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ORIGINAL ARTICLE

Colpocleisis: reoperation risk and risk of uterine and vaginal cancer: A nationwide cohort study

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Abstract

Introduction and hypothesis We aimed to evaluate the risk of reoperation and uterine (myometrial, endometrial, and cervical) and vaginal cancer after colpocleisis performed during the years 1977–2018. Furthermore, we also aimed to assess the development in colpocleisis procedures performed during the study period.

Methods Danish nationwide registers covering operations, diagnoses, and life events can be linked on an individual level owing to the unique personal numbers of all Danish residents. We performed a nationwide historical cohort study including women born before year 2000 who underwent colpocleisis between 1977 and 2018 ($N=2,228$) using the Danish National Patient Registry (DNPR). We followed the cohort until death/emigration/31 December 2018, whichever came first. Primary outcomes were number of pelvic organ prolapse (POP) operations performed after colpocleisis and uterine and vaginal cancer diagnosed after colpocleisis in a subgroup of women with the uterus in situ. This was assessed with cumulative incidences.

Results During follow-up (median 5.6 years) 6.5% and 8.2% underwent POP surgery within 2 and 10 years after colpocleisis respectively. Within 10 years after colpocleisis 0.5% ($N=8$) were diagnosed with uterine or vaginal cancer in the subgroup of women with their uterus ($N=1,970$). During the study time 37–80 women underwent colpocleisis yearly and the mean age increased (77.1 to 81.4 years).

Conclusion Despite smaller studies showing no recurrence after colpocleisis, we found that 6.5% underwent reoperation within 2 years. Few women were diagnosed with uterine or vaginal cancer after colpocleisis. The increased age at the time of colpocleisis indicates changed attitudes regarding surgical treatment for elderly women with comorbidities.

Keywords Colpocleisis · Obliterative procedure · Pelvic organ prolapse · Reoperation rate · Uterine cancer · Vaginal cancer

Introduction

Pelvic Organ Prolapse (POP) is frequent and increases with age [1]. Owing to the growing elderly population and the large lifetime risk of undergoing a POP surgery [2], the number of POP surgeries will increase considerably. Hence, knowledge about the postoperative prognosis is crucial.

In Denmark, every fifth woman undergoes a POP surgery, which can be either reconstructive or obliterative [2]. Obliterative procedures, also called colpocleisis, can be performed with or without hysterectomy. The latter is sometimes referred to as Le Fort colpocleisis. Colpocleisis involves removal of the vaginal epithelium and suturing the anterior and posterior fibromuscular vaginal wall together. When the colpocleisis is performed without a hysterectomy, bilateral channels are left open for uterus discharge whereas the vaginal canal is completely closed if performed concomitant with or after a hysterectomy [3, 4]. The vaginal closure eliminates any future possibility of vaginal coitus and complicates examination of the cervix and endometrium in the case of suspected malignancy. However, the colpocleisis has several beneficial factors, including the possibility of local anesthesia [5, 6], a low complication rate [7, 8], and low mortality [7]. Despite the drastic intervention, studies have shown high satisfaction and low regret rates [9–12]. Taking that into account, colpocleisis is a favorable treatment for women with a high anesthetic risk and no desire for future vaginal coitus [8].

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Previous studies on colpocleisis are limited by small study populations owing to the relatively low frequency of colpocleisis [10] and large long-term studies are needed to cover the success of colpocleisis. With this nationwide cohort study we aimed to evaluate the risk of reoperation and uterine and vaginal cancer after colpocleisis performed during the years 1977–2018. Furthermore, we aimed to assess the number of colpocleisis performed and the development in age of the women undergoing colpocleisis. We hypothesized a low risk of reoperations and uterine and vaginal cancers after colpocleisis.

Materials and methods

Settings

We conducted a historical cohort study including Danish women undergoing colpocleisis during the period 1977–2018. The Danish health care system is tax funded, entailing free and equal access for all citizens. Each individual has a unique ten-digit Civil Personal Register number [13]. Via this number all registers can be linked on an individual level. Nationwide registers with information about life and health events allow the possibility of large epidemiological studies with lifelong follow-up [13].

