‘LIMERIC’-study

LIMited wEdge ResectIon for Colon polyps

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Limited Endoscopic Assisted Wedge Resection for Excision of Colon Polyps

Short title	**Limited wedge resection for colon polyps**
Version	1.2
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SUMMARY

Rationale The detection rate of colon polyps difficult to resect endoscopically is rising. Available techniques such as EMR/ESD are not applicable to all cases. Segmental colectomy is associated with significant morbidity and mortality. Therefore, we introduced a limited endoscopy assisted laparoscopic wedge resections (EAWR) by using a linear stapler without anastomosis for the treatment of such polyps.

Objective To study the safety and radicality of limited EAWR for the treatment of difficult colon polyps. Therefore, our primary endpoint is the 30-day morbidity after an EAWR. One of the secondary endpoints are the costs related with the procedure.

Study design Prospective multicenter longitudinal cohort study.

Patient population Patients with a difficult colon polyp which cannot be resected by other available techniques (EMR/ESD), and with non-lifting residual adenomatous tissue in a scar after previous polypectomy and an endoscopic resection of a T1 carcinoma with low risk features, but with positive resection margins or a resection margin ≤1mm.

Methods Participating hospitals will enter the data of included patients in a web-based database (Castor).

Main study endpoints The 30-day morbidity after limited EAWR and radicality of the resected specimen.

Sample size 115 patients eligible for evaluation

1 INTRODUCTION AND RATIONALE

Endoscopic polypectomy is a well-established treatment for non-invasive colonic polyps.[1] The majority of non-invasive polyps can be readily excised with standard polypectomy. Most colon polyps can be safely removed by endoscopic polypectomy. In a recent meta-analysis summarizing the results of 6779 polyps of more than 2 cm polyps, the success rate was 91%, with a morbidity of 8% and a mortality of 0.3%. However, a surgical resection was also needed in 9%, mostly due an irradical resection.[2] For more challenging polyps, advanced endoscopic maneuvers such as endoscopic mucosal resection and endoscopic submucosal dissection, have improved resectability compared with standard polypectomy.[3-7] Despite these techniques, large or sessile polyps can still be technically difficult to remove endoscopically.[8] In the Netherlands, surgery following endoscopic resection mainly consists of segmental colectomy, which is associated with significant morbidity (20%) and mortality (3%). It is for this reason that several methods have been developed to fill the gap between endoscopic resection and major surgery. Laparoscopic-assisted polypectomy was first described in the early 1990s as an alternative approach to avoid major bowel resection for difficult benign polyps.[9] This combined endoscopic laparoscopic surgical approach has gained popularity due to acceptable recurrence rates and shorter hospital stay, lower morbidity, and improved functional outcomes compared with colectomy.[10.11] Several hybrid laparo-endoscopic procedures have been described to deal with difficult polyps to prevent segmental colectomy and its related morbidity.[12] The indications for these procedures are: the removal of difficult non-invasive polyps, non-lifting recurrence after irradical endoscopic resection, or resection of the scar after a prior endoscopic resection of an invasive T1 CRC without free resection margins but also without high risk features of lymph node metastasis. This, because resection of the draining lymph nodes is not a part of a laparoscopic local resection.

We recently developed a limited endoscopy assisted laparoscopic wedge resections (EAWR) by using a linear stapler without making an anastomosis. The technique is easy to learn by a laparoscopic colorectal surgeon, as it uses standard techniques and instruments already used in major surgery. In a small cohort of 8 patients we found promising results with low morbidity rate and no observed mortality. The next step for further developing the limited EAWR would be validation in a larger cohort. This study is initiated to prospectively collect the data concerning limited EAWR in the Netherlands, to evaluate the effectiveness and safety.

2 OBJECTIVES

This study is performed to evaluate the safety and effectiveness of limited EAWR for the treatment of difficult colonic polyps to prevent colonic resections with its related morbidity.

