“I feel reassured, but there is no guarantee.” How do women with a future childbearing desire respond to active surveillance of cervical intraepithelial neoplasia grade 2? A qualitative study

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Abstract
Introduction: In Denmark, women with a future childbearing desire diagnosed with cervical intraepithelial neoplasia grade 2 (CIN2) are recommended active surveillance instead of excisional treatment. However, we have limited and contradictory knowledge about how active surveillance of CIN2 may affect women emotionally. The aim of this study was to explore thoughts and emotional responses in women undergoing active surveillance of CIN2 and to explore how active surveillance may affect women’s future childbearing desire.

Material and methods: This qualitative study was conducted in the gynecological outpatient clinic, the Department of Obstetrics and Gynecology, Gødstrup Hospital, Denmark. Women of childbearing age undergoing active surveillance with colposcopy, biopsy and smear every 6 months due to CIN2 were eligible for enrollment. In-depth semi-structured interviews were conducted. The interviews were audiotaped and transcribed verbatim. A thematic analysis was performed using a phenomenological approach.

Results: A total of 20 women were included. All women experienced nervousness and anxiety when they were diagnosed with CIN2 initially. Their main concern was whether they had cancer. Most women carried on with their everyday lives with only minor occasional worries about CIN2, often prompted just before check-up. However, some women were particularly nervous and found the period between check-ups frustrating and challenging. Women did not want to postpone their plans for pregnancy because of CIN2, but experienced the worries and check-ups associated with active surveillance as disruptive elements in their family planning. Women preparing for fertility treatment had their startup unnecessarily delayed due to active surveillance of CIN2, as clinical guidelines were inconsistent across subspecialties. Various factors influenced women’s emotional well-being: life...
1 | INTRODUCTION

Cervical cancer continues to be a major public health problem among women worldwide, making it one of the World Health Organization’s focus areas. During 2012–2016, 371 women were diagnosed with cervical cancer annually in Denmark, and every year, 102 women have died from the disease. Cervical cancer incidence and mortality have declined significantly in developed countries after the introduction of cervical cancer screening. Screening allows for detection and subsequent treatment of precursor lesions, thereby reducing the risk of cancer development, and for detection of early-stage cervical cancer, leading to reduced mortality. Precursor lesions in the squamous epithelium (ie cervical intraepithelial neoplasia [CIN]) is typically graded as CIN1, CIN2 or CIN3, depending on the severity of precursor lesions. Historically, CIN2 has been treated with excision in most countries. However, due to high regression rates of CIN2 (up to 50–60%) and because excisional treatment is associated with increased risk of reproductive harm, several countries, including the Nordic countries and the USA, have implemented active surveillance of CIN2 in younger women. Active surveillance typically consists of semi-annual follow-up visits in colposcopy clinics for up to 2 years. During the active surveillance period, women may live with uncertainty and concern about whether CIN2 will regress or progress to CIN3 or cancer. It is well known that many women experience discomfort, worry and anxiety when they are diagnosed with abnormal cytology and during follow-up. Other studies have found that active surveillance of CIN2 does not appear to have an adverse impact on self-reported mental health-related quality of life, anxiety, depression and sexual function compared with conventional management. However, we have limited knowledge of women’s experience with active surveillance.

Here, we aimed to explore thoughts and emotional responses in women of childbearing age undergoing active surveillance of CIN2. Furthermore, we aimed to explore how active surveillance may affect women’s future childbearing desire.

2 | MATERIAL AND METHODS

2.1 | Screening and diagnostic work-up

In Denmark, cervical cancer screening is recommended to women aged 23–64 years every 3–5 years depending on age. Screening, including diagnostic work-up and treatment, is free of charge for all residents. Women with an abnormal screening test are referred for colposcopy and, according to national guidelines, all women have four biopsies collected regardless of colposcopic findings. If a CIN2 diagnosis is made based on histopathologic examination, women of reproductive age with a future childbearing desire (ie no upper age limit) are recommended active surveillance with follow-up visits every 6 months for up to 2 years. It is clinical practice that all women have a cervical cytology collected, as well as colposcopy-directed and/or random biopsies at each colposcopy visit. HPV testing is not routinely performed. Active surveillance has been recommended in Denmark since 2012. Excisional treatment is recommended in the case of progression to CIN3 or worse or persistent CIN2 after two years of follow-up.

2.2 | Setting, study design and participants

This qualitative study was conducted at the Department of Gynecology and Obstetrics, Gødstrup Hospital, Denmark from September 1, 2020 through January 1, 2021. To explore the personal

Conclusions: Women felt that worries and check-ups due to active surveillance of CIN2 were disrupting elements in their family planning, although they did not affect their every-day life. Some women, however, were particularly anxious, demonstrating the importance of including women’s experiences and preferences in clinical counseling. The fact that fertility treatment was delayed due inconsistent guidelines across subspecialties, suggests a need for a revision of current guidelines.

