postoperative medical consultations. One study outcome will be the development of chronic groin pain as assessed during scheduled postoperative follow-ups.

Despite a rising number of studies with different approaches to audiovisual consenting were conducted within the last two decades—there is still much uncertainty about the effects on a range of outcomes, as Synnot pointed out in their systemic review. Although slightly positive trends can be seen regarding improvements of knowledge and satisfaction, available evidence quality was considered low to very low quality. There was no sufficient evidence to draw conclusion on the effect on patients' anxiety. Furthermore, 'many relevant outcomes were not evaluated in (high-quality) randomised trials'.[2]

One reason for the uncertainty of effects may also be the design of many previous studies. To the best of the authors knowledge, many of these uncertainties still exist since the last update of the afore-mentioned Cochrane review. Until today, we are not aware of any published or ongoing double-blinded, multicentre randomised controlled trial (RCT) that investigated the effect of audiovisual consent in inguinal hernia repair.

With approximately 600–700 cases per year, inguinal hernia surgery is the most frequently performed procedure at the Cantonal Hospital Winterthur. Our location is, therefore, one of the national centre hospitals with the most inguinal hernias operations.

In our clinics, it is common practice to follow up on our patients in-house. In the course of these follow-up appointments, we have often made the experience that many patients report of postoperative inguinoscrotal haematomas that have only occurred at home. Those who have already been warned of this possible complication usually describe that they were not worried about it. Patients who have not been informed about this, often call for a doctor's opinion postoperatively. These experiences from the clinical routine lead us to speculate that providing profound information might influence the occurrence and the degree of complications (pain) and the subjective assessment of the complication. As a result, patient satisfaction may be improved. In the field of inguinal hernia plastic surgery using the total extraperitoneal (TEP) method, no studies have been conducted to date on the influence of additional video information on perioperative anxiety reduction, patient satisfaction and knowledge advantage.

The presented study could, therefore, show scientifically not only the importance of patient education (with the help of 21st century media) rather than consenting for legal reasons, but by the design of a control group that gets provided a mock video a biased reduced result.

METHODS AND ANALYSIS

Study design

This research project is a prospective, randomised, controlled multicentre study. As proposed by the Consolidated Standards of Reporting Trials guidelines for reporting of parallel group RCTs, we will perform both intention to treat (ITT) and per protocol (PP) analyses.[16] The World Health Organization Trial Registration Data Set and the study protocol data and version identifier is available online as online supplemental files 1 and 2, respectively.

Patients

We plan to include all patients >18 years who present as elective referrals for surgery for inguinal hernia at the Cantonal Hospital of Winterthur as well as at the GZO Hospital Wetzikon.

Inclusion criteria

Participants who meet all of the following inclusion criteria will be included in this research project:

- Unilateral or bilateral hernia with indication for surgical therapy.
- Male and female patients aged over 18 years.
- Signed informed consent form for trial participation.

Exclusion criteria

If one or more of the following criteria are met, the participant will be excluded from the research project:

- Patients who have had surgery for ipsilateral or contralateral inguinal or femoral hernia.
- Combination interventions (umbilical and inguinal hernia repair, eg,).
- Cognitive, audiovisual or linguistic handicap raising concern of complete understanding of the research project.

Recruitment procedure

Patients with unilateral or bilateral first-time inguinal hernias are recruited if there is an indication for surgery according to current international guidelines and existing medical evidence.

Patients will be informed about this research project during the first surgical consultation and will receive information about the possibility of potential study participation. This document, which will be handed out to the study participant, includes the information that an internet link/QR code will be issued following the normal clarification consultation, which will lead to one of three different clarification modalities that complement the normal consultation that has already taken place. In this context, it is explicitly explained to the study participant that the content of information provided does not differ between the three modalities. This fact ensures that study participation and randomisation itself does not imply any potential disadvantages for one or the other group. The video was carefully designed and structured focusing on not providing any additional information as compared with what all three groups (including patients wo do not participate in the study) are being told during the counselling. No advantages or disadvantages regarding the content of information received are therefore to be expected from participation or non-participation in the study; the treatment or further procedure is then carried out according to the respective trial centre-specific 'standard of care'. After the process of informed consent, a standardised surgical explanation is provided, independent of the patient's decision.

Study arms

Hernia video

As stated above, the video of the intervention group will provide a 5 min summary explaining the basic principles of endoscopic extraperitoneal hernia repair, its possible complications and the postoperative course. After having watched the video carefully, participants should be able to correctly answer to a multiple-choice test containing 12 questions related to the aforementioned topics.

