SATC·C | ADVANCED ADENOMAS EARLY COLORECTAL CANCER

DEPARTMENT OF SURGERY · ODENSE UNIVERSITY HOSPITAL

Annual Report 2018

SATC center

Department of Surgery

Odense University Hospital

Svendborg Hospital

Region of Southern Denmark

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Preface

The SATC Center, Department of Surgery, OUH

The SATC Center (SATCC) is embedded in the unit for Neoplastic Colorectal Research, Department of Surgery, Odense Universityhospital, Svendborg Hospital. It has undergone a rapid development during the first four years of its lifetime. Thus, 2018 became a year for consolidation, but also for further development in the areas described at its foundation i.e. development of a "National Reference Centre" for advanced adenomas and early colorectal cancer (in Danish: Store Adenomer og Tidlige Cancere i Colon og rectum" – SATC). The activities are described as:

Learning and Education:

The primary purpose of the learning center is to achieve a uniform and high-level standard for treatment of advanced adenomas and early colorectal cancer in the Region of Southern Denmark. Consistent application of the state-of-the-art treatment principles throughout the region could reduce the number of major surgical procedures significantly. Achieving the full clinical gain of recent years' breakthroughs requires intensive efforts to make the guidelines generally known and to increase the number of endoscopists trained in Endoscopic Mucosa Resection (EMR). This is a prerequisite for spreading the principles and competences regionally on a voluntary basis. Furthermore, it is in everybody's interest to develop the methods for a further expansion of the indication areas for organ-preserving treatment

Three new courses were introduced:

1. Endoscopic Mucosa Resection (EMR); Module 1 (The fundamentals) concerning management of early, small colorectal cancers and advanced polyps was launched October 2018.
2. The advanced EMR course, Module 2 took place February 2019.
3. Professional Communication; - intensive and dedicated education in the field of patient communication and nursing care of colorectal cancer patients.

All three courses were fully booked and the evaluation was very positive. All three courses will be repeated on a regular basis.

Besides hosting the courses on location in Svendborg, we delivered several presentations at meetings both in Denmark and abroad, promoting the SATCC and its field of interest.

Clinical Excellence:
Database hosting is a natural element of continuous quality improvement of clinical activity and significant efforts were invested in the updating of the EMR - ESD and TEM Database. The aim is to include new parameters necessary for further advancement and updating of the quality of our clinical activity.

The Endoconf System is our own invention. It enables real time communication as well as, transfer of images and videos from ongoing endoscopies to experts in another hospital in the region for immediate decision and avoidance of repeated colonoscopies by the expert centre. The Endoconf System has been the subject of great interest. Especially endoscopists in private practices expressed their interest in gaining the benefits of a SATCC specialist back up with this endo-videolink. The system and its possible terms of use are under constant development, while implementation is ongoing in the Region of Southern Denmark and actions to reach out to the practitioner colonoscopists are being planned. We anticipated some challenges in setting up a secure, high quality data transfer system for this system and together with the IT department some time was spent solving this to ensure transmissions of steady and sufficient quality.

In April, we had the pleasure of welcoming Professor and Chief Consultant Geerard Lucien Beets – head of the Department of Surgery, Netherlands Cancer Institute, Amsterdam, for his official affiliation with the SATCC as Associate Professor. The official welcome ceremony included a mini-symposium, where he delivered an excellent speech about his research in the area of non-surgical treatment of colorectal cancer, e.g. Watchful Waiting. The SATCC has huge expectations for the collaboration with both our Associate Professors; Professor Beets and Professor Robert J. C. Steele from Dundee.

Research:
It has become increasingly difficult to distinguish between the research in our unit, which is SATCC research and which is not. We have previously defined SATCC research as research funded by the SATCC grant, but the external funding of our unit has increased significantly and has amounted to 11.5 mio DKK during the last two years. We have therefore redefined SATCC to include all research in the area of advanced adenomas and early cancers. More than 20 scientific papers have been published in the last two years within this area, two PhD students have submitted their theses for review, and further one student will do so within a few months. Last but not least, three large international clinical trials are under preparation for start in 2019.