Data sources

The Danish Civil Registration System (CRS) contains information about migration and vital status for all people living in Denmark [14].

The Danish National Patient Registry (DNPR) has been a nationwide registry with clinical data on patients since 1977, including administrative data, diagnoses, treatments, and examinations [15]. All data on POP surgeries performed in private and public hospitals in Denmark are registered in the DNPR. Reporting to the DNPR is compulsory by law [15]. Data is available via Statistics Denmark. From 1977 to 1995 surgeries were coded according to The Danish Classification of Surgical Procedures and Therapies. Since 1996, surgeries have been coded according to The Nordic Classification of Surgical Procedures (NOMESCO). Diagnoses were coded according to the eighth edition of the International Classification of Diseases (ICD) until 1994 and afterward according to tenth edition of the ICD.

Study population

We identified women born before 2000 who had a Danish address at some point during the years 1977–2018 through the Danish CRS. We included all women undergoing primary colpocleisis at a Danish hospital during the period 1977–2018 on POP indication using the DNPR (diagnostic and surgical codes in Appendixes 1 and 2). Exclusion criteria were concomitant POP surgeries not compatible with colpocleisis (Appendix 2).

Statistical analyses

Primary outcomes were reoperation for POP after colpocleisis and diagnosis with uterine (including myometrial, endometrial, and cervical) or vaginal cancer after colpocleisis. Secondary outcome was the development in yearly number of colpocleisis procedures during the years 1977–2018 and the age at the time of colpocleisis.

Reoperations were defined as a POP surgery performed a minimum of 60 days after primary colpocleisis. Exact operation codes for POP surgeries as well as diagnostic codes for cancer are listed in Appendixes 1 and 2.

Women were censored at the time of death, emigration, or 31 December 2018, whichever came first.

To evaluate the development of colpocleisis we constituted three temporal cohorts of 14 calendar years according to the year of colpocleisis: early (1977–1990), intermediate (1991–2004), and late (2005–2018). To evaluate the development in age as well as the number of colpocleisis procedures performed during the three temporal cohorts we applied *t* tests.

The risk of reoperations was assessed with cumulative incidences. Furthermore, different risks within the temporal cohorts were compared using Cox regressions adjusted for age as a continuous variable.

The risk of uterine and vaginal cancer was assessed with cumulative incidences in a subgroup of women excluding women who had undergone hysterectomy prior to or concomitantly with colpocleisis (Appendix 2). Women who underwent hysterectomy after colpocleisis were censored at the time of hysterectomy.

Statistical significance was defined as a p value < 0.05 and 95% confidence intervals not including 1. All calculations were performed using STATA (version 17; StataCorp, College Station, TX, USA). Strengthening the Reporting of Observational Studies in Epidemiology guidelines were followed [16].

The study was approved by the Danish Data Protection Council Jnr. P-2020–683. According to Danish law, ethical approval is not required for non-intervention, register-based studies.

Results

This historical cohort study included 2,228 women. Of the women included, 98.7% were over 60 years of age at the time of colpocleisis, and mean age was 79.2 years ± 7.5 SD (Table 1).

Table 1 Characteristics for the cohort undergoing colpocleisis

	Total	Subgroup: uterus in situ at the time of colpocleisis
Colpocleisis, *N*	2,228	1,970
Person years	15,519.2	14,409.9
Mean age for colpocleisis, years (SD)	79.2 (7.5)	79.4 (7.6)
Median follow-up time, years	5.6	6.0

N number, *SD* standard deviation

Of the 2,228 women undergoing colpocleisis, 167 underwent reoperation. Within 2 and 10 years after the colpocleisis 6.5% (95% confidence interval [CI] 5.5–7.7]) and 8.2% (95% CI 7.0–9.5) of the women had undergone a reoperation respectively. The reoperation risk was highest in the first 2 years following the colpocleisis (Fig. 1). We found a statistically significant increase in the risk of reoperation from the colpocleisis performed early (1977–1990) to the colpocleisis performed during the intermediate period (1991–2004; HR 1.67, [95% CI 1.16–2.39]). However, we saw no overall trend regarding risk of reoperation and calendar year of colpocleisis (Fig. 2).

