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Abstract

Background: The idea to enter the thoracic cavity via the esophagus or the abdominal cavity via the stomach (or any organ alongside the GI tract) was first described by the author in his Patent Pending application at the US Patent office (see below). The Transesophageal surgical approach was never attempted in literature before. The development of the novel Transesophageal access devices as one aspect of the MicroAccess approach could potentially have a significant impact in the way current surgical techniques are implemented. Hypothesis: The objective was to evaluate the feasibility and the safety of the MicroAccess Transesophageal devices in animals to achieve intrathoracic and/or intracardiac access. Methods: The MicroAccess Prototype devices were studied in four dogs. The procedure consists of four distinct techniques: (1) secure and seal an esophageal segment (2) Esophageal capture, puncture and insertion of surgical device in to the posterior mediastinum. (3) Pericardial capture, puncture and insertion of a guide wire into the pericardial space and (4) insertion of a catheter inside the left atrium. The procedure was done under dual ultrasonic guidance from the esophageal position and under direct endoscopic visual guidance in the intrathoracic position. Results:

Access to the posterior mediastinum was successful in all 4 dogs (100%) with clear visualization of surrounding structures. Three different maneuvers were performed successfully namely; access to the posterior mediastinum, access to the pericardial space and access to the lumen of the left atrium and injection of a contrast material. All maneuvers were successful. The atrial puncture was achieved and closed. The esophageal puncture was sealed by means of intraesophageal balloons for two hours without leak until animals were sacrificed. Conclusion: The new MicroAccess Transesophageal technique was successfully implemented to intracardiac access. The method is a new minimally invasive method that is feasible and safe. More research needs to be done for more precise devices to perform complex procedures.

Introduction

The access to the human heart and thorax was always a challenge and required complicated equipments including Cardiopulmonary Bypass (Gibbon 1954). The Micro-Access novel approach might potentially have a significant impact on the current surgical techniques. The technique is Patent Pending at the United States Patent and Trade Mark Office file number 60/167,147 on November 23 1999.2 The esophagus has been used in the past as a conduit to obtain tissues for biopsy using Fine Needle Aspiration (FNA). (Silvestri et al., 1996 & Williams et al., 1998). The bacterial flora of the esophagus is not much different from the pharynx in normal subjects (Gagliardi et al., 1998 & Mannell 1983). Access to the heart was always a challenging task specially its posterior aspect. The current known approaches are the open sternotomy approach, Trans Catheter approach and Thoracoscopic approach (Kirklin and Kirklin 1990, Khan et al., 1992 & Mack et al., 1992). Each of these techniques has its disadvantages, adverse effects and limitations Roach et al., 1996 & Mohr et al., 1998). Although technological advances in Cardiothoracic and Minimally Invasive surgeries made cardiothoracic surgery safe and reliable, serious drawbacks are related to the access Harrison et al., 1994). Nevertheless, there has never been an acceptable approach to reach and manipulate the posterior aspect of the heart until now either due to access difficulty or concomitant complications (Haissaguerre et al., 1996, Ernst et al., 1999 & Robbins et al., 1998).

The new MicroAccess methodology offers direct access to the ever hard to reach posterior mediastinum as well as other intrathoracic structures. It can be used in any segment of the GI tract to gain access to various organs related to it. The healing of the mucosa is much faster than the skin with hypothetically faster recovery from surgery (Schaffer and Barul 1998). MicroAccess technique was developed to obtain reliable and safe transluminal access. We assessed the feasibility of the approach and evaluated the results of the intervention in acute pilot animal experiment.