KEYWORDS
active surveillance, cervical cancer prevention, cervical intraepithelial neoplasia, decision aid, family planning, young women

Key message
Women undergoing active surveillance of CIN2 may suffer from anxiety, frustrations and existential considerations, and may consider these factors disruptive in their family planning. Decision aids to support deliberations about choice of management may help women to cope with this situation.
experience of women diagnosed with CIN2 and undergoing active surveillance, we designed an exploratory qualitative interview study based on an interpretative phenomenology. An iterative approach to data collection and analysis was applied in line with the interpretative phenomenological tradition.18

Women were eligible for enrollment if they had been diagnosed with CIN2, were currently undergoing active surveillance for CIN2, were of reproductive age, had undergone active surveillance while having a future childbearing desire, and were able to speak and understand Danish. Women were recruited consecutively by a gynecologist or nurse in the outpatient clinic by convenience sampling. Women who agreed to participate received additional written and oral information about the study. Upon enrollment, all women signed an informed consent form. Recruitment took place until information power was obtained as defined by Malterud et al.19 All interviews were conducted by the first author (JH). Before each interview, enrolled women completed a short questionnaire, including questions on demographic characteristics. Of note, educational level was grouped into three categories: low (1–10 years), medium (11–14 years) and high (>15 years) according to the educational nomenclature (ISCED) from Statistics Denmark.

The study consisted of data from semi-structured interviews. An interview guide was developed with inspiration from the literature18,20 and through conversations with local gynecologists, nurses and researchers who had experience with active surveillance of CIN2. Observations in the gynecologic outpatient clinic over a single day provided additional inputs and directions for the interviews. The interview questions were intended to provide space for the women's reflections and descriptions. Open-ended questions and follow-up questions were asked to promote this process.

Our research questions were as follows:

How do women perceive the CIN2 diagnosis?
How do women experience being diagnosed with CIN2 and subsequently undergoing active surveillance?
How are women’s future childbearing desire affected by active surveillance of CIN2?

Interviews were recorded digitally and subsequently transcribed verbatim by a graduate student with experience in transcription. Quality of the transcripts was evaluated by JH by re-listening to the audio files and checking whether the transcribed material was identical to the audio files. Audio files and the transcribed material were stored in a secure database according to Danish legislation.

2.3 | Data analysis

Thematic content analysis21 was used to identify and analyze patterns in the transcribed data. The primary analysis was performed by JH and PK. To generate the first codes, all interviews were thoroughly read and re-read. Three interviews were test-coded independently by JH and PK and any discrepancies in coding were discussed and resolved.

To present key elements of participant’s statements, codes were read and sorted into main themes and sub-themes to generate a ‘map’ of the content and topics across the data and to summarize the variation and regularities within. The thematic map was discussed by all authors and refined. Concurrently we created a Table (Table 2) summarizing vivid, compelling quotes to provide information about coherence in data.

2.4 | Ethics approval

The study was registered on July 8, 2020 to the record of processing activities for research projects in Central Denmark Region (J. No. 1-16-02-302-20).

3 | RESULTS

A total of 20 women were eligible and subsequently enrolled and interviewed. Mean age of participants was 31 years. Half of women included (55%) had received lower-level education and 85% were living with a partner (Table 1). All women had a future childbearing desire (n = 19, 95%) or had previous experience with planning to conceive while undergoing active surveillance of CIN2 (n = 1, 5%). More than half (60%) had at least one child, and 25% were in current fertility-treatment. All women had had at least one follow-up. Three women (15%) chose being interviewed at the hospital and five (25%) wanted the interview to take place in their home (data not shown). Because of Covid-19, 12 interviews (60%) took place either by telephone or virtually using a secure digital platform. Duration of the interviews was approximately 30 minutes (range 25–40 min).

We identified two main themes: (1) The mental journey and (2) Mediating factors (Table 2).

3.1 | The mental journey

Women’s immediate reactions to the CIN2 diagnosis were characterized by anxiety, frustration and existential considerations. After the women received additional information on CIN2, including consequences and perspectives, they felt calmer and more reassured. As expressed by two women of CIN2 they felt occasional anxiety when they were reminded about the diagnosis.

The women’s mental journey followed these steps: first, a strong emotional response, including anxiety, frustration and existential considerations, and secondly, coping with feelings of certainty and hope, as well as uncertainty and worry before check-ups.