Of the women with their uterus in situ ($N=1,970$) 8 were diagnosed with a uterine or vaginal cancer corresponding to a cumulative risk of 0.5% (95% CI 0.2–1.2) within 10 years after colpocleisis.

The yearly number of women who underwent colpocleisis ranged from 37 to 80 (Fig. 3). There was a statistically significant decrease in the number of colpocleisis procedures performed from the early to the intermediate and from the early to the late period, but no significant difference between the intermediate and late periods. The mean age for women undergoing colpocleisis significantly increased during the study period from 77.1 to 79.6 to 81.4 years in the early, intermediate, and late groups respectively (p value <0.001).

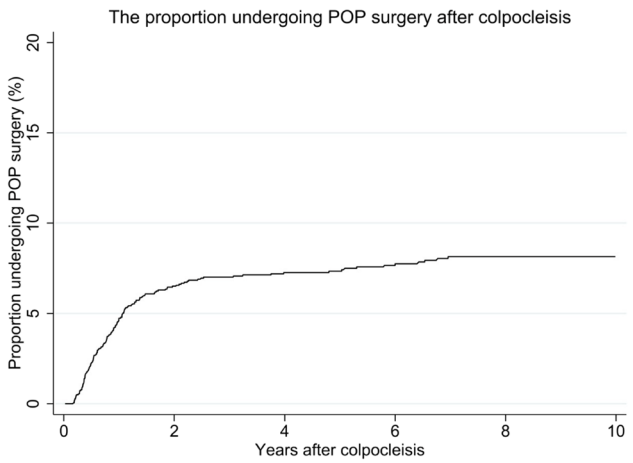

Fig. 1 Cumulative incidence curve for the risk of undergoing a new pelvic organ prolapse (*POP*) surgery after colpocleisis

Discussion

Main findings

We found a substantial reoperation risk of 6.5% and 8.2% after 2 and 10 years after the colpocleisis respectively. We found a low risk of uterine and vaginal cancer after colpocleisis. Further, we saw increased age at the time of colpocleisis during the study period.

Interpretation of results

Although we found a substantial risk of reoperations, a recent American study by Shah et al. ($N=845$) found a low reoperation risk of 0.8% [17]. Our cohort study is characterized by a very controlled entry and exit of the cohort and owing to nationwide registers, all operations are registered, even if performed in other regions. This entails thorough and complete follow-up. Furthermore, the Danish health care system is free of charge and the access to a reoperation is therefore not affected by financial status. These factors may explain why we find higher rates of reoperations than in the American study.

Like the American study, other smaller studies ($N=35$ to 278) also found a low risk of recurrence: 0.4% [9] and 0% [10, 11, 18]. The mean ages were substantially lower (72.4–75.4 years), which may reflect a different population. The follow-up time of 3–5 years was shorter than the follow-up time for our study; however, longer than 2 years, during which we find the steepest rate of reoperation.

Contrary, a small British study ($N=23$) found that 8.7% experienced recurrence and one woman underwent reoperation (4.3%) [19]. Furthermore, Kotani et al. showed a recurrence rate of 8.7% ($N=6$ out of 69) and a reoperation risk of 2.9% ($N=2$ out of 69), with a median follow-up of 13 months [20]. This is in line with our findings.

We showed the reoperation risk to be highest during the first 2 years following colpocleisis, which is consistent with the literature [20, 21].

