Robotic-assisted benign hysterectomy – learning curve for surgeons and a randomized comparison of robotic single-site hysterectomy vs. multi-port laparoscopic hysterectomy

Background:
Robotic-assisted surgery in gynecology is one of the fastest growing fields of robotic surgery. In Denmark yearly 4000 hysterectomies are performed on benign indications (1) and minimal invasive technique used in hysterectomies has increased from 35 % to 80 %. These include vaginal, laparoscopic assisted and lately robotic-assisted hysterectomy The robotic surgical system Da Vinci was introduced in 2000. By 2016, 3803 units were established worldwide and 644 of them in Europe. Hysterectomy and prostatectomy is by far the most common operations performed with the Da Vinci robot Robotic-assisted surgery is an alternative to conventional laparoscopy allowing better ergonomy for the surgeon and precise movements due to endo-wristed instruments.
Robotic surgery in benign gynecology is still a matter of debate, due to expensive costs and lack of evidence of superiority to conventional laparoscopy regarding perisurgical outcome.

A new approach in hysterectomy is the robotic single-site technique (R-SS), which is based on one single incision compared to standard four incisions in multiport robotic- as well as conventional laparoscopy. This wound-sparring technique may reduce postoperative pain, allowing shorter hospitalization, shorter sick leave and better cosmesis. Since fast-track regimes are gaining ground in gynecology there is a need for detailed information about the new surgical technique, especially whether it can replace conventional multiport laparoscopy.

Determination of learning curves for a novel surgical technique like the robot provides valuable information regarding safety as well as applicability. For these reasons proper knowledge is important to which extent e.g. BMI, uterine size, and docking time at the robotic console influence the procedure. Secondly, the proper patient selection could be established for the various surgical options. To date, there are no detailed reports on robotic single-site hysterectomy using the newest robotic technology, the da Vinci, Xi system.

Multi-port versus Single-site in laparoscopic surgery
The advantage of laparoscopic hysterectomy compared to abdominal hysterectomy is associated to the lack of large abdominal wound, resulting in shortened hospitalization, faster postoperative recovery, and less postoperative pain(1) (Aarts, Nieboer et al. 2015) However, multiport laparoscopy is not without risks. A laparoscopic hysterectomy requires 4 trocar incisions, including muscles-splitting incisions. Reports suggest a 5% risk of neuropathic pain, as well as increased risk of infection and hernia at the trocar site (2) (Shin and Howard 2012).

In an attempt to improve the benefits of laparoscopic surgery, such as minimizing wound lesions as well as optimizing cosmetic results, the laparoscopic single-site technique was developed. This technique is based on one single multichannel device placed through a 2 cm, relatively hidden, peri-umbilical skin incision. The device allows optics and multiple instruments access to the abdomen (Fig.1). A recent randomized study showed less bleeding (median 20 vs 50 ml) in robotic single port compared to laparoscopic multiport hysterectomy (3)(Paek et al 2016). In the largest randomized study to date Kim et al found transfusions rates were the most frequent complication required in 4.0% of single-port cases and 7.9% of multiport cases (3a) (Kim et al 2015). A review and metaanalysis comparing laparoscopic single-site with conventional multiport laparoscopic hysterectomy found that laparoscopic single-site was feasible and safe (4) (Sandberg, la Chapelle et al. 2017). There was no significant difference between the two techniques regarding complication rate, conversion risk and postoperative pain. However, the quality of evidence in the studies was low and various other observations like cosmesis was not consistently established.

Women's expectations; surgical safety and cosmesis

Surgical safety and cosmesis are important considerations for patients undergoing laparoscopy. A study by Golkar et al. (5)showed that preoperatively patients were mostly concerned about the surgical safety but, postoperatively, the patients mainly focused on the cosmetic result Another prospective comparative study showed that the laparoscopic single-site incision was the preferred abdominal incision judged by questionnaire (6)(Yeung et al. 2013). Thus, there is a need for constantly improving and developing the end-points of care in our minimal invasive techniques.

Economic issues

Cost-analysis on R-SS compared to laparoscopic multiport hysterectomy in benign gynecology has a knowledge gap. A retrospective study suggests increased cost per case using R-SS compared to laparoscopic multiport hysterectomy (7)(El Hachem et al. 2016). A variety of circumstances influences the analyses such as already established infrastructure for robotic surgery at the hospital, high volume versus low volume robotic centers and experienced robotic teams. Cost-effectiveness analyses are essential in order to provide a responsible utilization of health care resources and includes determination on sick-leave, consultation to healthcare (ex kontakt I amb ell e.l. pga kir.relaterede problemstilling). If out-of-hospital costs are included these may vary between countries; however, the phase between hospital stay and return to work may imply extra cost for the patient, need for reimbursement from health insurances, visits to medical professionals due to related morbidity a.s.o. If rehabilitation with RSS is shorter and includes less extra medical cost and visits the total cost may be less.

