Sponsor/Sponsor-Investigator	Ente Ospedaliero Cantonale
Study Title:	The effect of informational videos on preoperative anxiety and satisfaction levels in patients undergoing elective ambulatory surgery. A prospective, randomized, controlled clinical trial.
Short Title/Study ID:	CERU-1801
Protocol Version and Date:	Version 1.1
Trial Registration:	www.clinicaltrials.gov NCT03581097
Study Category with Rationale	Provide the determined study category with explanation for this category
Background and Rationale:	Anxiety is a common disorder in patients undergoing invasive procedures, reaching up to 60-80% in some series of these patients. Perioperative anxiety is associated with hemodynamic effects (like arterial hypertension and arrhythmias); it can have an impact on final surgical outcome, on anaesthetics drug dosage and also on rising of post-operative pain perception, leading to a substantial amount of analgesics prescription and post-operative hospitalization days. Finally, perioperative anxiety can reduce patient's overall satisfaction about quality of perioperative care. Perioperative satisfaction is largely based on patients' expectations; it forms part of the surgeon's reward: satisfied patients are more likely to maintain good relationships with the surgeon, to abstain from the so-called "doctor shopping", to avoid malpractice proceedings and to recommend own surgeon to others. Last but not least, satisfied patients are more likely have better compliance about postoperative prescriptions and to attend follow-up appointments. In not life-threatening procedures however, main source of preoperative anxiety is often the anaesthesia outlook rather than surgery itself, largely related to a lack of information about anaesthetic procedure. These fears are largely underestimated in routine minor procedures (such as ambulatory surgery) and therefore real risk is not properly addressed. Due to lack of time and resources, this could have a significant impact on global patient satisfaction. Also if major complications are surgery-related (e.g. cardiac mortality), anxiety is also associated with poor surgical outcome. How to identify and treat patients who will likely benefit from more information about anaesthesia is an important question that remains relatively unaddressed. However, it's

	known that more information about surgery reduces the level of anxiety and apprehension.
Objective(s):	For these reasons we developed this study with a short educational video concerning global management of local anaesthesia on outpatient hand surgery. The aim of this trial was to assess the impact of this educational video about perioperative patients' anxiety levels.
Outcome (if applicable, see Basisformular): Primary Outcome Secondary Outcome	The **principal outcome** was to see and analyse the difference in preoperative anxiety between the two groups measured on our adapted visual analogue scale (VAS-A). **Secondary outcomes** were to perceive any disparity in patient's satisfaction degree measured through final questionnaire, and any variance in vital parameters that are usually affected by anxiety (like arterial blood pressure [mmHg], respiratory rate [breath per minute] and heart rate [beat per minute]) in all patients. A subgroup analysis was than performed, but applied to specific subgroups, like anxious patients, higher anxiety score (3 or more) and patients at their first experience with surgery.
Study Design, see Basisformular:	This is a prospective, randomized, controlled clinical trial.
Inclusion/Exclusion Criteria, see Basisformular:	**Inclusion criteria** were patients older than 18 years, ASA I-III patients undergoing elective hand-surgery operation and patients anesthetized by IVRA. **Exclusion criteria** were patient refusal, on-going anxiolytic or anti-depressive therapy, diagnosis of anxiety or psychiatric disorders, general contraindications to IVRA, limited compliance or language barriers.
Measurements and Procedures:	Patients were admitted on the same day of surgery in the day-hospital clinic, 2-3 hours before the operation; all vital parameters (non-invasive arterial blood pressure, respiratory and heart rate) were measured and they were asked to indicate their initial level of anxiety using some validated instrument, like the VAS-scale (discussed right below). Patients were randomized with a free web tool (available at www.randomizer.org) in a consecutive order into two parallels groups; last Author was the responsible of this randomisation and he was not directly involved in patient treatment. Surgeon and investigators involved in subsequent data analysis were blinded to group assignment.
Study Product/Intervention according to KlinV, if applicable:	One hour before surgery, patients assigned to the video-group (group I) visualised a *Patient Education Video*, a brief video (6 minutes). Patients in the film group watched the movie using a laptop computer equipped with headphones, and VAS score (Visual Analogue Scale) was repeated after the film. Video was recorded by the Anaesthesiology department team, in order to explain and show in a detailed way on a model, the sequence of events, which occurs between the arrival of patients in the operating room and the performance of intra-venous regional anaesthesia. The video began with an actress interpreting a patient scheduled for an elective outpatient hand surgery procedure acceding the day hospital clinic. It showed the interaction between the patient and the nurses who explain in details what is going to happen next and lead her through the preparation routine. The camera then followed the patient as she is accompanied to the induction room and the video showed all the details of the checks made as the patient accedes the operating room, the time-out and the preparation for the anaesthetic procedure, with the monitoring of the vital parameters. Than the intra-venous regional anaesthesia procedure was shown in details as an anaesthesiologist explains it step by step. The video concluded with the patient being brought to the operating room and staying awake and pain free as a simulated procedure begins.
Comparator(s) (if applicable):	Patients assigned to the control group (group II) did not see the video and underwent an otherwise identical preoperative preparation procedure.
Study Duration:	Around 8-9 months