We found a low incidence of uterine and vaginal cancer of 0.5% after colpocleisis. The incidence is consistent with other Nordic studies analyzing the risk of cervical,

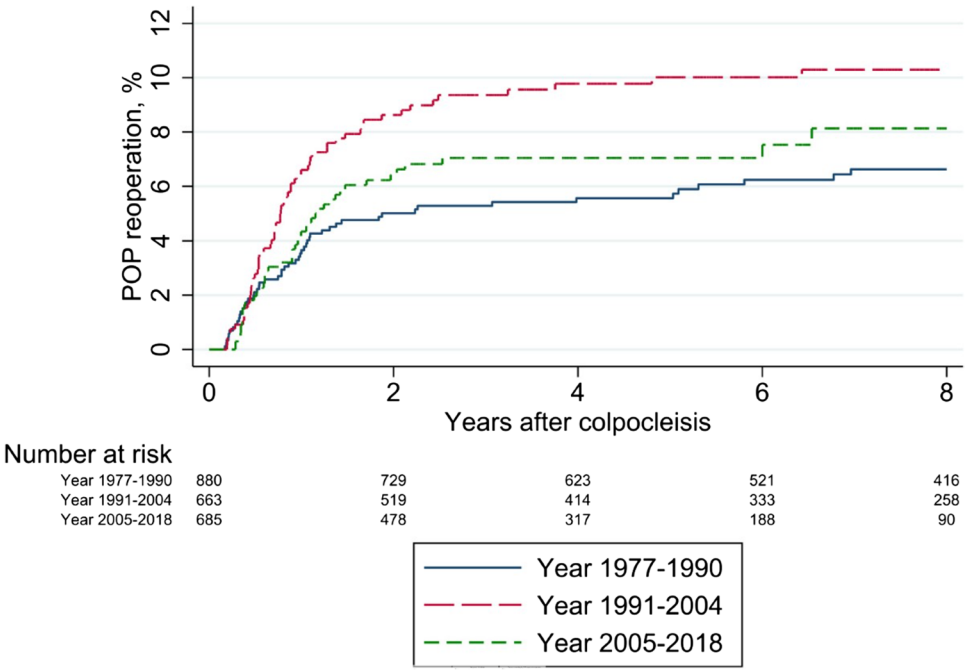

Fig. 2 Risk of reoperation after colpocleisis by year of colpocleisis. *POP* pelvic organ prolapse

endometrial, and vaginal cancer in the elderly background population [22, 23]. Our findings are also in line with those of our previous studies, finding a low risk of endometrial cancer (1%) and cervical cancer (0.1%) after the Manchester procedure. These studies were based on larger but younger cohorts [24, 25]. The low incidence of cancer in the present study may reflect that the average age of being diagnosed with uterine and vaginal cancer is younger than this cohort.

Other studies report the risk of unanticipated uterine malignancy to be 0.3% (2.6% including premalignant cases) and 0.8% [26, 27]. These studies are performed in younger cohorts; thus, the relevance for women undergoing colpocleisis is doubtful.

Despite a low risk of uterine cancer, the question regarding hysterectomy prior to colpocleisis is up for debate. A large study ($N=7{,}431$) by Raina et al. found an increased risk of perioperative complications after colpocleisis performed concomitantly with hysterectomy compared with colpocleisis alone (11.4% vs 9.5%, OR 1.93 [95% CI 1.45–2.57]) [28]. Likewise, the study by Bochenska et al.