Summary:

R-SS hysterectomy is a novel technique, which may be superior to conventional laparoscopic multiport hysterectomy in select patients regarding sick-leave, cosmesis and and postoperative pain. We, therefore, aimed at evaluating the learning curve using different robotic equipment (DaVinci Si Multiport surgical system and Davinci Xi multiport and single site surgical system) in our cohort since 2014 to determine its applicability in our hospital setting. Secondly, we perform a randomized trial to compare R-SS hysterectomy with conventional laparoscopic multiport hysterectomy with regard to outcome postoperative rehabilitation, cosmesis, and the operational cost

Aim of study
Our study aims to evaluate R-SS with respect to:

Primary outcome:

- Length of hospital stay and time to return to daily activities /work
- Cosmesis; pre-and postoperative evaluation
- Postoperative pain (VAS)

Secondary outcome

- Learning curve for robotic-assisted hysterectomy including R-SS hysterectomy
- Patient satisfaction with the cosmesis
- Duration of operation incl. detailed information of time consumption of defined steps at hysterectomy, operation- and console time, blood loss, conversion rates, additional ports, port-site hernias, time at hospital, re-admission
- Cost-effectiveness analysis for the R-SS hysterectomy

Materials and Methods

Study 1:
Detailed learning curves for robotic surgery- single site and multiport hysterectomy – a prospective, controlled study. A retrospective study of all robotic hysterectomy since 2014

The prospective controlled study compares R-SSH with robotic multiport hysterectomy (the controls) and will be performed at the Department of Gynecology, Herning Hospital, between September 2016 to end of December 2017. Sample size is estimated based on recommendations from the literature (8)(Cala V. et al. 2012). The study consists of two sub-studies (A and B). Each of the two sub-studies includes 40 procedures performed by two experienced laparoscopists with 20 procedures each.
A: Determination of learning curve for two similar experienced surgeons, for 40 robotic *multiport* hysterectomies – 20 hysterectomies per surgeon.
Inclusion criteria for the learning curve studies are hysterectomy on benign indication, ASA group 1 or 2, BMI (body mass in kg/heights in metres2) less than 35 kg/m2 (for R-SS hysterectomy less than 30), uterine size less than 300 g estimated by ultrasound, using Ferraris formula.
Exclusion criteria are risk of adhesions, prior extensive abdominal surgery and prior midline incision, cutis laxa of abdomen surgery, endometriosis, and more than 1 cesarean section.
The procedure is video recorded and peri-and postoperative data are collected prospectively. Various steps during the procedure are determined such as various split time measurements like docking time, console time, vaginal cuff suturing, incision start, skin-to-skin and closure time. Uterine size and blood loss, as well as patient demographic data are registered.

B. The on-going study estimates the learning curve for *R-SS* hysterectomy. In- and exclusion criteria as for Study 1 except for inclusion criteria of BMI less than 30 kg/m2

C. Further, a retrospective cohort from the first robotic hysterectomies in 2014 until recently will be evaluated. The surgeries in the prospective studies are performed using the Da Vinci Xi surgical system and in the retrospective study using the Da Vinci Si Multiport system. Due to its design only crude incidences on perioperative variables will be evaluated.

Study 2
Robotic single-site hysterectomy compared to laparoscopic multiport hysterectomy – a prospective randomized controlled study; cosmetic satisfaction and surgical outcome.

The study is scheduled to start May 2018 and compares R-SS hysterectomy to laparoscopic multiport hysterectomy. Procedures are performed by an experienced three-surgeon team. Patients are randomized to either laparoscopic multiport hysterectomy (N=62) or R-SS hysterectomy (N=62) by random numbers in sealed envelopes prepared by a third party. Eligibility criteria are the same as for study 2B (i.e. BMI < 30 kg/m2). Patient's satisfaction with body image and cosmesis is assessed at different time points pre- and postoperatively by means of multidimensional body-self relations questionnaire – appearance evaluation sub-scale and POSAS. Postoperative pain and analgesia use will

be registered as well as secondary outcome parameters as described above. A follow-up at one, three, and six month include self evaluation of the scar and registration of port-site hernias, vaginal dehiscence or other complications (Vercellia et al). Interviews and diaries will include time of return to home and work, daily activities including sexuality
The R-SS hysterectomy is performed using da Vinci, Xi robotic system. One single port, diameter 2 cm is applied at the umbilicus. Applying an additional assistant port is defined as conversion of procedure
The laparoscopic multiport hysterectomy is performed using our standard equipment and 4 trocars, 5 mm each.