Materials of Methods

Equipment :

The MicroAccess devices are mainly two units. The Main Unit (MU) stays in the esophageal lumen and is responsible for esophageal cleaning, isolation of an esophageal segment by means of outside inflatable balloons and vacuum suction, ultrasonic guidance from the TEE probe that runs across one of its channels and a separate channel for the Side Unit (SU). The SU Carries the visual endoscope and delivers surgical tools to the thoracic cavity. The MU and SU were provided by MicroAccess and were specifically designed for the experiment Mesallum 1999). The TEE ultrasonic guidance was obtained by an HP SONOS 500 unit with a Hewlett Packard Model 21362A 5.0 Mhz single Plane TEE Probe. The Endoscopic probe was the Olympus Bronchoscope XBF-1T20Y with the CLV-10 light source. We used a Brockenbrough Stainless steel curved needle with an outer trocar and inner solid sharp ended stylet Fig. 1. The needle ran through the lumen of the endoscope 2.8 mm working channel. We used 5 cc of IV contrast material injected in the left atrium.

Animal Study

The study protocol was approved by a review committee at the Cairo School of Veterinarian Medicine. All animals received humane care in compliance with the Guidelines for the Care and Use of Laboratory Animals of Cairo School of Veterinarian Medicine, Cairo, Egypt.

Four dogs (weight 10.5 to 24.3 kg) were anesthetized with Nembutal (30 mg/kg IV), and anesthesia was maintained with 2% isoflurane. Respiration was maintained with a volume-control respirator. The ECG was monitored continuously throughout the procedure. Arterial blood gases were determined every 30 minutes, and bicarbonate was added as needed to maintain a physiological pH between 7.35 and 7.45. Blood samples for cultures, blood counts and chemistry were drawn every 30 minutes starting one hour before the procedure and continued two hours after the procedure when the animals were sacrificed. Animals remained anesthetized and sedated all the time.

The MU was introduced down the animals esophagus to position the side opening in a predetermined location above the left atrium and below the carina using TEE guidance. The wash/vacuum system of the MU was initiated and the esophageal wall segment secured. The SU carried the Olympus Bronchoscope in one of its two lumens and the Brockenbrough needle in the other lumen. The esophageal wall was pulled away from outside structures by means of negative pressure vacuum. The needle was used to make a puncture in the esophageal wall under visual guidance. The opening was dilated using a balloon catheter. The SU was passed across the lumen and its distal tip balloon was inflated to achieve seal. The endoscope was introduced in the posterior mediastinum for exploration in the first animal. The second animal experiment entailed the same previous steps plus the use of the Brockenbrough needle to enter the Oblique Sinus of the heart behind the left atrium. The pericardium was captured by the alligator clip of the endoscope to allow easy puncture. A guide wire was place into the pericardial space to achieve intrapericardial access. The third and fourth animal experiment entail the same steps plus actually puncturing the wall of the left atrium with fine tip of the needle Fig. 2 and injecting dye in the fourth animal.

X-rays were taken serially following the dye injection. The dye started to delineate the left atrial walls, mitral valve and pulmonary veins Fig. 3.

The atrial puncture site was clamped together by the alligator clamp for 10 minutes until bleeding stopped. The hemostasis was successful in 100% of the animals (2 dogs). The SU was pulled back to outside the body. The esophageal puncture site was compressed against the inflated balloon of the MU until the animals were sacrificed. Finally, the heart was excised, and the success of these manipulations was confirmed. The pericardial space, the mediastinum and the lumen of the left atrium were explored for evidence of leak or clots. Tissue samples were taken from the surgical field and sent for cultures.

Results

The Esophagus was punctured and sealed in four animals (100%) under TEE guidance. The exit site was delineated and marked. The mediastinum was accessed in four animls under both visual and ultrasound guidance. The left atrium was successfully entered in two animals (100%) with successful dye injection in one animal. No evidence of or leak of esophageal or gastric secretions in the field. No evidence of bactremia or bacterial infection in all blood cultures and tissue samples. There were some non-hemodynamically significant arrhythmias during left atrial puncture. Animals remained hemodynamically stable throughout the procedure.

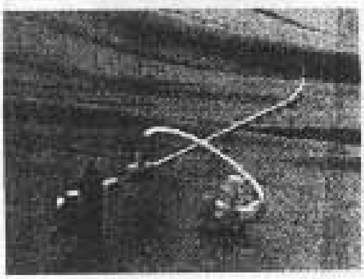

Fig. 1 : Brockenbrough Needle.