Head of SATC Professor Gunnar Baatrup

Head of SATC Consultant Niels Buch

SATC Center Organisation

SATCC is located in the House of Research (Forskningens Hus), Department of Surgery, OUH Svendborg Hospital, Baagøes Allé 15, entrance 41, 5700 Svendborg, Denmark.

Department of Surgery Management

Executive Consultant Claus Christian Vinther

Head Nurse Susanne Barren

SATCC Secretariat

Consultant Niels Buch, Head of Centre

Professor Gunnar Baatrup, Director of Research

Education Secretary and Responsible for Communication Lene von Fintel Sostack

Staff Doctor Anders Høgh

Project Nurse Anja Wulle

Project Nurse Mette Lundwald Rasmussen

Student Assistant Nishaja Velmurugan

External Advisors

External advisors are employed by the SATCC in order to benefit from sparring and assistance on an international top level in advanced adenomas and early cancers. Together with the other employees in the SATCC, the advisors' primary task is to ensure the high professional quality in the provided courses, as well as to give presentations. The advisors are experts in their respective fields.

Senior Advisors: Professor Neil Borley, Cheltenham General Hospital, UK and Professor Deirdre McNamara, Trinity College, Dublin.

Advisors: Radiologist Søren Rafaelsen, Vejle Hospital and Professor Ismail Gögenur, Zealand University Hospital.

The advisors have helped us to ensure the level of excellence.

Regional Working Group

A regional working group, consisting of specialist doctors from each of the specialist units in the region's other hospitals, has been formed. The working group's task is to pave the way for regional prioritisation and coordination of the centre's activities, including the preparation of education programmes/concepts.

Executive Consultant Claus Christian Vinther heads the working group, which is assisted by the secretariat.

Advisory Board

Additionally, the centre has an Advisory Board, which provides advice and sparring on visions, strategies, and professional matters within the core area. Members of the Advisory Board:

Claus Duedal Pedersen, Chief Consultant, Dept. of Clinical Development, OUH University Hospital, Svendborg Hospital.

Birger Endreseth, Trondheim, Surgical Clinic, St. Olav's Hospital, Norway.

Deidre Mc Namara, Associate Professor, Head of dept. Clinical Medicine, Tallaght Hospital,Trinity College Dublin.

Professor Regina Beets-Tan, Dept. of Radiology, The Netherlands Cancer Institute, Amsterdam.

Activity 1: SATCC Education and Learning

Again this year, we have held courses for both doctors and nurses. Thanks to the grant, employees of the Region of Southern Denmark are exempted from the course fee.

We started out the year with a new addition to our palette of courses.

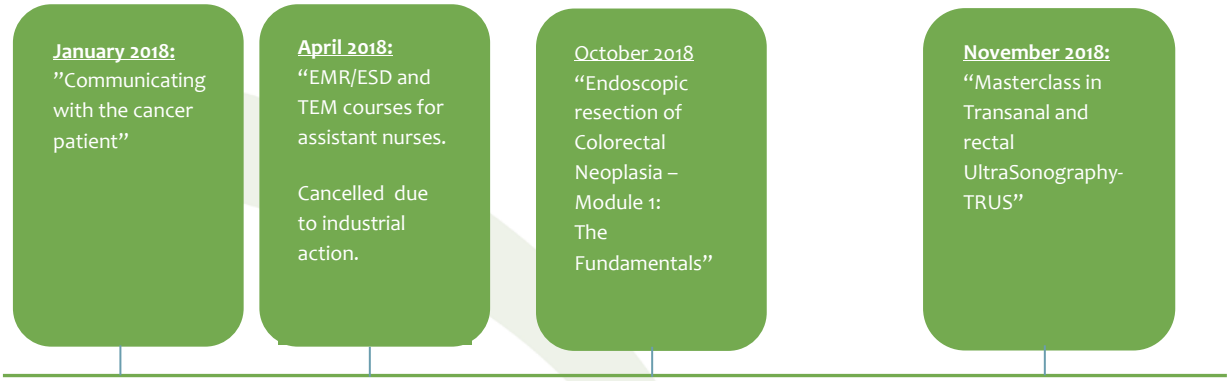
"Communicating with the cancer patient" is an intensive course with only 10 participants. The course takes theories as a starting point, but the participants also work with actors and act out an actual situation for the group. This means that the intensity of the course is key.