1) The primary aim of this study is to assess the safety of limited EAWR

2) The secondary aims of the study are
   - effectiveness of EAWR, defined as the number of radical resection (margin of normal colonic mucosa of at least 1mm)
   - morbidity of limited EAWR 3 months after the procedure
   - recurrence rate at 6 months
   - total procedure related costs of limited EAWR
   - implementation of limited EAWR in the Netherlands

3 STUDY DESIGN

The is study is designed as a prospective multicenter longitudinal cohort study. All patients who are referred by a gastroenterologist to a colorectal surgeon for surgical resection are suitable for inclusion. Written Informed consent will be obtained and the patient and procedure related items will be registered in a web-based database by the investigator of the concerning hospital.

4 STUDY POPULATION

4.1 Patient population

- Patients with a colonic polyp meeting the inclusion criteria for a limited EAWR.
  All patients with written informed consent will be entered in the web-based data base, also when they eventually do not undergo the limited EAWR for any reason.

4.2 Inclusion criteria

- Patients with a colonic polyp meeting one of the following criteria.
    - A difficult non-invasive polyp that cannot be removed by standard EMR/ESD technique as assessed by an experienced gastroenterology expert panel.
    - A non-lifting recurrence of adenomatous tissue after irradical endoscopic removal.
    - Resection of the scar after a prior endoscopic removal of an invasive T1 CRC without free resection margins but without high risk features of lymph node metastasis (after revision of the histological specimen by an expert panel of two specialized colorectal pathologists).
- age >18 year

4.3 Exclusion criteria

- Pregnancy
- > 50% circumferential growth of the polyp

5 METHODS

5.1 Main study endpoints

Primary endpoints:

- Proportion of 30-day morbidity of a limited EAWR according the Clavien-Dindo classification. Serious morbidity is defined as a Clavien-Dindo grade III or higher.

	Definitions
I	Any deviation from the normal postoperative course without the need for pharmacological treatment other than the "**allowed therapeutic regimens**", or surgical, endoscopic and radiological interventions
II	Requiring **pharmacological** treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring **surgical, endoscopic or radiological intervention.**
IV	**Life-threatening complication** requiring critical care management; CNS complications including brain haemorrhage and ischemic stroke (excluding TIA), sub-arrachnoidal bleeding.
V	**Death** of a patient

Secondary endpoints:

- Technical success of limited EAWR
- The number of radical resections, defined as both free lateral and vertical resection margins at histology of at least 1 mm normal colonic mucosa.
- Percentage of patients who eventually did not undergo a limited EAWR
- Perioperative complications due to limited EAWR, defined as bleeding, perforation or infection.
- Proportion of 3-month mortality after a limited EAWR
- Recurrence of adenomatous tissue or carcinoma at 6 months
- Long-term morbidity of limited EAWR, defined as the development of a stenosis of the colon
- Total procedure related costs of a limited EAWR

5.2 Other study parameters

All data regarding limited EAWR procedures will be prospectively collected in a web-based Database (Castor). The CRF (case report form) is added as appendix 1. The histologic specimen will be evaluated by the procedure mentioned in paragraph 5.4.3.

5.3 Study procedures

5.3.1 Expert panel

Before procedure, a multidisciplinary expert panel consisting of gastroenterologists and surgeons will evaluate each case. For thorough evaluation, endoscopic images of the polyp from 4 different angles are required.

1) *at least 1 overview white light image;*
2) *one white light image with zoom function;*
3) *one overview image with narrow band imaging (NBI);*
4) *one image with NBI with zoom function.*

The panel consists of four gastroenterologists specialized in endoscopic removal of polyps by EMR/ESD. Only when two gastroenterologists and the referring gastroenterologist reach consensus, and when one of the surgeons considers an EAWR technically feasible, inclusion will follow.

