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Long-term consequences of subtotal and total abdominal hysterectomy

Follow-up of a randomized clinical trial and an observational study

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Summaries

2.1 English summary

This thesis is based on 4 articles *(Articles 1-4).* The aim was to compare subtotal (SAH) and total (TAH) abdominal hysterectomy for benign indications 14 years after the operation.

The follow-up is based on a randomized clinical trial (RCT) carried out in 1996 to 2000. An observational study (OS) carried out simultaneously with the RCT was also included in a registry-based study of cervical cancer screening after hysterectomy.

The women who participated in the RCT were followed-up by a questionnaire covering the pre-specified outcomes: Urinary incontinence (primary outcome), constipation, quality of life, pelvic organ prolapse, pain, satisfaction with sex-life, hospital contacts, vaginal bleeding after SAH (secondary outcomes) and lower urinary tract symptoms (exploratory analyses).

An objective assessment of lower urinary tract function and pelvic organ prolapse including pad-weighing test, urinary flow, residual urine, POP-Q measurement, and bladder diary was performed.

Finally assessment of the cervical cancer screening program was carried out. Data were retrieved from Patobank regarding adherence to the cervical cancer screening program and cervical pathology after hysterectomy.

We contacted 304 women. The Questionnaire was answered by 197 (64.8%) women (SAH: 97, TAH: 100). Mean follow-up time was 14.1 years and age at follow up was 60.1 years.

Urinary incontinence was more common after SAH (n= 32, 33.3%) than after TAH (n=20, 20%) (RR: 1.67, 95%CI: 1.02-2.70, P=0.035) *(Article 1).* Exploratory analyses showed that this difference was primarily due to a difference in the number of women with stress urinary incontinence after SAH and TAH *(Article 2).* No difference was found between SAH and TAH regarding the secondary outcomes.

Of those who answered the questionnaire, 100 (SAH: 53, TAH: 47) women participated in clinical examinations *(Article 3)*. After SAH 31 (59.6%) women had objective pelvic organ prolapse compared with 33 (70.2%) after TAH (P=0.27). We found a higher median maximum flow rate (Qmax) after SAH (30.3 ml/sec) than after TAH (27.1 ml/sec) (P= 0.042) and a higher median functional bladder capacity after SAH (531.7ml) than after TAH (443.3 ml) (P=0.0147) according to the bladder diary. The registry study of cervical screening *(Article 4)* included 501 women (SAH: N= 259, TAH: N= 242). Almost one in ten (9.7%) of the women were not invited to screening after SAH. Adherence to screening was 61.4%; 30.1% were screened less frequently than every 5 years and 8.5% were not screened at all. After TAH 14.5% were not invited, 6.6% adhered to screening and 65.7% were not screened. We found minimum one abnormal test in 28 (10.8%) women after SAH and one after TAH. No cervical cancers were found.

In conclusion, we found no evidence favouring SAH compared with TAH; contrarily we found more cases of urinary incontinence after SAH. Furthermore, we found that cervical cancer screening after hysterectomy is not optimal: Some SAH women were not invited and most TAH women were invited, though they did not have a cervix. One in ten had abnormal cervical smears after SAH. The long-term outcomes presented in this thesis suggest that total hysterectomy should be the first choice of hysterectomy for benign indications.

2.2 Dansk Resumé

Afhandlingen er baseret på fire artikler *(Artikel 1-4)*. Formålet med afhandlingen var at sammenligne subtotal (SAH) og total (TAH) abdominal hysterektomi på benign indikation med hensyn til langtidsfølger 14 år efter operationen.

Sammenligningen er baseret på et randomiseret klinisk studie (RCT) der inkluderede kvinder i årene 1996-2000. Et observationsstudie der blev udført samtidig med RCT'en blev også inkluderet i et registerstudie angående cervix cancer screening efter hysterektomi.

Kvinderne modtog et spørgeskema der omhandlede urininkontinens (det primære effektmål), prolaps, smerter, obstipation, tilfredshed med seksuallivet, livskvalitet, hospitalskontakter og vaginal blødning efter SAH (sekundære effektmål) samt urininkontinens subtyper og andre vandladningsgener (uddybende analyser).

En objektiv klinisk undersøgelse bestående af blevejningstest, uroflowmetry, residualurinmåling, POP-Q måling og væskevandladningsskema blev også foretaget.

Herudover foretog vi en evaluering af cervix cancer screening efter hysterektomi på baggrund af kvinderne i det randomiserede studie samt det sideløbende observationsstudie. Data om deltagelse i screening samt patologisvar blev indhentet fra Patobank.

Vi kontaktede 304 kvinder. Spørgeskemaet blev besvaret af 197 (64,8 %) kvinder (SAH: 97, TAH: 100) *(Artikel 1)*. Gennemsnits opfølgningstid var 14,1 år og gennemsnitsalderen ved opfølgningen var 60,1 år. Antallet af kvinder der angav at være urininkontinente var 32 (33,3 %) efter SAH og 20 (20 %) efter TAH (RR: 1,67, 95 % CI: 1,02-2,70, P=0,035). Uddybende analyser viste at denne forskel primært skyldtes forskel i hyppigheden af stress urininkontinens mellem SAH og TAH *(Artikel 2)*. SAH og TAH var sammenlignelige med hensyn til de sekundære effektmål.

Af dem der besvarede spørgeskemaet deltog 100 (SAH:53, TAH: 47) kvinder i kliniske undersøgelser *(Artikel 3)*. Efter SAH observeredes grad 2 prolaps hos 31 (59,6 %) kvinder sammenlignet med 33 (70,2 %) kvinder efter TAH (P=0,27). Vi fandt højere median maksimal flow rate (Qmax) hos kvinder efter SAH (30,3 ml/sec) end hos kvinder efter TAH (27,1ml/sec) (P= 0,042) og højere median funktionel blærekapacitet efter SAH (531.7ml) end efter TAH (443.3 ml) (P=0,0147) ifølge væskevandladningsskemaet.

Studiet om cervix cancer screening inkluderede 501 kvinder (SAH: 259, TAH: 242) *(Artikel 4)*. Efter SAH blev 9,7 % af kvinderne ikke inviteret til screening. Tilslutning til cervix cancer screening efter SAH var 61,4 %; 30,1 % blev screenet mindre end hver femte år og 8,5 % blev ikke screenet. Efter TAH blev 14,5 % ikke inviteret til screening, tilslutning til screening var 6,6 % og 65,7 % blev ikke screenet. Hos 28 (10,8 %) kvinder i SAH gruppen fandt vi mindst én abnorm prøve. I TAH gruppen havde én kvinde en abnorm prøve. Alle abnorme prøver blev fulgt op med relevante undersøgelser. Vi fandt ingen tilfælde af cervix cancer.

Vi har ikke fundet evidens for at SAH er TAH overlegen. Tværtimod, fandt vi flere urininkontinente kvinder i gruppen der fik foretaget SAH. Ydermere, fandt vi at screening for cervix cancer efter hysterektomi ikke er optimal: Nogle kvinder blev ikke inviteret efter SAH og de fleste kvinder blev inviteret efter TAH selvom de ikke har en cervix. Én ud af ti kvinder oplevede abnorme celleprøver efter SAH. Ifølge resultaterne fra denne afhandling bør total hysterektomi være førstevalg ved benign sygdom.