3.1.1 | Anxiety, frustration and existential considerations

All women experienced anxiety and frustration when receiving the diagnosis. The women’s main concern was whether they had cancer
and whether the lesion would progress to cancer. This concern was occasionally present in their minds during the active surveillance period. Additionally, several women had concerns about their femininity and ability to conceive. As expressed by two women: “I was worried if it [CIN2] was the cause of my infertility issues?” (ID8); “What was I worth as a woman?” (ID1). Some women described thoughts about dying and about how the rest of the family would cope on their own. One woman had felt less inclined to continue fertility treatment, thinking CIN2 made her sick.

3.1.2 | Certainty and hope

Most women described feeling calm and finding reassurance as they received additional information about their diagnosis. They sought information and support from family and friends, the Internet, their general practitioner, and healthcare providers in the gynecologic outpatient clinic. All women underlined the importance of being informed that CIN2 is not cancer, as this information helped the women to cope in the situation. One woman expressed: “I regret that I was unnecessarily scared at first. It could have been avoided if the information had been readily available” (ID 11). The women had confidence in the information from the gynecologist, and none had postponed their plans for pregnancy due to CIN2 or active surveillance. For example, one woman described that her pregnancy plans had a strong priority and preceded her worries about CIN2. All women described how they hoped that CIN2 would regress during follow-up, without any treatment.

3.1.3 | Uncertainty and worry

In general, women stated that they had occasional thoughts and concerns about the potential risk of progression from CIN2 to cancer while undergoing active surveillance. As one woman put it: “I feel reassured, but there is no guarantee” (ID17). Women who had a current or previous experience with active surveillance during pregnancy described thoughts about whether CIN2 would progress during pregnancy, during which time no routine check-ups are recommended in Denmark. A couple of women had considered excisional treatment to get rid of the uncertainty. Most women carried on with their everyday lives where concerns about the diagnosis were not prominent, yet were present in their consciousness. However, one woman described herself as being a very anxious person who occasionally would panic and imagine the worst-case scenario. All women experienced various degrees of anxiety and mental discomfort prior to semi-annual check-ups and pending test results.
3.2 Mediating factors

We identified several factors that influenced women’s psychological reactions to CIN2 diagnosis and active surveillance, such as life circumstances and need for information.

3.2.1 Life circumstances

Women described it as stressful to have to worry about CIN2 during active surveillance concomitantly with planning a pregnancy, which should be joyful. Three women who were in fertility treatment...
described how being followed with check-ups for CIN2 at the same time as hoping to start fertility treatment had caused frustration. They elaborated that there had been contradictory information on whether or not it would be advisable to start fertility treatment from the general practitioner, from nurses and gynecologists in the gynecologic outpatient clinic, and from nurses and fertility doctors in the fertility clinic.

3.2.2 | Need for information

When women received the message about being diagnosed with CIN2, they felt an immediate need for additional information about their situation. Some women referred to a leaflet they had received in the outpatient clinic, which they found informative. However, one woman stated: "when you get a leaflet stuck in your hand from the Danish Cancer Society it affects you in a strange way" (ID19). Some women recalled receiving information on CIN2 in the outpatient clinic at the time of colposcopy, but as one woman expressed: "I didn't really listen because cervical precancer is something the neighbor gets" (ID16). Some women felt emotional discomfort and physical pain in relation to gynecological examination, including colposcopy and biopsy. In general, women described it as helpful when the gynecologist and nurses were understanding, empathetic and informed, and provided guidance during the procedure.

4 | DISCUSSION

Our findings indicate that most women who undergo active surveillance lived an everyday life where worries were not prominent but remained present in the women's consciousness. A study from 2010 reported stronger emotional reactions from women aged 25–35 undergoing active surveillance.\(^\text{13}\) In the previous study, women felt their lives were put on hold, and they were sad, irritable and anxious when receiving the diagnosis and especially in the time period prior to check-ups and when waiting for test results. Moreover, the women were concerned about risk of progression. These findings are in line with our results. Upon receiving the CIN2 diagnosis, women in the present study expressed an immediate need for additional information and support to cope. These needs resulted in fear, frustration and existential considerations. Some women used the information provided to them during the consultation in the gynecologic outpatient clinic at the time of colposcopy, but they also stated that they didn't feel the information was relevant to them at that time. A previous qualitative study about information needs among women with CIN and their perceptions about communication and management of information by healthcare providers supports this.\(^\text{22}\) The study indicated that lacking knowledge about the consequences and perspectives that come with a CIN2 diagnosis is a known problem which makes it difficult for women to understand and cope in the situation. Taken together, these findings suggest that women would benefit from receiving more information on potential psychological side effects related to active surveillance and which may provide a framework for deliberations about choice of management (ie excisional treatment vs active surveillance). In a situation with two or more valid approaches, the best choice should depend on how individuals value the risks and benefits of treatments.\(^\text{26}\) This process may be supported by a decision aid tool that can help healthcare professionals and patients consider potential options in terms of a specific diagnosis. The decision aid is meant to facilitate the process of clarifying the individual's preferences and of making decisions about form of treatment that are appropriate for individual specific situations.\(^\text{25}\) To the best of our knowledge, clinical guidelines that take into account the patient's psychological point of view with respect to the choice of CIN2 management are rare. In a recent Australian study in which women were hypothetically diagnosed with CIN2, 80% of younger women preferred active surveillance over surgery, primarily because they were concerned about reproductive harm.\(^\text{23}\)