Study Schedule:	From April to December 2013
Investigator(s):	**1. Dr. med. Fusetti Cesare** Medico Aggiunto, Dip. Chirurgia della Mano ORBV, Bellinzona **2. Dr. med. Musiari Michele** Medico Assistente, Serv. Anestesia ORBV, Bellinzona **3. Dr. med. Ceruti Samuele** CapoClinica Medicina Intensiva, HUG, Geneva **4. Dr. med. Cafarotti Stefano** VicePrimario Chirurgia Toracica, ORBV Bellinzona **5. Dr. med. La Regina Davide** VicePrimario Chirurgia Generale, ORBV Bellinzona **6. Dr. med. Saporito Andrea** VicePrimario Serv. Anestesia e Rianimazione ORBV, Bellinzona
Study Centre(s):	This is a single-centre study, to ORBV, Bellinzona
Statistical Analysis incl. Power Analysis	A power analysis was conducted before starting recruitment. According to Ayral et al, as well according to estimated clinically relevance of diminution for anxiety, assuming a reduction of at least 50% in preoperative anxiety level as clinically significant, 45 patients per group were necessary (allowing for drop-outs) to reach a 95% level of significance with a power of 90%. We conducted a statistical frequency analysis regarding common vitals parameters and anxiety level according to VAS-scale at arrival in the hospital, before to go to the pre-operative room and at arrival at the pre-operative room, performing a statistical frequency analysis comparing all these three steps and all subgroup according to secondary outcomes.
GCP Statement:	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.

Recruitment Procedure (if applicable: Advice/Flyer have to be submitted ; if applicable, please indicate the Localisation / Medium (which Newspaper)

All patients underwent two surgical pre-operative visits, during which they received detailed information about surgical procedure and provided their informed consent.

Study Procedure/Flowchart with Timelines: Study specific Examinations have to be clearly identified

Patients were randomized with a free web tool (available at www.randomizer.org) in a consecutive order into two parallels groups; last Author was the responsible of this randomisation and he was not directly involved in patient treatment. Surgeon and investigators involved in subsequent data analysis were blinded to group assignment. One hour before surgery, patients assigned to the video-group (group I) visualised a *Patient Education Video*, a brief video (6 minutes) better described below. Patients assigned to the control group (group II) did not see the video and underwent an otherwise identical preoperative preparation procedure. Patients assigned to the two different groups were kept always separated while waiting for surgery.

After the end of the video and at least 30 minutes before the transfer to the operating room (OR), investigators asked patient to indicate again its own anxiety level. Non-invasive arterial blood pressure, cardiac and respiratory frequency were recorded once again on arrival in the OR and monitored continuously throughout the anaesthetic and surgical procedure.

IVRA was performed by an anaesthesiologist and a nurse in the induction room outside the OR using a standardized procedure. Two intravenous lines were placed on each hand; after tourniquet inflation, a total volume of 40 ml of chloroprocaine 0.5% was injected intravenously in the operated limb. The patient was then transferred to the OR and 10 minutes after local anaesthetic injection, the surgeon tested loss of sensitivity with a pinprick test, after which surgery began.

As anxiety is a highly subjective psychiatric disorder, according to other investigational groups we felt that the best way to determine the state of anxiety is to let it evaluate directly by the patient. The VAS score (Visual Analogue Scale) is a valid instrument used for measuring anxiety. We chose an adapted VAS score (VAS-A), a semi-quantitative numerical scale (0 – 5 level) to measure patients' anxiety level, asking each patient to subjectively quantify its own anxiety, putting a mark on this visual scale, representing its actual anxiety degree.

At the end of the surgical procedure all patients were transferred directly to the day-hospital clinic. Between 1 - 3 hours after the operation all patients completed a satisfaction questionnaire with close evaluation from 0 to 10 regarding these topics: environment, equipment, organization, waiting time, pharmacy, nurses, professionalism, information, dedicated time. Moreover, video-group patients received a specific feedback questionnaire about the video, in which they were asked about personal satisfaction and video's education value (like informative and a valuable source of information for patients before local anaesthesia). Finally, we asked them if the educational movie made them more anxious or calmer.

Risks/ Inconveniences, which are Study specific:

No risk, because the intervention is a movie of 6 minutes.

Coverage of Damages: Insurance (yes/no)? Sum?

No

Storage of Data-and Samples for Future Research Aims: yes/no?,
All data were registered and stored in a specific and protected archive in Anaesthesia Department, accessible only by first and last Author. These data won't be used for further studies.

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