Holo CTO proctoring study

Norwegian feasibility study on the use of mixed reality technology in CTO proctoring

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Academic trial by Sørlandet Hospital Arendal , Arendal, Norway

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Site protocol

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1. Background

1.1 CTO

Chronic total occlusion (CTO) of one or more coronary vessels are relatively common findings in coronary angiography. One large-scale registry showed that up to 20% of patient with coronary artery disease had a CTO. (1) Compared to percutaneous coronary intervention (PCI) of non-occluded vessel, CTO PCI has a lower success rate, and a higher complication rate. They are time consuming and more complex, and several different strategies and various equipment is applied. This suggests more systematic procedure planning, consistent approach and a need for systematic training.(2) At most institutions, CTO PCI is performed by two operators, enabling discussions of findings and strategy during the procedure. Although only one operator at a time can be “hands on” during CTO PCI, large amounts of information is processed during the procedure, and unexpected findings and difficulties often occur. At our institution, a single operator performs CTO procedure. Procedures are often pre-planned

together with an external operator. This is helpful, but does not allow for discussion and adjustments during the intervention. We believe that CTO PCI performed in a team will be more robust and accurate than that of single operator working alone.

1.2 CTO Proctoring

Several studies have showed a relationship between physician volume and outcomes of percutaneous coronary interventions (PCI) with better outcomes reported for high volume operators when compared with low volume operators.(3) Proctoring in medicine is related to better outcomes. Specifically, in CTO PCI systematic proctoring has demonstrated improved success rates, and an increased ability to treat lesions that are more complex. (4). Most likely, proctoring together with operator volume is one of the foundations to the introduction and execution of CTO procedures. Proctoring traditionally involves an expert operator (proctor), visiting the institution, performing the procedure together with the local operator. This involves increased cost, and current travel restrictions makes traditional one-on-one proctoring challenging. To our knowledge, the feasibility of real time proctoring using modern web based communication tools has never been assessed in interventional cardiology.

1.3 Microsoft HoloLens in proctoring

This study aims to evaluate the Microsoft HoloLens as a potential platform in proctoring and effective real time communication between PCI operators located at different geographical locations. The proctor and the local operator interact using a head mounted mixed reality (MR) display, enabling the proctor to see the same image as the operator, from any distanced location.

1.4 Mixed reality in medicine

The Microsoft HoloLens is a mixed reality head mounted display, which allows users to interact with their environment using a Hologram. Mixed reality (MR) like augmented reality (AR) and virtual reality (VR) are defined like extended reality. Extended reality describes the spectrum of virtuality continuum (5). While VR are interactions fully immersed in a synthetic environment, AR allows the user to see their native environment while placing 2D or 3D images within true background. Mixed reality is a new class of experience and allows 3D visualization of imaged data and contact-free interaction with the data in the sterile environment allowing the operator to have increased control and manipulation over digital objects without obstructing the normal visual field. At the same time this technology can provide a possibility of collaboration between operators in a unique way, which can simulate the interaction as if working in a team in the same non-virtual operating space.(6)

1.5 Microsoft HoloLens in medicine

To our knowledge, this device has never been used in clinical practice connected to interventional cardiology but HoloLens and similar devices have been explored within surgical innovation (7), education in medicine (8) to treat anxiety during procedures (9) and in stroke rehabilitation .(10)

In cardiological practice, mixed reality devices have been used in intraprocedural visualization connected to electrophysiology procedures (11) and in pediatric cardiology (12), (13).

We believe that communication and interaction through HoloLens or similar devices can be especial useful nowadays in a pandemic. There is an increasing interest in this subject and we expect that telemedicine and virtual interaction are going to play significant roles in the future of medicine, particularly in situations like the current health crisis. (14)

2. Study objective

2.1 Primary objective

Assess Microsoft HoloLens as an interactive communication device in remote proctoring, and enhancement of teamwork in complex CTO procedures.