Expert panel:	Gastroenterologist:	1. Drs. J.M.J. Geesing
		2. Dr. L.M.G. Moons
		3. Dr. J.S. Terhaar sive Droste
		4. Dr. W.H. de Vos tot Nederveen Cappel
	Surgeons:	1. Dr. H.L. van Westreenen
		2. Dr. E.S. van der Zaag

For irradically removed low-risk T1 CRC, the histology will be revised by an expert panel prior to a limited EAWR to ascertain the absence of high risk features for lymph node metastasis i.e., lymphangioinvasion, grade of differentiation, depth of invasion, and risk of local recurrence (resection margins, tumor budding grade 2/3). The expert panel consists of two specialized colorectal pathologists from UMC Utrecht.

Expert panel:	1. Dr. M.M. Laclé
	2. Prof. Dr. G.J.A. Offerhaus

5.3.2 Participating surgeons

- Surgeons performing a limited EAWR must have attended an e-learning concerning the technique and possible pitfalls of the technique.
- Participating surgeons have performed at least 100 laparoscopic colon resections.

5.3.3 Limited EAWR

All included patients will undergo split-dose bowel preparation. Patients are placed in French position under general anaesthesia. The surgeon starts with a diagnostic laparoscopy with three trocars. At first, the spot in the colon is identified and the concerning part of the colon will be mobilized. This is to ensure the ability to place the linear stapler, to make a limited EAWR possible. Secondly, the colonoscopy is performed by the gastroenterologist. A suture is placed laparoscopically with intraluminal endoscopic visualization through the base of the polyp. (figure 1, appendix 3) In case of a polyp close to the mesentery, the colonic wall can be dissected from the mesentery. The marginal artery of the colon should be preserved. Traction is given on the suture to enable positioning of the linear stapler. (figure 2, appendix 3) Before stapling off the polyp the patency of the lumen (i.e., the lumen of the colon or in case of a cecal lesion the lumen of the ileum) as well a total inclusion of the polyp is checked endoscopically by the gastroenterologist. (figure 3, appendix 3) The resected specimen will be removed in an endobag through the 12mm trocart. The surgeon as well as the endoscopist will check the colon for signs of bleeding or perforation before ending the procedure.

5.3.4 Handling of resected specimen

The specimen will be sent to the pathologist. It is important the pathologist receives the resected specimen in toto, without manipulation of the staple line by the surgeon. And also, not in formaldehyde. In other words, fresh. The pathologist removes the staples, the lateral and deep margins will be inked with different colors, the specimen will be stretched on a paraffin block (or mesh), photographed and fixed for 24 hours at room temperature. After fixation, longitudinal sections of limited length and width of the whole specimen will be included and the specimen will be accessioned in toto. Histological diagnosis of polyps or tumors is carried out in accordance with the current guidelines. The histological type and resection margins in mm (horizontal and vertical) of the lesion will be judged. In case of invasive carcinoma, the Kikuchi levels are used for pT1 tumors. Incomplete (R1) resection is defined as tumor invasion of margins/resection plane and/or radicality cannot be determined due to coagulation artefacts//tangential cut and so forth. Tumor grade and presence or

absence of invasion in lymph- or blood vessels needs to be addressed specifically, as well as tumor budding.

5.3.5 Follow-up

The impact of EAWR on quality of life, bowel function and pain, will be evaluated using two questionnaires, one at baseline and one at 3 months after the procedure through a telephone conversation. We will use the EQ-5D-5L (appendix 2), a short questionnaire to assess quality of life.

Complications will be registered in the CRF. An adverse event is defined as a Grade II-III complication according to the Clavien-Dindo classification. (see paragraph 5.1) A serious adverse event is defined as a grade IV-V complication.

Following current practice, a new colonoscopy will be performed at 6 months after limited EAWR to evaluate the scar for residual adenomatous tissue or recurrent cancer. Inspection of the scar will be performed with both white light inspection as well with advanced imaging (NBI or chromo-endoscopy), followed with biopsies even in the absence of visual residual adenomatous tissue or cancer.

