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RObotic versus conventional LAparoscopic Fundoplication: a randomised controlled double-blind assessment of quality of life

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Registration date 29/01/2008	**Overall study status** Completed	
Last Edited 31/05/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
25/2004

Study information

Scientific Title
RObotic versus conventional LAparoscopic Fundoplication: a randomised controlled double-blind assessment of quality of life

Acronym
ROLAF trial

Study objectives
Robotic-assisted laparoscopy contains many technical improvements which are the basis of a theoretical advantage over standard laparoscopy. The future of robotic surgery depends on the additional gain that it could provide compared to standard laparoscopy. Experimental studies have demonstrated a benefit of speed and precision for the robotic system for tasks which require accurate and fine movements in a very limited working space. A surgical procedure which could exemplarily be improved by robotic assistance is the fundoplication. The basis for such a hypothesis is that robotic assistance with its potential benefits may lead to a more precise preparation in the narrow hiatal space and as a consequence to a more accurate and longer-lasting fundoplication. Among the many perspectives of the advantages of robotic fundoplication (surgeons', medical institutions', health care systems', etc.,) we assume the most important one is that of the patients' benefit in terms of quality of life (QOL). Therefore, the present study was conceived in order to compare the two existing surgical methods under the consideration of the patients' perspective in terms of quality of life and functional outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee of Heidelberg on the 9th March 2004.

Study design
Pilot randomised controlled single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux disease

Interventions
Patients were randomised to either robotic assisted (RALF) or conventional laparoscopic (CLF) Nissen fundoplication the day before surgery. Intraoperative randomisation was not applicable in the study set-up due to technical and logistical reasons. However, none of the patients was aware of the surgical method applied.

RALF was performed by a single surgeon after having passed a learning phase of 30 procedures. CLF was performed by three different surgeons including the one responsible for RALF, all highly experienced in laparoscopy, with at least 30 CLF procedures performed before.

For the surgical procedure, patients from both groups were positioned in combined French and reversed Trendelenburg position. The standard setting for CLF was with the surgeon standing between the patient's legs, the first assistant positioned to the patient's right, and the laparoscopic tower being placed at the cranial extremity of the patient. For RALF the daVinci® Surgical System (Intuitive Surgical, Mountain View, California, USA) was used; the movable robotic module with its three robotic arms was positioned directly cranial to the patient's head. The surgeon, sitting at the master console aside the operating table, was steered the actuator arms of the robot while the first assistant stood to the patient's left, watching the procedure on a conventional monitor. He assisted by exchanging robotic instruments, adjusting the settings of the machine or employing conventional laparoscopic instruments.

After creating a pneumoperitoneum of 12 mmHg using the Veress needle all trocars were placed in standardised positions. For RALF a 12-mm trocar for the 30° angled dual scope and two 7-mm robotic trocars for robotic instruments were used. A 10-mm accessory trocar was intended for assistance, for example by clipping and suction using conventional laparoscopic instruments. Similar standard trocars, only differing in two 5-mm instead of 7-mm trocars for standard laparoscopic instruments and an equally angled scope were used for CLF. In both groups a rigid 5-mm Nathanson liver retractor (Mediflex®, Surgical Instruments, Islandia, New York, USA) was used for adequate exposition of the oesophageal hiatus through an additional subxiphoidal incision.

Operative steps were similar in both groups. With a 32-F orogastric tube in place the mobilisation of the oesophagus started after incision of the lesser omentum, close to the right pillar and continued on the anterior part of the phreno-oesophageal membrane. Phreno-oesophageal attachments to the right and left diaphragmatic pillars were completely dissected. To facilitate this procedure a band was placed around the lower oesophagus and used for adequate positioning of the oesophagus. Then the dissection was extended into the lower mediastine for complete mobilisation of the distal oesophagus. Short gastric vessels were not divided. The hiatus was narrowed by a various number of non-resorbable sutures, depending on the enlargement. Finally a "short and floppy" Nissen fundoplication was performed with three interrupted sutures, the middle one being anchored to the anterior oesophageal wall to prevent displacement of the wrap.

The total duration of follow-up for both treatment arms is 36 months; clinical visits are scheduled at 1, 3, 6, 12 and 36 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary objectives of the study were to investigate the quality of life and functional outcome in patients undergoing either laparoscopic or robot-assisted fundoplication. The primary outcomes are measured after 12 months.

Secondary outcome measures
A set of surgical and non-surgical parameters related to the operation are analysed as secondary objectives, such as:
1. Operating time, assessed intraoperatively
2. Intraoperative blood loss, assessed intraoperatively
3. Complications, assessed intraoperatively
4. Conversions, assessed intraoperatively
5. Morbidity, recorded during the first postoperative months
6. Postoperative length of hospital stay, measured during the hospital stay
7. Costs, measured during the hospital stay

Overall study start date
01/04/2004

Completion date
31/08/2006

Eligibility

Key inclusion criteria
1. Males and females
2. Over 18 years of age
3. Informed consent
4. Ability to complete the quality of life questionnaires
5. History of chronic (greater than 6 months) symptomatic gastro-oesophageal reflux disease requiring proton pump inhibitor therapy (greater than 3 months) and/or oesophagitis (objectively documented by endoscopy)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. History of upper abdominal surgery
2. Obesity with a body mass index (BMI) greater than 40 kg/sqm
3. Zollinger-Ellison syndrome
4. Primary oesophageal disorders:
4.1. Achalasia, scleroderma
4.2. Primary oesophageal spasms
4.3. Any oesophageal motility disorder
5. Gastric dysmotility
6. Inflammatory bowel disease
7. Dysplastic changes in a columnar lined oesophagus
8. Stricture of oesophagus
9. Malabsorption syndromes
10. Malignant diseases
11. Current unstable diabetes mellitus.
12. Severe cardiovascular, pulmonary, pancreatic, liver, renal or cerebro-vascular disease that might interfere with the evaluation of the study
13. Psychiatric disorders
14. Alcohol and/or drug abuse or any condition associated with poor compliance
15. Actual and past (greater than 3 months) treatment for Helicobacter pylori eradication (subjects should not be enrolled within 3 months after therapy)

Date of first enrolment
01/04/2004

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
Germany

Study participating centre
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University/education

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ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Government

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - this trial was conducted within the setting of the "Research training group 1126: Intelligent Surgery - Development of new computer-based methods for the future workplace in surgery"

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2007	31/05/2019	Yes	No
Results article	results	01/05/2009	31/05/2019	Yes	No