Study 3
Socio-economical consequences of R-SS hysterectomy versus conventional laparoscopic hysterectomy

Study details in preparation
Instrumental cost
Hospital stay
Post-hopsitalization cost. sick days, extra visits to the out-aptient clinic, genereal practioner, medical expenses

Sample size calculation was based a PhD- study on fast track hysterectomy, which showed a difference in return to work of 4 days and SD ±8. 62 women in each group are needed for a power of 80% (beta=0.2) to replicate this study. To include those not working, we calculated that with an expected VAS of 0.86 ±0.2 and 62 in each group the sample was sufficient to detect of difference of 0.1 in VAS; still, with a power of 80%. All calculations are based on two-sided testing with alpha = 0.05.
The retrospective study was approved by the Data Authority (no. 1-16-02-913-17). The randomized trial is registered at clinicaltrials.gov (NHS).

Statistics

For statistical calculations of proportions the χ2-test with Yates' correction for discontinuity or the Fisher's Exact-test was used. For continuous variables Student's t-test, Mann-Whitney's U –test, and Wilcoxon's Signed Rank test was used when appropriate. Questionnaires with partial answers were included in the calculations, if possible. ANOVA and Kruskal Wallis' test was performed between group variables. Post-hoc test with Newman-Keul's test was performed between group pairs, if ANOVA was significant. Repeated measurements were evaluated with 2-way ANOVA and surgical procedure as group variable with potential confounding variables like age, BMI, surgeon, and additional surgery added. The distribution of BMI, age, blood loss, split times during operation, hospital stay and time of return to daily activities and work were evaluated by means of Kaplan-Meyer analysis. The level of significance was a two-sided $p < 0.05$. Logistics regression analysis was performed with surgical procedure as dependent variable and the various split times, surgeon, age, BMI, parity, as independent variables. Learning curves were established for each individual surgeon, surgical procedures, and combined monitored over time of the studies. Data are given as mean ±SD if following Gaussian distribution and median (minimum, maximum) if non-Gaussian distributed. IBM SPSS Statistics 20 was used as the statistical software

Research plan

Study 1; jan 2017-june 2018
Study 2; may. 2018-jan. 2020
Study 3; 2020-2021

Responsibility:

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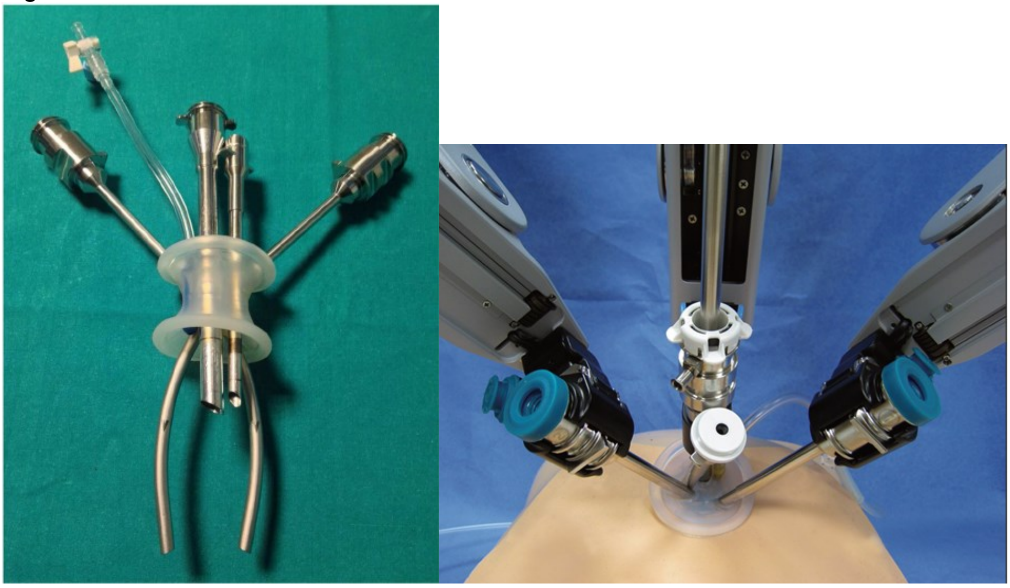
Figure 1



Single-site device Da Vinci Si system

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