5.3.6 Calculation of the costs

Data will be gathered in the electronical case record form for:

1. Instruments used: number of trocarts, use of stapling (number, size), use of ligasure/ultracision, use of endobag;
2. Time needed to perform the procedure by the surgeon;
3. Total time in the operating room of the patient;
4. Total time of presence of the gastroenterologist and his/her team in the operating room;
5. Length of hospital stay;

Healthcare costs will be calculated by multiplying used healthcare services by the appropriated unit cost prices. Bottom-up micro costing will be applied. For all other healthcare services reference prices, will be used where available. Costs will be discounted to correct for inflation.

6 STATISTICAL ANALYSIS

The sample size is calculated on the correct estimation of the morbidity of 5% with a desired precision estimate of 4%, and a 95% confidence interval. Based on these parameters the sample size should be 115 cases.

Parametrically distributed continuous data are summarized as mean ± standard deviation (SD). Non-parametric continuous data are summarized as median with interquartile ranges (IQR). Categorical data are summarized as frequencies with percentages.

7 PUBLICATION POLICY

The coordinating investigator and principal investigators will be first, second and last author. For each participating center, a realistic number of patients that should be included is calculated based on the number of outpatient visits. All local participating investigators who include at least 80 percent of the estimated number of patients will be granted co-authorship, regardless of the total number of authors. The order of authors will be based on: (1) scientific input and (2) number of inclusions per center. For purposes of abstract presentation and publication, any secondary publication will be delegated to the appropriate principal authors.

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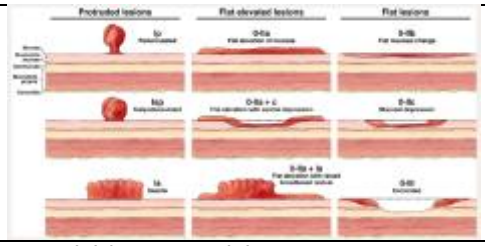
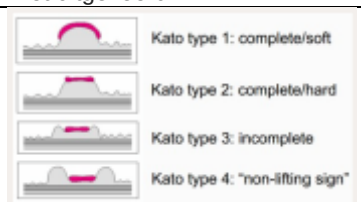
9 APPENDIX