The course "Endoscopic Resection of Colorectal Neoplasia-Module 1: The Fundamentals" was also held for the first time, where endoscopists from home and abroad shared a day full of theory, but also hands on workshops.

In continuation of the first module 1, we will offer a module 2 in 2019, a two-day course that prepares endoscopists to overcome challenges, gain confidence, and demonstrate their "readiness" to perform EMR. The course is designed to specifically teach standardised knowledge and motor skills in colo-rectal EMR. Enrollees will participate in a half-day of detailed introduction to EMR and a one-day of intensive, standardised, hands-on training.

For the fourth time we host the course "Masterclass in Transanal and Transrecal UltraSonography", where both national and international experts gave lectures in basic anal and rectal anatomy, as well as in diagnostics concerning fistulas, abscesses, sphincter defects, benigne and malignant polyps, and rectal cancer. Furthermore, there were live sessions with endoscopic and ultrasonographic examinations.

Courses 2018



Every second year we host a SATCC Symposium – the next will be in 2019.

Activity 2: EndoConf

EndoConf is a real-time audio-video-link system between an endoscopy room and an expert endoscopist on duty.

The audio-video-link carries an audio signal, a video signal from the endoscopy room, and a video signal from the endoscope. Thus, the system enables a live mini-conference between the endoscopist from any of the endoscopy units in the Region of Southern Denmark and an expert endoscopist at Surgical Department A, Odense University Hospital.

EndoConf has been tested to make sure that the quality of image and sound makes it reasonable to give medical advice from the data received on a tablet. Both image and sound received very good ratings in the tests.

We are currently working on a computerised administration system to allocate the calls from the EndoConf unit to the different portable tablets, for the expert surgeon 'on duty'.

An agreement has been established with a partner from the private sector, who will borrow and test the EndoConf system, before acquiring it.

The deployment of the system to the endoscopy units across the Region of Southern Denmark has been delayed due to difficulties in applying the video-call-system. We expect the deployment to take place in autumn 2019.

Furthermore we have looked into and tested the patentability, although with a negative result.

Activity 3: SATCC Website

The website www.satccenter.com was launched in March 2018. It is a platform for registration and communication as well as continued development of a network for the participants, who have attended our courses.

After a course has been held, a closed website will be available for the participants, where they can find presentations as well as ask questions directly to the presenters or chairmen. We have had great response to this opportunity.

Activity 4: SATCC Clinical Excellence

As described above, an accelerated development of the clinical excellence in the Department of Surgery has now been taking place for 3-4 years, since the first grant from the Danish Cancer Society. We have further expanded the tracks that were set out then.

The SATCC grant is not intended to contribute directly to this development, but the SATCC activity depends on a strong professional environment, and the department management (Department of Surgery, OUH) has contributed to strengthening the quality of the clinical activity. On a national level, we are already in the lead concerning activity level, number of dedicated people, and number of publications.

First and foremost, we have upgraded equipment and specialist competences in a group of dedicated doctors and nurses. We are working to organizationally strengthen the endoscopic activity by placing it under the responsibility of a dedicated specialist.

Activity 5: SATCC Research

The SATCC acts as a principal investigating centre and as a collaboration hub in a number of trials with a main focus on early rectal cancer and significant polyps of the colorectum. The SATCC acts as a national catalyst in a growing area of early detection and organ preserving treatments of the colon and rectum.

The STAR TReC phase 2 trial is an ongoing international randomised study assessing the safety of chemoradiotherapy and adjacent local excision of early cancers in the rectum. The study is about to finish inclusion and is not far from launching the phase 3 trial, incorporating a "patient preference"

design to accommodate and facilitate the patients' wish to sustain their rectum. Interim results are promising.

The project "DETECT" is a study testing the applicability of Dual Energy CT for stage assessment of rectal cancer. Dual energy CT is an advanced radiomic tool aiding the clinicians in tissue differentiation based on unique quantitative measurements. We are testing its accuracy in assessing lymph nodes and tumour regression grade after chemoradiation therapy for rectal cancer to establish a potential route of deferral from major surgery to local excision or an active surveillance based on complete tumour disappearance after chemoradiotherapy.