2.2 Secondary objective

a) To assess image quality, sound quality, multitasking, comfort, sterility, practicality, spatial awareness and possibility of communication with assisting nurse.

b) Can use of HoloLens in CTO procedures increase effectiveness compared with conventional way of communication between operator and distanced proctor/co-operator

c) Advantage of communication with HoloLens compared with traditional communication tools.

d) To asses feasibility of using HoloLens in invasive cardiology procedures

e) Does application of HoloLens technology cause limitations, including loss of spatial awareness, spatial disorientation, cabling, battery life and device discomfort.

f) Does interaction between operator and proctor affect procedural endpoints like contrast volume, procedure time, fluoroscopy time, costs and procedural success

3. Methods

3.1 Design

Feasibility study to asses effectiveness of Microsoft HoloLens as an interactive communications tool in CTO PCI procedures.

3.2 Patients

Consecutive patients are included based on the following criteria:

3.2.1 Inclusion criteria

3.2.1.1 Clinical inclusion criteria

• Stable angina pectoris, or dyspnoea as an angina equivalent

• Age ≥18 yrs.

• Able to provide written informed consent

3.2.1.2 Angiographic inclusion criteria

• One or more completely occluded coronary arteries with Thrombolysis In Myocardial Infarction (TIMI) flow 0.

•An estimated occlusion duration of at least 3 months

3.2.1.3 Myocardial viability

• Absence of Q-wave in ECG leads corresponding to the occluded vessel, or documented viability of the main territory by MRI or echocardiography

3.2.1.4 Procedural inclusion criteria

• Clinical indication for CTO PCI regardless of operative technique

3.2.2 Exclusion criteria

• STEMI within 72 hours

•Cardiogenic shock

•Active bleeding or coagulopathy

• Life expectancy < 2 years

•Relevant allergies (aspirin, clopidrogrel, ticagrelol, contrast compounds)

•Severe peripheral artery disease

•Clinical unstable angina

3.3 Study process

Study will be conducted by two participants where one is defined as expert or proctor and the other as operator who will perform the CTO procedure. Operator carries out the procedure in our institution while expert is located 300 km away. The plan is to conduct ten CTO procedures where the operator uses Hololens during the procedure and communicates with the proctor from the beginning to the end of procedure. Expert uses conventional laptop computer connected to Hololens to communicate and guide operator.

Guiding is performed by communication (sound) and Holographic interaction through Remote Assist software or similar Hololens applications. All participants are trained how to operate Hololens.

3.4 Statistics

3.4.1 Statistical analyses will be performed in IBM SPSS for Windows (IBM Corp., Armonk, NY, USA). Values will be presented as mean ± standard deviation, median (interquartile range) or no (%) as appropriate.

3.5 Data management

Each participant will be given a unique study subject number. A list of participating patients and their respective study numbers will be kept in a secure place in a locked office. Patient data will be stored in a de-identified manner in a secure database.

4. Ethical aspects

4.1 This study is conducted in accordance with the protocol, applicable regulatory requirements and the declaration of Helsinki. The primary investigator has the responsibility to obtain approval of the study protocol, the patient information and the informed consent.

4.2 Risks, side effects, advantages and disadvatanges in participating in the study

Complex CTO PCI is in itself associated with decreased success rate and higher complication risk compared to ordinary PCI in non-occluded vessels. This study group finds no reason to believe there should be safety concerns connected to the use of Hololens guiding as by the described study protocol. The operator who will perform procedures is highly experienced with large volume of CTO procedures and treatment is based on proven treatment techniques. We are confident that interaction between operator and proctor during the CTO PCI may have differentiating potential in terms of procedural outcome due to complexity of CTO and great variation of techniques. In the case of disturbance or operators discomfort with device, the operator will simply remove device and continued procedure in the traditional fashion. We do not see ethical problems in using Hololens in CTO PCI procedures.

5. Patient information and informed consent

Patients will get written information about the study. Informed consent for participation in the study will be obtained from all patients. The patients will be informed that taking part is entirely voluntarily and that they can withdraw for study whenever they want. Withdrawal, or refusal to participate, will not influence treatment. Originals of signed consent forms will stay at the hospital and the patient will get a copy. It is the responsibility of investigators to ensure that informed consent has been acquired.

6. Biological material

Biological material will not be drawn or stored in the study

7. Enrolment period

Enrolment is expected to conclude in first quarter of 2022

8. Publication

Results will be published in a peer reviewed international cardiovascular journal.

9. Study group

A study group is responsible for this protocol, administrates the study implementation and progression.

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