9.1 Appendix 1

Step 1 Patiënt karakteristieken

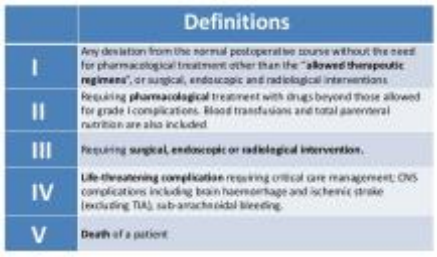
1.1	In- en exclusiecriteria	Inclusion criteria: • Age >18 year • Patients with a colonic polyp meeting one of the following criteria. - Non-invasive polyp not removable by standard EMR/ESD technique* - Non-lifting recurrence of adenomatous tissue after irradical endoscopic removal. - Resection of a scar after a prior endoscopic removal of an invasive T1 CRC without free resection margins but without high risk features of lymph node metastasis^ Exclusion criteria: • Pregnancy • > 50% circumferential growth of the polyp
1.2	Geslacht	Man/Vrouw
1.3	geboortedatum	dd-mm-yyyy
1.4	ASA score	ASA 1: Patiënten zonder lichamelijke of psychische aandoening behalve waarvoor ze geopereerd worden ASA 2: Patiënten met lichte tot matige afwijkingen, en zeer jonge of zeer oude patiënten die overigens niets mankeren ASA 3: Patiënten met ernstige afwijkingen die hen in normale activiteiten hinderen, behalve waarvoor ze geopereerd worden ASA 4: Patiënten met levensbedreigende ziekte aan bijv. lever, nieren of hersenen, waardoor zij al invalide zijn
1.5	Gebruikt patiënt bloedverdunners?	Ja/Nee
1.6	Heeft patiënt in het verleden een abdominale operatie ondergaan?	Ja/Nee
1.7	EQ-5D-5L at baseline	dd-mm-yyyy
1.8	MOBILITIET, onderdeel van 1.7	Ik heb geen problemen met lopen Ik heb een beetje problemen met lopen Ik heb matige problemen met lopen Ik heb ernstige problemen met lopen Ik ben niet in staat om te lopen
1.9	ZELFZORG, onderdeel van 1.7	Ik heb geen problemen met mijzelf wassen of aankleden Ik heb een beetje problemen met mijzelf wassen of aankleden Ik heb matige problemen met mijzelf wassen of aankleden Ik heb ernstige problemen met mijzelf wassen of aankleden Ik ben niet in staat mijzelf te wassen of aan te kleden
1.10	DAGELIJKSE ACTIVITEITEN, onderdeel van 1.7	Ik heb geen problemen met mijn dagelijkse activiteiten Ik heb een beetje problemen met mijn dagelijkse activiteiten Ik heb matige problemen met mijn dagelijkse activiteiten Ik heb ernstige problemen met mijn dagelijkse activiteiten Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren
1.11	PIJN/ONGEMAK, onderdeel van 1.7	Ik heb geen pijn of ongemak Ik heb een beetje pijn of ongemak Ik heb matige pijn of ongemak Ik heb ernstige pijn of ongemak Ik heb extreme pijn of ongemak
1.12	ANGST/SOMBERHEID, onderdeel van 1.7	Ik ben niet angstig of somber Ik ben een beetje angstig of somber Ik ben matig angstig of somber Ik ben erg angstig of somber Ik ben extreem angstig of somber
1.13	Uw gezondheid VANDAAG isonderdeel van 1.7	1-100
1.14	Ruimte voor eventuele opmerkingen	

Step 2 Poliep/tumor karakteristieken

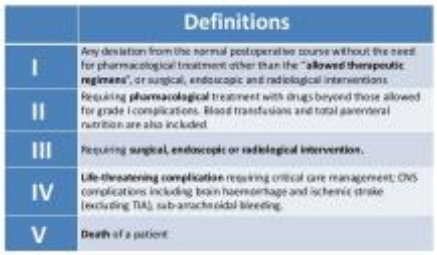
2.1	Is de indicatie voor deze lesie door een panel beoordeeld?	Ja/Nee
2.2	Datum van colonoscopie waarin poliep/tumor is gedetecteerd	dd-mm-yyyy
2.3	Locatie poliep	Coecum Colon ascendens Flexura hepatica Colon transversum Flexura lienalis Colon descendens Sigmoid Rectumsigmoid Rectum
2.4	Geschatte lengte poliep (door MDL-arts)	in mm
2.5	Geschatte breedte poliep (door MDL-arts)	in mm
2.6	Poliep morfologie	Paris l-p Paris l-s Paris l-sp Paris 0-IIa Paris 0-IIa + c Paris 0-IIa + ls Paris 0-IIb Paris 0-IIc Paris 0-III
2.7	Voorbeeld Paris-classificatie	
2.8	Oppervlaktepatroon poliep	Granulair/Non-granulair
2.9	Zijn er morfologische maligne kenmerken aanwezig?	Depressie Excavatie Spontane bloeding Grote nodule Erythemateus gebied
2.10	Hoe is de lifting?	Kato I Kato II Kato III Kato IV Niet uitgevoerd
2.11	Voorbeeld Kato-criteria	
2.12	Wat is de Hiroshima classificatie beoordeeld met NBI?	Hiroshima A: microvessel intensity vague/invisible, Hiroshima B: regular surface pattern, regular thickness of vessels Hiroshima C1: irregular surface pattern, homogeneous thickness of vessels Hiroshima C2: irregular surface pattern, heterogeneous thickness of vessels Hiroshima C3: unclear surface pattern, avascular area, scattered microvessel fragments Not assessed