SATCC is a collaborator of the international watch and wait database, contributing to the very valuable data obtained for rectal cancer patients with a complete disappearance of their rectal cancer after chemoradiotherapy, the so-called "watch and wait" programme.

SATCC is the holder of a large database recording parameters for all local excisions of rectal tumours and endoscopic resections of colonic lesions. Data from the database has resulted in a number of publications and national guidelines to aid in the management of significant polyps and early colorectal cancers.

VORATES is a trial investigating the role of postoperative chemoradiotherapy for locally resected rectal cancers. Evidence is building towards a general ethos of rectal preservation instead of major resections for early rectal cancers. VORATES is a randomized study randomizing between postoperative chemoradiation and active surveillance of locally excised rectal cancer.

Publication activity based on the above counts 10 peer reviewed papers in international journals, approx. 10 papers in the pipeline, as well as 3 national guidelines in the period 2018-2019.

Publications from SATCC 2018:

Blanes-Vidal, V., et al., *Capsule endoscopy vs. colonoscopy vs. histopathology in colorectal cancer screening: matched analyses of polyp size, morphology, and location estimates.* Int J Colorectal Dis, 2018. **33**(9): p. 1309-1312.

Buchbjerg, T., et al., *Increased Rate of Incidental Colorectal Malignant Polyps: A Single-Center Experience.* Surg Res Pract, 2018. **2018**: p. 3465931

Buijs, M.M., et al., *Can coffee or chewing gum decrease transit times in Colon capsule endoscopy? A randomized controlled trial.* BMC Gastroenterol, 2018. **18**(1): p. 95.

Buijs, M.M., et al., *Intra and inter-observer agreement on polyp detection in colon capsule endoscopy evaluations.* United European Gastroenterol J, 2018. **6**(10): p. 1563-1568

Buijs, M.M., et al., *Assessment of bowel cleansing quality in colon capsule endoscopy using machine learning: a pilot study.* Endosc Int Open, 2018. **6**(8): p. E1044-e1050.

Kroijer, R. and G. Baatrup, *[The effect of primary colonoscopy versus follow-up colonoscopy in screening for colorectal cancer].* Ugeskr Laeger, 2019. **181**(7).

Kobaek-Larsen, M., et al., *Effect of the dietary polyacetylenes falcarinol and falcarindiol on the gut microbiota composition in a rat model of colorectal cancer.* BMC Res Notes, 2018. **11**(1): p. 411.

Kobaek-Larsen, M., et al., *Back-to-back colon capsule endoscopy and optical colonoscopy in colorectal cancer screening individuals.* Colorectal Dis, 2018. **20**(6): p. 479-485.

Kroijer, R., et al., *Booster medication to achieve capsule excretion in colon capsule endoscopy: a randomized controlled trial of three regimens.* Endosc Int Open, 2018. **6**(11): p. E1363-e1368.

Mikkelsen, E.M., et al., *Colonoscopy-related complications in a nationwide immunochemical fecal occult blood test-based colorectal cancer screening program.* Clin Epidemiol, 2018. **10**: p. 1649-1655

Activity 6: SATCC Database

The database has been evaluated and intensely discussed in 2018 due to the fact that the basis and support for the existing platform will "expire" within a relatively short period of time, i.e. probably 4-5 years. Additionally, the difficulties in recruiting new departments in the common data registration seem to increase when presenting to local hospitals' IT departments. The basic platform is actually relatively unknown among the supportive IT departments, although it is completely safe and well documented. Due to the declining use of this platform in general, we foresee problems with long-term supportive functions and thus difficulties in maintaining both quality and further development. Therefore, the planned update of the database might be combined with a fundamental new platform i.e. Open Red Cap, which is a well known system to every hospital department in Denmark, and to the supportive IT departments. At present, Vejle and Esbjerg in the Region of Southern Denmark as well as Aarhus, are actively joining the database reporting EMR and ESD procedures. The primary goal is a complete reporting within the Region of Southern Denmark for all locally excised early cancers and large polyps, including follow-ups. The second goal is to become a nationally accepted database with secretary function and basis in the Department of Surgery OUH, Svendborg (House of Research). The research in this field is expected to redefine the used surgical / endoscopic methods, including validation of new minimally invasive methods such as TEM-ESD and eFTR (endoscopic Full Thickness Resection).