



Original article

Views of healthcare professionals about the role of active monitoring in the management of ductal carcinoma in situ (DCIS): Qualitative interview study



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ABSTRACT

Background: Ductal carcinoma in situ (DCIS) is an in-situ (pre-cancerous) breast malignancy whereby malignant cells are contained within the basement membrane of the breast ducts. Increasing awareness that some low-risk forms of DCIS might remain indolent for many years has led to concern about overtreatment, with at least 3 clinical trials underway internationally assessing the safety of active monitoring for low-risk DCIS. This study aimed to understand healthcare professionals' (HCPs) views on the management options for patients with DCIS.

Methods: Qualitative study using semi-structured interviews with HCPs involved in the diagnosis and management of DCIS in Australia and New Zealand. Interviews were audio-recorded, transcribed and analysed thematically using Framework Analysis method.

Results: Twenty-six HCPs including 10 breast surgeons, 3 breast physicians, 6 radiation oncologists, and 7 breast care nurses participated. There was a strong overall consensus that DCIS requires active treatment. HCPs generally felt uncomfortable recommending active monitoring as a management option for low-risk DCIS as they viewed this as outside current standard care. Overall, HCPs felt that active monitoring was an unproven strategy in need of an evidence base; however, many acknowledged that active monitoring for low-risk DCIS could be appropriate for patients with significant co-morbidities or limited life expectancy. They believed that most patients would opt for surgery wherever possible.

Conclusions: This study highlights the important need for robust randomised controlled trial data about active monitoring for women with low-risk DCIS, to provide HCPs with confidence in their management recommendations and decision-making.

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1. Introduction

Ductal carcinoma in situ (DCIS) is an in-situ (pre-cancerous) breast malignancy whereby malignant cells are contained within

the basement membrane of the breast ducts. Incidence has increased greatly since the introduction of organised breast screening, and DCIS now represents approximately 20% of screen-detected cancers, with around 2600 new cases diagnosed annually in Australia [1]. DCIS is a spectrum of disease, ranging from indolent low-grade lesions, to high-grade lesions at higher risk of progression to invasive breast cancer. There are concerns that screening has led to overdiagnosis and overtreatment of low-risk DCIS [2,3]. Across all grades of DCIS, estimates of rates of progression to invasive cancer vary from 14% to 53% [4], yet local therapy is similar to treatment for invasive cancer. Thus many women receive surgery, radiotherapy and/or hormonal treatments that may not improve overall survival (especially for those with low-grade DCIS) but could potentially impact other aspects of health and quality of life [5,6]. While healthcare professionals (HCPs) and researchers are concerned about possible overtreatment of low-risk DCIS, women often opt for more aggressive treatments such as mastectomy and even bilateral mastectomy rather than lumpectomy [7], even though these treatments do not improve breast cancer-specific survival [8]. Radiotherapy following breast conserving surgery significantly reduces the risk of local recurrence [9], but remains controversial given the associated morbidity and lack of survival benefit [10,11].

Given the potential harms of overdiagnosis and overtreatment, active monitoring has been proposed as an alternative management option for low-risk (screen detected, mainly low- and some intermediate-grade) DCIS [12,13]. This approach consists of carefully monitoring the patient but not treating unless the condition progresses. The impact of this strategy on clinical and psychosocial outcomes is currently being evaluated in randomised controlled trials (RCTs) in the UK, Europe, and US [14–16]. These trials compare standard treatment for low-risk DCIS to active monitoring every 6 or 12 months ± endocrine therapy to determine whether women diagnosed with low-risk DCIS can safely avoid surgery. Results are anticipated over the next decade [3].

DCIS is challenging to explain to patients, and there is no consensus among HCPs about what terminology to use and how best to explain what DCIS is and the risk of progression [17,18]. Not surprisingly, women are often confused about the meaning of a DCIS diagnosis [19] and have exaggerated risk perceptions and anxiety [20]. Furthermore, DCIS patients have high unmet needs for information and treatment decision support, which has important implications for women’s capacity to participate in shared decision making about management [6,21,22]. Given the current challenges faced by HCPs in relation to DCIS, as well as the potential for overdiagnosis of DCIS [23] this study aimed to understand HCPs’ views on the management options for DCIS as well as their benefits and harms, and explore key influences on treatment decision making. The goal of this research is to underpin communication strategies for discussion of active monitoring as a possible future management option in low-risk DCIS.

2. Methods

2.1. Design

This study used semi-structured qualitative interviews to explore HCPs’ experiences and views about managing DCIS, and in particular their feelings about the proposed monitoring approach for low-risk DCIS. Ethical approval was granted by the University of Sydney Human Research Ethics Committee (2016/878).

2.2. Sample and recruitment

The sample included 26 HCPs involved in the management of

DCIS, including breast surgeons, breast physicians, radiation oncologists and breast care nurses in public and private settings throughout Australia and New Zealand.