2.13	Voorbeeld Hiroshima classificatie	
2.14	Wat is de indicatie voor de endoscopisch geassisisteerde laparoscopische wigresectie?	Poliep in divertikel Poliep op moeilijke locatie Poliep lift niet Poliep met ingroei in appendix Verdenking T1 CRC waarvoor en-bloc resectie Recidief weefsel (gefibroseerd) in llitteken van eerder verwijderde poliep Litteken van Rx/R1 resectie van een laag-risico T1 CRC Andere indicatie, namelijk
2.15	Zijn er eerder biopten genomen van het litteken of de poliep?	Ja/Nee
2.15.1	Wat was de PA van de biopten?	Adenoom (ongedefinieerd) Adenoom, laaggradige dysplasie Adenoom, hooggradige dysplasie Adenocarcinoom Anders
2.16	Optie voor uploaden foto's lesie	
2.17	Optie voor uploaden foto's lesie	
2.18	Optie voor uploaden foto's lesie	
2.19	Optie voor uploaden foto's lesie	
2.20	Ruimte voor eventuele opmerkingen	

Step 3 Wigresectie

3.1	Datum endoscopisch geassisteerde laparoscopische wigresectie	
3.2	Is de procedure technisch geslaagd?	Ja/Nee
3.2.1	Indien niet geslaagd, reden	
3.2.2	Moest er geconverteerd worden?	Nee Ja, naar segmentele colonresectie Ja, oncologische resectie Ja, naar open chirurgie
3.2.3	Reden dat er geconverteerd moest worden	
3.3	Is er PERI-operatief een complicatie opgetreden?	Ja/Nee
3.3.1	Wat voor complicatie en hoe is dit behandeld?	
3.3.2	Wat is de score van de complicatie op schaal van Clavien-Dindo?	I II III IV V
3.3.3	Voorbeeld Clavien-Dindo	
3.4	Starttijd procedure	Tijd incisie
3.5	Eindtijd procedure	Tijd sluiten huid
3.6	Starttijd endoscopie in OK	
3.7	Eindtijd endoscopie in OK	
3.8	Totale tijd van de patient in de OK	In minuten
3.9	Aantal trocarts	
3.10	Gebruik van vessel sealer?	Ja/Nee
3.10.1	Indien ja, type vessel sealer	Ultracision Ligasure Thunderbeat Voyan Anders
3.11	Type stapler	Medtronic Johnson&Johnson Anders
3.12	Aantal cartridges	
3.13	Maat van de cartridges	In mm
3.13.1	Maat van de cartridges	In mm
3.13.2	Maat van de cartridges	In mm
3.14	Use of endobag?	Ja/Nee
3.15	Macroscopisch radicale resectie?	Ja/Nee
3.16	Ruimte voor eventuele opmerkingen	

Step 4 Postoperatief beloop en PA uitslag

4.1	Datum opname	dd-mm-yyyy
4.2	Datum ontslag	dd-mm-yyyy
4.3	Is er een POSToperatieve complicatie opgetreden?	Ja/Nee
4.3.1	Complicatie(s) die is/zijn opgetreden (meerdere antwoorden mogelijk)	Wondinfectie Lekkage stapellijn Urineweginfectie Pneumonie Ileus Stenose Abcesvorming Overlijden Anders
4.3.2	Hoe is de complicatie behandeld?	
4.3.3	Datum optreden complicatie	dd-mm-yyyy
4.3.4	Wat is de score van de complicatie op schaal van Clavien-Dindo?	I II III IV V
4.3.5	Voorbeeld Clavien-Dindo	
4.4	Histologie resectiepreparaat	SSA/P zonder dysplasie SSA/P met laaggradige dysplasie SSA/P met hooggradige dysplasie Adenoom laaggradige dysplasie Adenoom hooggradige dysplasie T1 CRC T2 CRC Anders
4.4.1	Anders, namelijk	
4.5	Verticale resectiemarge	R0-resectiemarge R1-resectiemarge Rx-resectiemarge onbekend
4.6	Verticale vrije marge	In mm
4.7	Horizontale resectiemarge	R0-resectiemarge R1-resectiemarge Rx-resectiemarge onbekend
4.8	Horizontale vrije marge	In mm
4.9	Lengte resectiepreparaat	In mm
4.10	Breedte resectiepreparaat	In mm
4.11	Dikte resectiepreparaat	In mm
4.12	Wat is het beleid nav de histologie?	Wait & see (endoscopische follow-up) Aanvullend oncologische chirurgie Anders
4.12.1	Anders, namelijk	
4.13	Ruimte voor eventuele opmerkingen	