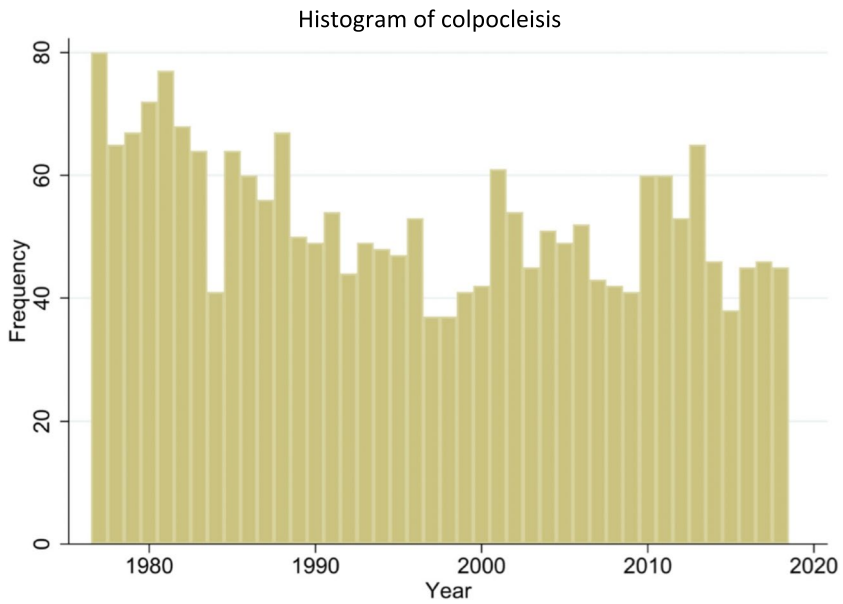

Fig. 3 The distribution of colpocleisis procedures performed among Danish women between 1977 and 2018. Frequency indicates the yearly number of colpocleisis procedures

reported an increased risk of serious medical complications after colpocleisis with concomitant hysterectomy [8]. In the decision on concomitant hysterectomy at the time of colpocleisis, the low risk of uterine and vaginal cancer should be weighed against the risk of perioperative complications [8].

Few women younger than 60 years ($N=28$) underwent colpocleisis. These women were not representative of the average patient undergoing colpocleisis. These women were excluded in a sensitivity analysis, which showed no material changes of the results (data not shown).

We found that the age of women undergoing colpocleisis increased during the study time. This may indicate a changed attitude regarding the surgical treatment of elderly women with comorbidities and high anesthetic risk. The attitude may be affected by improved perioperative optimization of patients with comorbidities over the last 42 years.

Our previous study showed that colpocleisis procedures constitute 2.0–4.4% of the apical prolapse surgeries in Denmark during the years 2010–2016 [29]. This is comparable with the US study showing that obliterative procedures constituted up to 2.19% [30].

Strengths and limitations

Our study is strengthened by the use of large population-based health registers with virtually complete and accurate data [13]. To our knowledge this is the largest cohort study assessing reoperation risk and risk of uterine and vaginal cancer after colpocleisis. Our data extend over 42 years with a median follow-up time of 5.6 years and for many women, lifelong follow-up. Especially when addressing the risk of cancers, lifelong follow-up is crucial. The mandatory registration entails high accuracy and completeness of the registration of gynecological surgeries [31]. Selection bias is minimized owing to consistent and prospective collection of data independent of this study. Furthermore, the Danish health care system is tax based, which entails free treatment regardless of financial status.

This study also has important limitations including inherent weaknesses of register-based research such as misclassification. Because the data collection extends over 42 years, we have limited surgical details. These include valid operative information such as concomitant perineorrhaphy or plication of the levator ani muscle, experience of the surgeon, and information about perioperative complications. Owing to the variation in registration of surgical codes we could not distinguish between different types of colpocleisis.

There has not been a standardized practice concerning cancer screening prior to colpocleisis during the study period, in which the ultrasound was implemented. Currently, there is no national guideline for cancer screening prior to colpocleisis.

Another limitation is the lack of clinical parameters such as body mass index, pelvic organ prolapse quantification (POP-Q), symptoms, and short-term complications such as infections. We do not have information about ethnicity. The majority of the Danish population is Caucasian; thus, the results might not be generalizable to all races.

The total number of colpocleisis procedures may be underestimated owing to our inclusion criteria requiring registration of POP diagnosis at the time of colpocleisis.

As this study is based on reoperations, we must assume that the number constitutes the tip of the iceberg of women experiencing symptoms from recurrence.

Conclusion

Despite smaller studies showing no recurrence after colpocleisis, we found that 6.5% underwent reoperation within 2 years. Assuming that reoperations constitute the tip of the iceberg of women with recurrence, more women may suffer from symptoms. We found a low risk of uterine and vaginal cancer after colpocleisis. The increasing age at the time of colpocleisis during the study period indicates changed attitudes regarding surgical treatment for elderly women with comorbidities.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00192-023-05566-6

Authors' contributions M. Hammerbak-Andersen: project development, analysis and interpretation of data, manuscript writing; N. Klarskov: project development, interpretation of data, manuscript editing; K.R. Husby: project development, data management, analysis and interpretation of data, manuscript editing. All authors have approved the final version submitted for publication and are responsible for the entire work.

Declarations

Conflicts of interest None.

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