HCPs were recruited through relevant professional organisations which advertised the study and distributed the Participant Information Statement through their mailing lists. HCPs emailed researchers directly to express interest in participating. Researchers then emailed the consent form and arranged a telephone interview. Before starting each interview, the interviewer verbally explained the study, gave the participant an opportunity to ask questions, and ensured written consent was provided. ‘Snowballing’ recruitment technique, whereby participants forwarded study information to eligible colleagues, was also used.

2.3. Data collection

The semi-structured interview schedule (see Box 1 for overarching topics and Appendix 1 for the complete interview schedule) was developed by a multidisciplinary team of public health and medical researchers, breast clinicians, psychologists and a consumer representative. The interview schedule was piloted on each type of HCP (surgeon, breast physician, radiation oncologist, and nurse) and revised accordingly. To avoid bias, the interviewer did not suggest any specific ways to manage DCIS but rather asked HCPs about the management options available and investigated their views on these options. Later in the interview, HCPs were specially asked about their views on active monitoring. Interviews were conducted over the telephone by two public health researchers with experience in qualitative methods (BN, JH) between December 2016 and August 2017. Interviews lasted 20–55 min and were audio-recorded, then transcribed verbatim.

2.4. Analysis

Framework Analysis was used to conduct the thematic analysis [24]. This analysis method is a rigorous way to classify and organise data according to key themes, concepts and emergent categories. BN and JH began by reviewing transcripts and developing a list of topics and themes identified using an inductive perspective, with reference to notes made throughout the interview process. Those themes, along with the interview schedule (deductive approach), formed the basis of the coding framework. Two additional researchers (JJ, KM) reviewed the coding framework, and changes

Box 1

Overarching interview schedule topics

- Clinician characteristics
- Managing DCIS
 - Implications of DCIS diagnosis for patients
 - Management options for DCIS including advantages and disadvantages
 - Role in and factors influencing management decision making
- Communicating with patients about DCIS
 - Approach to explaining what DCIS means and management options
 - Main challenges to discussing DCIS and deciding about treatment
- Future directions
 - Active monitoring versus immediate surgery
 - Adjuvant radiotherapy
 - Terminology
- Management of DCIS in older women (over 70) – similar topics to above covered but specifically in relation to women over 70

were discussed and made accordingly. Once a coding framework was agreed upon by the research team, BN coded all interviews in Microsoft Excel, treating individual interviews as the unit of analysis and using a codebook to help guide the coding. JH double-coded a sub-set of interviews, ensuring that these included different types of HCP. Coding similarities and differences between researchers were discussed, with the framework re-assessed accordingly and modifications agreed on. Once coding was complete, BN, AD and JH examined the framework to identify overarching themes. These themes were discussed with an additional researcher (KM) and then with the entire research team.

3. Results

Participant characteristics are outlined in Table 1. The study findings are organised into three main themes and several sub-themes. Participant quotations are incorporated to illustrate HCPs' experiences and views, with additional examples in Table 2. There was diversity in clinician perspectives, but we did not observe striking differences between specialty groups.

3.1. Views about DCIS diagnosis

There was a strong overall consensus that a diagnosis of DCIS requires active treatment. Most HCPs commented that if left untreated, an unknown percentage will develop into invasive cancer at some point in time and that this proportion depends on DCIS grade. They acknowledged uncertainty around which DCIS cases at an individual level will recur.

"15–20% of these would go on and form an invasive cancer in 5–10 years' time. Especially if they've got the poor prognostic signs like high grade, necrosis, that sort of thing." (S_F_4YE)

Many HCPs felt that a diagnosis of DCIS presents a window of opportunity to intervene early but also allows time to make an

Table 1
Healthcare professional characteristics.

Characteristic	No. of participants (n = 26)
Specialty	
Breast surgeon (S)	10
Breast physician (P)	3
Radiation oncologist (R)	6
Breast care nurse (N)	7
Years of experience (YE)	
<10	6
10–19	12
20–29	7
30+	1
Type of hospital or practice	
Public	11
Private	7
Both	8
Location of hospital or practice	
Urban	18
Rural	8
Sex	
Female (F)	18
Male (M)	8
Number of DCIS patients managed/year ^a	
<10	2
10–49	15
50+	6
Unsure	3

^a Self-reported estimates.

informed decision.

"They should be under no pressure to come up with a yes or no answer ... I think it's important that we don't try to rush the situation." (R_M_40YE)

3.2. Views about DCIS management

3.2.1. Overall views about best management for DCIS

All participants advocated surgical excision of all grades of DCIS as standard treatment. For the most part, surgery was viewed as the means of curing DCIS.