The retrograde dye flow into the Pulmonary veins was shown clearly during the injection Fig-4.

Fig 2 : Tip of Transesophageal Catheter inside the left atrium.

Fig. 4 : Retrograde filling of Pulmonary Veins shown clearly.

X-rays were taken serially following the dye injection. The dye started to delineate the left atrial walls, mitral valve and pulmonary veins Fig-3.

The Anterograde flow was also elicited across the mitral valve and into the left ventricle Fig-5.

Fig 3 : Dye injected from the Transesophageal Catheter into the left atrium.

Fig. 5 : Anterograde flow of Dye across Mitral Valve into the Left Ventricle.

Discussion

The access to the human heart has always been a challenge and a complicated target to reach (Kirklin & Kirklin 1990). This is specifically true for the posterior aspect of the heart that has the left atrium. The left atrium and surrounding pulmonary vessels are the core of many very important cardiothoracic procedures (Cox et al., 1991). Minimally invasive surgery is currently being advocated in the field of cardiac surgery [Shetty et al., 1996]. The current approaches to the thoracic cavity suffer form serious limitations and disadvantages (Gibbon 1954, Kirklin and Kirklin 1990, Khan 1992 & Mack et al., 1992). We tested the MicroAccess Transesophageal approach to access the heart. The MicroAccess approach describes a transluminal access to the organs along the length of the GI tract (Mesallum 1999). The Transesophageal approach describes a way to minimally invasively deliver surgical tools to the interior and exterior of the heart and performs procedures therein while the heart is beating. It can be obviously used to perform intra abdominal surgery via a similar transgastric technique using the MicroAccess methods and apparatus. The current study tested the MicroAccess Transesophageal approach in four dogs. The access was successfully achieved in 100% of the animals without significant complication. This technique represents a safe, less invasive and precise approach for a wide variety of cardiothoracic procedures. The dual ultrasonic and visual guidance assures the operator of precise location and implementation of surgical tools.

This could open a most exciting spectrum of possible implementations of the device in the future for a variety of procedures including Coronary Bypass Grafting, Valve manipulations, Mapping and Ablation, Congenital defect repairs, tumor or vegetations removals, Insertion of Stents or Pace Makers, Insertion of pressure sensors, and delivery of drugs, chemicals, cells or genetic materials to the heart or thoracic organs. The potential of the transgastric approach is beyond the scope of this study but of course can be achieved using the same MicroAccess methods and apparatus.

The success to reach the thoracic cavity and the left atrium via the MicroAccess Transesophageal approach makes it possible to perform operations that were thought to be difficult or almost impossible. The fact that the posterior pericardium does not feel pain, as well as the esophagus and tissues involved in the procedure allows for performing the interventions without the need for intubation or general anesthesia. This makes the technique highly advantageous over current techniques. The fast healing and the absence of outside scarring add to the advantages of the technique. This means less postoperative pain and faster recovery with less post operative hospital stay time, morbidity and cost.

In summary, we successfully showed the feasibility and safety of the Transesophageal Access to the left atrium of the heart in an animal experiment. The experiment showed the potential of the Transluminal approach described in the above mentioned Patent application to be applied in numerous Cardiothoracic as well as Abdominal procedures.

Limitations

The current experiment was performed using the MicroAccess devices under development. There was no closure device to seal the atrial or the esophageal puncture. There is ongoing development of the MicroAccess apparatus for an endoscopic closure device as well as other precise devices. The Transgastric approach to perform abdominal procedures still needs to be tested.

Future Research

We suggest testing the MicroAccess Approach in more animals to test the safety and the feasibility of delivering more specialized tools for intrathoracic interventions. We also recommend using the MicroAccess approach in other parts of the GI tract to perform interventions in the abdominal cavity e.g. Transgastric or Transintestinal. The approach can be refined to be virtually used in any natural tract to access organ along side said tract. The MicroAccess technology can also enable Robotic surgery to perform in areas difficult to assess even with open fields. The technology also allows for Telemedicine to operate from a distant location as the access is minimally invasive and precise.

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