Step 5 Follow up endoscopie

5.1	Datum follow-up endoscopie	dd-mm-yyyy
5.2	Litteken geidentifieerd?	Ja/Nee
5.3	Macroscopisch restweefsel zichtbaar?	Ja/Nee
5.4	Biopten genomen?	Ja/Nee
5.5	PA van de biopten of het restweefsel	Adenoom (ongedefinieerd) Adenoom, laaggradige dysplasie Adenoom, hooggradige dysplasie Adenocarcinoom Anders
5.5.1	Anders, namelijk	
5.6	Is er sprake van stenosering?	Ja/Nee
5.7	Ruimte voor eventuele opmerkingen	

Step 6 Telefonische follow up
E-mail het telefoonnummer van patiënt naar l.w.leicher@isala.nl voor de telefonische follow-up

6.1	Datum telefonisch contact	
6.2	VAS dag 1	
6.3	VAS dag 7	
6.4	VAS dag 30	
6.5	Klachten en/of complicaties	
6.6	EQ-5D-5L	dd-mm-yyyy
6.7	MOBILITEIT, onderdeel van 6.6	Ik heb geen problemen met lopen Ik heb een beetje problemen met lopen Ik heb matige problemen met lopen Ik heb ernstige problemen met lopen Ik ben niet in staat om te lopen
6.8	ZELFZORG, onderdeel van 6.6	Ik heb geen problemen met mijzelf wassen of aankleden Ik heb een beetje problemen met mijzelf wassen of aankleden Ik heb matige problemen met mijzelf wassen of aankleden Ik heb ernstige problemen met mijzelf wassen of aankleden Ik ben niet in staat mijzelf te wassen of aan te kleden
6.9	DAGELIJKSE ACTIVITEITEN, onderdeel van 6.6	Ik heb geen problemen met mijn dagelijkse activiteiten Ik heb een beetje problemen met mijn dagelijkse activiteiten Ik heb matige problemen met mijn dagelijkse activiteiten Ik heb ernstige problemen met mijn dagelijkse activiteiten Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren
6.10	PIJN/ONGEMAK, onderdeel van 6.6	Ik heb geen pijn of ongemak Ik heb een beetje pijn of ongemak Ik heb matige pijn of ongemak Ik heb ernstige pijn of ongemak Ik heb extreme pijn of ongemak
6.11	ANGST/SOMBERHEID, onderdeel van 6.6	Ik ben niet angstig of somber Ik ben een beetje angstig of somber Ik ben matig angstig of somber Ik ben erg angstig of somber Ik ben extreem angstig of somber
6.12	Uw gezondheid VANDAAG is onderdeel van 6.6	1-100
6.13	Ruimte voor eventuele opmerkingen	

9.2 Appendix 2

EQ-5D-5L taken by telephone 3 months after procedure

Zet bij iedere groep in de lijst hieronder een kruisje in het hokje dat het best past bij uw gezondheid VANDAAG.