Mock video

This video is a general documentation of the 'typical' day of surgery in the day clinic. The information is essentially limited to the pictorial representation of the individual wards which the patient will pass through during the operation (arrival at the clinic, admission, transport to the operating theatre, recovery room, discharge).

The video explicitly does not provide any information that could be helpful for answering the quiz questions or for medical understanding of the operation itself.

Control group

The link of the third group leads to a digital version of the information sheet, which has already been discussed with all patients and handed out to all patients during the informed consent discussion. The digital version of the informed consent form allows the patient to read the information again. The third group, thus, corresponds to the standard of care.

Randomisation procedure and allocation concealment

Patients who can be included in the study according to the above stated criteria will receive a numbered, sealed envelope containing a link/QR code for one of the three aforementioned modalities along with the information sheet that was used for the standardised surgical explanation. Study participants are encouraged to follow the link assigned to their group at home. Patients are randomised using variable permuted blocks of 4, 6 and 8 using a computer-generated random sequence. Sequentially numbered, opaque, sealed envelopes containing the randomisation cards will be made by a research coordinator not involved in the study and kept in a locked office.

All study participants present themselves 1–2 days after the first consultation at the anaesthesiological consultation to assess their ability to receive an anaesthesia. Following the anaesthesia consultation, the study participants receive the multiple-choice quiz as well as the STAI. For this time frame, no unblinding strategy is foreseen. A discussion of the quiz/questionnaires with the anaesthesiologist is not planned.

According to national guidelines, the operation is carried out on an outpatient basis for unilateral procedures whereas for bilateral hernia an overnight stay is planned. Four weeks postoperatively, all patients are checked in our surgical consultation where clinical parameters as well as the data for the secondary outcomes are documented (STAI). All study participants are consulted again for a telephone follow-up about 3 months postoperatively. During this consultation, the occurrence of chronic groin pain will be assessed using the Numeric Rating Scale (NRS).

Intervention groups

The intervention video will not contain any additional information as compared with the information provided

during the consultation. It is intended to provide a lay summary of the planned surgical intervention, associated risks and as well as the postoperative course. Therefore, patients randomised to the mock or control group will not have any disadvantage in terms of provided information, as all the information in the hernia video is discussed during the consultation and provided in the information sheet that is handed out to all patients as according to standard procedure in our clinics.

After 1–2 days, the preoperative anaesthesiological assessment will take place at which a validated questionnaire will be handed out (primary outcome). As it is common practice in Switzerland, patients will enter the Hospital at the day of surgery. Based on national regulations, unilateral inguinal hernia interventions are planned in a day hospital setting while for a two-sided operation an overnight stay is planned. Postoperative analgesia is standardised and includes paracetamol (500 mg four times a day) and metamizole (1000 mg four times a day). The decision regarding discharge from the hospital is left to the discretion of the responsible physician.

The number of accesses to the individual link and how much of the video the patients watched will be electronically registered (server-based recording) for all patients.

Blinding

As described above, the proposed study design provides blinded allocation to the intervention or control groups. Neither the study participant nor the investigator involved in the explanatory consultation can identify the group allocation. The study will thus achieve double-blind status.

Statistics

Sample size calculation

Based on a previous study,[17] we calculated, a priori for the investigation of the primary outcome, a total number of 183 patients. This number was calculated for the primary outcome. According to this case number estimation 61 patients per group should be included. Using g-power,[18] an analysis of variance analysis was performed and a drop-out rate of 15% was postulated (power=0.8; α=0.05; f=0.25; N(min)=159).

Statistical analysis

Data analysis and evaluation are based on an ITT principle, an additional stratification by study centre as well as a PP analysis will be carried out. Quiz scores as well as the STAI and the ICF scores will be compared using the Kruskal-Wallis Test implementing appropriate correction methods for multiple comparisons. For categorical variables, χ^2 or Fisher's exact tests will be used. For all results, CIs as well as the minimal clinically significant difference will be reported if appropriate.

Furthermore, descriptive statistics will be reported using the mean and SD or median and IQR as appropriate. Statistical analysis is performed using SPSS Version 26 (IBM) and GraphPad Prism (GraphPad software).

Patient and public involvement

The development of the study hypothesis is based on a thorough review of available evidence in this research area. Patients or patient representatives of any kind were not involved in the development of the study protocol. Clinical experience shows that many patients repeatedly express understanding during the informed consent discussion. However, in the further course, especially in the perioperative setting, questions asked by the patients lead to the assumption that the supposedly very comprehensible content conveyed by the healthcare provider has not been fully understood. During conduction of the study, patients will not be informed about the results of the ongoing trial since there is no planned interim analysis. The patients will not be exposed to any additional stress due to the study design. After completion of the study, we plan to make the videos available to all patients requiring endoscopic inguinal hernia mesh repair.