Some women in the present study considered undergoing excisional treatment to get rid of the uncertainty and worry, as also suggested elsewhere.\(^\text{14,15}\) However, the previous studies suggest that women's quality of life does not depend on treatment method. One study found that choice of therapy may have an influence on physical quality of life and coping strategies, but not on risk of depression, anxiety or mental well-being.\(^\text{14}\)

Preparation and transition to motherhood is considered an important and major life event, and it is a process that affects women on a psychological, social, physical and existential level.\(^\text{26}\) Women in the present study did not want to postpone their plans for pregnancy due to CIN, but found it stressful to have to worry about risk of progression while planning a pregnancy. Those in fertility treatment experienced conflicting information from general practitioners, gynecologic outpatient clinics and fertility clinics and were frustrated because the fertility process was delayed. Our findings demonstrate the importance of solid and consistent information and guidance from healthcare professionals so couples do not have their plans for family formation disturbed and unnecessarily delayed.

It is well known that colposcopy and biopsy in itself can result in adverse psychological and physiological consequences, including anxiety, distress, embarrassment, physical pain and discomfort.\(^\text{27}\) Several women in our study had similar experiences. Previous research indicates the need for a more standardized approach, including the use of local anesthetics during procedures and providing practical and detailed information provided to women to reduce stress and anxiety, especially among anxious women.\(^\text{28}\) Importantly, a previous study reported that women with a high level of anxiety at colposcopy were less likely to find information leaflets and videos helpful.\(^\text{29}\) Therefore, future studies should focus on "very anxious" women in an attempt to find any useful measures to reduce their anxiety, as they appear to derive very low satisfaction from the existing arrangements. Improving comfort during colposcopy may be important to minimize the risk of women failing to return for follow-up.\(^\text{30}\)

A key strength of the present study was the open and exploratory approach, which encouraged the women to express positive and negative experiences with active surveillance, and to discuss the
topics of greatest importance to them. Women were interviewed by an experienced midwife with knowledge on reproductive care and educated in interview techniques. Furthermore, to ensure high information power and internal validity, we constructed the study with a clear aim and a meaningful sample of women. The participating women represented sociodemographic variations in terms of age, marital status and parity, which is considered a strength.

Important limitations should also be addressed. First, women with higher education may have been underrepresented compared with the general population, which may indicate a risk of selection bias. However, enrolled women likely reflect the source population (women with CIN) as it is well known that a CIN diagnosis is associated with lower socioeconomic status. Secondly, some women did not have children, some had children, some were currently trying to conceive, and some were pregnant. We found differences between these women but the study did not have enough power to address this issue systematically. Further research is necessary to address this issue. Thirdly, we were unable to collect data on the specific information women received at the time of diagnosis or during follow-up. Therefore, we cannot know whether all women received the same information. Consequently, our findings suggest a need to explore which information women need in order to be reassured.

5 | CONCLUSION

Our results indicate that women undergoing active surveillance for CIN2 may live an everyday life where worries are not prominent but which are present in the women’s consciousness. However, for some women, active surveillance was associated with major concerns which affected their daily life. Women did not postpone their plans for pregnancy due to active surveillance but felt it disrupted their family planning. A responsive and prompt healthcare service and patient-centered information are therefore critical. These findings may provide a framework for deliberations about shared decision-making and choice of management, weighing pros and cons about excisional treatment vs active surveillance.

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CONFLICT OF INTEREST

AH and PK have received a speaker’s fee from Astra Zeneca outside the submitted work. AH has received reagents at a reduced cost from Roche, Denmark, outside the submitted work. The remaining authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

AH and JH conceived the study and wrote the study protocol with input from PK, BF and HB. JH and HB recruited participants and JH collected the study data. JH, PK and AH analyzed the data, assisted by HB and BF. JH, PK and AH interpreted the data and JH drafted the manuscript with input from AH, PK, BF and HB. All authors commented on the manuscript and approved the final version.

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