MOBILITEIT

Ik heb geen problemen met lopen	[ ]
Ik heb een beetje problemen met lopen	[ ]
Ik heb matige problemen met lopen	[ ]
Ik heb ernstige problemen met lopen	[ ]
Ik ben niet in staat om te lopen	[ ]

ZELFZORG

Ik heb geen problemen met mijzelf wassen of aankleden	[ ]
Ik heb een beetje problemen met mijzelf wassen of aankleden	[ ]
Ik heb matige problemen met mijzelf wassen of aankleden	[ ]
Ik heb ernstige problemen met mijzelf wassen of aankleden	[ ]
Ik ben niet in staat mijzelf te wassen of aan te kleden	[ ]

DAGELIJKSE ACTIVITEITEN ***(bijv. werk, studie, huishouden, gezins- en vrijetijdsactiviteiten)***

Ik heb geen problemen met mijn dagelijkse activiteiten [ ]

Ik heb een beetje problemen met mijn dagelijkse activiteiten [ ]

Ik heb matige problemen met mijn dagelijkse activiteiten [ ]

Ik heb ernstige problemen met mijn dagelijkse activiteiten [ ]

Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren [ ]

PIJN/ONGEMAK

Ik heb geen pijn of ongemak [ ]

Ik heb een beetje pijn of ongemak [ ]

Ik heb matige pijn of ongemak [ ]

Ik heb ernstige pijn of ongemak [ ]

Ik heb extreme pijn of ongemak [ ]

ANGST/SOMBERHEID

Ik ben niet angstig of somber [ ]

Ik ben een beetje angstig of somber [ ]

Ik ben matig angstig of somber [ ]

Ik ben erg angstig of somber [ ]

Ik ben extreem angstig of somber [ ]

- We willen weten hoe goed of slecht uw gezondheid VANDAAG is.
- Deze meetschaal loopt van 0 tot 100.
- 100 staat voor de beste gezondheid die u zich kunt voorstellen. 0 staat voor de slechtste gezondheid die u zich kunt voorstellen.
- Markeer een X op de meetschaal om aan te geven hoe uw gezondheid VANDAAG is.
- Noteer het getal waarbij u de X heeft geplaatst in onderstaand vakje. UW GEZONDHEID VANDAAG =

MEETSCHAAL

De beste gezondheid die u zich kunt voorstellen

De slechtste gezondheid die u zich kunt voorstellen

100 75 50 25 0

|----------|----------|----------|----------|

9.3 Appendix 3

Figure 1 A suture through the base of the polyp under endoscopic visualization

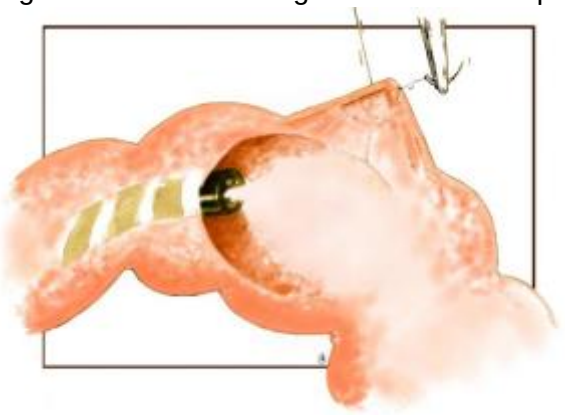


Figure 2 Traction on the suture to enable positioning of the linear stapler

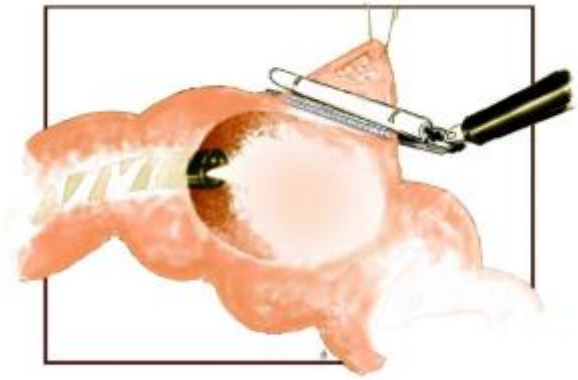


Figure 3 Before stapling off the patency of the lumen is checked endoscopiccaly