OUTCOMES

Primary outcome

The primary outcome measures the score of correctly answered questions, which were asked in the quiz. It is a questionnaire with questions regarding background, indication, implementation, complications and postoperative course of TEP procedures. The questions asked check relevant aspects for the patient with regard to the planned operation. The structure of the multiple-choice quiz takes the 'single best option'. The questions are clearly posed and the correct answer is based on current guidelines for the management of inguinal hernia, which have been published by the European Hernia Society (EHS), American Hernia Society, International EHS (IEHS) and the European Association for Endoscopic Surgery and Other Interventional Techniques as a consensus document under the umbrella organisation 'HerniaSurge'.[19]

Secondary outcome

There are three secondary outcomes.

The anxiety score is determined using the Spielberg state anxiety inventory (STAI) test,[8] which validity has been shown by Vigneau and Cormier[20] as well as Bieling *et al*.[21] The inventory is based on a 4-point Likert scale and consists of 40 questions on a self-report basis. Scores range from 20 to 80 with higher scores indicating greater anxiety.

Patient satisfaction with regard to doctor–patient communication is recorded by the validated ICF questionnaire (Picker Institute Germany)[22] during a standard follow-up consultation 4 weeks after endoscopic inguinal hernia repair. The ICF questionnaire comprises 38 items concerning the patient's experience of the examination atmosphere, the comprehensibility of the physician's statements, the participation in decisions, the course of the conversation as well as sociodemographic characteristics of the patient. The items are assessed on an 11-point

Table 1 Project plan

	First outpatient appointment	Second outpatient appointment	Operation	Follow-up 1 (30 days)	Follow-up 2 (90 days)
Study consent	×				
Inclusion and exclusion criteria	×				
Consent discussion with surgeon	×				
Video (intervention, mock or link to informed consent brochure)	×				
Preoperative assessment with anaesthesiologist		×			
Multiple choice quiz		×			
STAI		×			
Operation			×		
ICF				×	
Follow-up examination				×	
Follow-up questionnaire					×

ICF, Individual Clinician Feedback; STAI, State-Trait Anxiety Inventory.

Likert scale from 0 to 10, with 0 as the most critical and 10 as the most positive experience.

To assess the effect on chronic pain, the pain is assessed using the NRS score during the follow-up consultation about 4 weeks after inguinal hernia repair as well as approximately 3 months postoperatively. The NRS requires the patient to rate his or her pain on a scale from 0 to 10, in which 0 is no pain (best outcome) and 10 the worst pain imaginable (worst outcome).[23]

The project plan is depicted in table 1.

ETHICS AND DISSEMINATION

Independent ethics committee

The research project has been reviewed by the Cantonal Ethics Committee (BASEC-No 2020–01548) and was considered as not requiring formal approval according to the Swiss Human Research Act.

Implementation of the project according to ethical guidelines

This project will be carried out in accordance with the project plan, the current version of the Helsinki Declaration and Swiss legislation.

Information for participants and declaration of consent

Before the start of the project, each participating person must give his or her written consent, after having been fully informed about the nature, significance and scope of the project in an understandable way, both orally and in written form. The content of this information is documented on the declaration of consent. The participating person is informed that participation is voluntary and that he/she can withdraw his/her participation at any time without affecting his/her further medical care.

The declaration of consent to participate in the research project is dated and signed by the participating person and the physician (investigator/subexaminer) involved in the consultation. A copy of the signed participant information/consent form will be handed over to the participating person.

Until a legally valid declaration of consent has been obtained, no actions in connection with the project may be carried out.

Data entry, coding, confidentiality and storage

Collection, coding, storage and evaluation of personal data within the project are carried out in accordance to Swiss data protection regulations. Prerequisite for data collection is the voluntary consent of the participating person as part of the declaration of consent prior to the participation in the present research project. The medical information of the participants collected during this project will be kept strictly confidential and will not be disclosed to third parties. Confidentiality is guaranteed by encryption, access is granted exclusively to the study personnel (principal investigator and coinvestigators). The completed questionnaires will be stored in sealed containers.

Dissemination and authorship eligibility guidelines

The project management will make every effort to publish the results of this project in a peer-reviewed medical journal. In order to reach a broad public, an open-access publication will be prioritised. The publication and presentation of the results will be in accordance with the guidelines of CONSORT (Consolidated Standards of Reporting Trials).[16]

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Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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