3D laparoscopic live donor nephrectomy - a feasibility study

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This study focuses on feasibility and safety of 3D laparoscopic donor nephrectomy during the dissection of the renal artery and vein.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41166

Source
ToetsingOnline

Brief title
3D LDN

Condition

- Other condition

Synonym
kidney procurement among healthy live kidney donors

Health condition

gezonde nierdonoren

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Olympus

Intervention

Keyword: 3D, donor nephrectomy, live donor, surgical technique

Outcome measures

Primary outcome

Duration of dissecting the renal artery and vein, and their branches.

Secondary outcome

Multiple vascular anatomy, kidney function (eGFR), total operation time,

quality of life, pain scores, intra- and postoperative complications, length of

hospital stay and costs.

Study description

Background summary

Transplantation is the only treatment offering long-term benefit to patients with chronic kidney failure. In the last decade a huge increase in the use of living donors has been realized for renal transplantation. Live donor nephrectomy is performed on healthy individuals who do not benefit directly from the procedure themselves. In order to guarantee safety for the donor, it is important to optimize the surgical approach. The first laparoscopic live donor nephrectomy was performed by Ratner et al. in 1995 (1). Compared to minimally invasive open techniques, laparoscopic kidney donation is associated with a better quality of life, less pain, shorter hospital stay and earlier return to work (2).

During the development of the surgical techniques the minimal invasive LDN procedure has remained the same, except from the extraction site of the kidney. Offering all the potential benefits of a minimally invasive procedure, including less pain, less blood loss and less need for blood transfusions while safety is increased. Moreover, it can enable a shorter hospital stay, a quicker recovery and faster return to normal day activities. LDN is among the few endoscopic surgical procedures in which the great abdominal vessels are in the operation field. A significant percentage of the total blood volume passes the large renal vessels every minute. These vessels have to be preserved to allow proper placement in the recipient without compromising the donor*s safety. Misjudging accessory renal arteries may result in complications in the

recipient. Misjudging aberrant renal veins, gonadal veins, adrenal veins and arteries may lead to serious (sometimes life threatening) bleeds during nephrectomy. It will be obvious that anatomical variations in the renal hilum, including multiple arteries, veins and branches demand accurate surgical techniques.

With the introduction of this new technique to safely procure a donor kidney, the surgeon*s armamentarium got expanded and now this technique has been widely accepted as the first choice of treatment. However, with this technique, the surgeon*s lost their 3D vision and hand/wrist movements. The Da Vinci robot has been designed to improve upon conventional laparoscopy by giving these functions back to the surgeon with 540º degrees wrist movements of the instruments instead of 180º and 3D vision for the surgeon only. However, the DaVinci robot is quite expensive in purchase and maintenance, and requires extra training of surgeons to get DaVinci certified.

Two of our surgeons are DaVinci certified surgeons whom perform robot-assisted LDN. During these procedures a special operating team of nurses and surgeons is needed who have experience with the DaVinci robot. Furthermore the DaVinci robot is shared with other specialties. Both conditions make it impossible to operate all live kidney donors with the DaVinci robot.

In our center 2D-laparoscopic LDN is the treatment of choice for live donor nephrectomy for the past 15 years. Our surgeons perform over 130 laparoscopic LDN per year and have been excellent trained in this procedure. The two-dimensional images on the monitor certainly have their disadvantages. Three-dimensional laparoscopy was introduced in the 1990s, but with the latest developments of better monitors and high definition, it has started to become established in the operating rooms (3, 4). With the implementation of three-dimensional images on the monitor during laparoscopy, we would like to combine our expertise in LDN with 3D vision; enabling 3D vision for the surgeon, but also for the assisting surgeon and nurse. Since we*re only adding a 3D camera, no extra training or certificate is required for our transplant surgeons. This way, we will be able to increase the number of live kidney donors who will undergo a 3D procedure and subsequently maximize donor safety.

Study objective

This study focuses on feasibility and safety of 3D laparoscopic donor nephrectomy during the dissection of the renal artery and vein.

Study design

The 3D LDN study is a single center prospective study. Live kidney donors will be included to evaluate if addition of a 3D camera is feasible for donor nephrectomy.

Intervention

Three-dimensional donor nephrectomy will be performed using the Olympus EndoEye Flex 3D 10 mm camera and Sony LMD-2451MT/TG 3D monitor. The patient is placed in lateral decubitus position. Four trocars are used; two laparoscopic ports for instruments of the operating surgeon and two laparoscopic ports for the assisting surgeon for one instrument and the 3D camera. The nephrectomy will be carried out in the same way as the conventional 2D laparoscopic procedure. The donor is positioned in right lateral decubitus position. Then, the first trocar is inserted periumbilically and a pneumoperitoneum is created by CO2 insufflation, after which a 30° video-endoscope is introduced and three additional trocars are inserted. The left hemicolon is dissected from the lateral abdominal wall and mobilized medially. Gravity aids the further mobilisation. The kidney is located behind the hepatic or splenic flexure. Gerota*s fascia is opened and the kidney is exposed from a varying amount of surrounding perirenal fat. Next, the ureter is exposed until it crosses the gonadal vein. The renal vessels are dissected and encircled with red or blue vessel loops to facilitate identification of the artery and vein from different directions, respectively. The vessel loops also enable safe manipulation of the vessels during the hilar dissection. The venous branches of the renal vein, especially in case of left sided donor nephrectomy, are clipped and divided with scissors. When the kidney, ureter, vein and artery are all fully dissected, a 5 to 8 cm horizontal suprapubic incision or Pfannenstiel incision is made as extraction site, while maintaining pneumoperitoneum. An endobag is introduced via a small incision in the peritoneum. Subsequently, the distal ureter is clipped and divided with scissors, secondly the renal artery is divided with an endostapler and last the renal vein is divided with an endostapler. The kidney is placed in the endobag and extracted via the incision. All procedures will be monitored during the entire procedure for analysis of the primary outcome and can be controlled by others to prevent observer-bias.

Study burden and risks

Burden of 2 hours maximum, filling out questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All, properly Dutch speaking, live kidney donors who are medically capable of donating one of their
kidneys can be included.

Exclusion criteria

A history of kidney surgery or adrenal gland surgery on the side chosen for
surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49790.078.14