"Breast cancer surgery is really safe, really easy, and you can do it on people in their 90's if you have to. So general anaesthesia and surgery to the breast ... is simple and safe. So I'm happy to offer it to almost everybody who walks in the door." (S_M_10YE)

There was a mix of opinions whether radiotherapy was standard treatment following wide local excision, or purely dependent on the grade of DCIS ascertained from pathology following excision.

"... depending on the size and the grade. So certainly on the higher grade and the larger DCIS, I think [radiotherapy] is still of benefit in my mind. But certainly those lower grade, small DCIS, no, that could potentially be overtreatment." (N_F_10YE)

Hormonal therapies were only considered as adjuvant therapy for some patients. Very few HCPs mentioned or entertained active monitoring as a standard management option.

3.2.2. Possible practice changes post-surgery (the debate over radiotherapy in DCIS)

HCPs viewed radiotherapy as potentially helpful adjuvant therapy in DCIS which reduces the probability of local recurrence, but they also acknowledged that "so far there hasn't been an obvious contribution to survival." (R) There was a common feeling among a handful of HCPs that radiotherapy may be overused.

"I personally feel that surgery for most of the DCIS would be enough. And the role of the adjuvant treatment is probably limited." (S_M_8YE)

HCPs discussed that radiotherapy decisions in DCIS are not always clear-cut. Most participants described adopting an individualised approach weighing up whether radiotherapy would be worth undergoing given the patient's baseline risk of recurrence, age and overall health, and the risk of negative side-effects.

"It's not black and white with regards to those treatment decisions. You know, there's advantages and disadvantages in every single patient. In some cases, it's much more clear that the advantages ... outweigh the disadvantages of having treatment. And other cases it's much more in between." (R_F_16YE)

3.2.3. Circumstances in which 'no surgery' is an option

Regarding circumstances where no surgery is a valid management option, HCPs believed that it would have to be low-grade DCIS within the confines of a clinical trial or in patients whose advanced age, reduced life expectancy and/or significant co-morbidities meant the risks of surgery outweighed the risk of disease progression.

Table 2
Main themes and sub-themes with additional supporting quotes.

Themes and sub-themes	Support quotes
Views about DCIS diagnosis	"That's the implication, that you have a very early identified strong indicator that at some point you're going to develop an invasive cancer." (N_F_13 YE) "There's a lead-time between the manifestation of DCIS and carcinoma ... the tissue changes that occur can be seen on mammogram and ultrasound very early. So there's a lesion that warrants, it allows us to intervene before the carcinoma occurs." (R_M_6 YE)
Views about DCIS management	
Overall views about best management for DCIS	"It's very hard to quantify what the potential survival benefit is of performing surgery on DCIS. But it is established that is the recommendation. So guidelines do state that DCIS should be treated surgically and should be excised." (S_M_22 YE)
Possible practice changes post-surgery (the debate over radiotherapy in DCIS)	"Radiation is not usually considered necessary. So the majority would be having some form of local excision and then a discussion about whether any further treatment is warranted. And that would depend largely on the pathological nature of the disease, and also the patient's wishes." (R_M_40 YE)
Circumstances in which the 'no surgery' option is applicable	"I think there's already a trend to be less aggressive in older women because we know that they tend to get less aggressive pathology." (P_F_20 YE)
Views about and potential issues with active monitoring	
Views on where things currently stand in relation to active monitoring	"But at the moment, I'm not convinced that there's any evidence that not performing surgery is safe." (P_F_20 YE) "I have been talking to women lately about the fact that ... the research is telling us that it might be safe to observe some of these cases, but we're not quite there yet. And it's interesting because there's a small proportion that say oh that's good, it would be good not to have to go through all this. But more often it seems to be, like, oh my god, you mean you're going to leave this thing in my breast?!" (P_F_20 YE)
Uncertainty confirming DCIS diagnosis without surgery	"Surgical excision as a first stage is really crucial because we get a lot of information from the pathology that we just can't get from our imaging and biopsies. We just don't have good enough ways of detecting the true pathology. And whether it's invasive or not, and also the extent, and those things are important." (P_F_20 YE)
Feasibility of active monitoring in DCIS	"It depends on, I guess at the end of the day about the resources for every individual breast unit in terms of, how many clinics do they have and how many breast care nurses or breast physicians who can review DCIS and also the quality of their mammograms." (S_F_8 YE) "As a secondary regional centre we'd be guided by guidelines and what the larger centres are doing ... if there's a momentum in that regard and larger centres started doing it first, we would follow their schedule, 'cause you'd need a very strict protocol of surveillance." (R_M_6 YE) "I'm in a rural area they decide they don't want to go away and have radiotherapy, and I mean it's a common sort of a thing, and ... they decide to have a mastectomy." (N_F_8 YE)
Need for evidence to support monitoring	"I feel very unhappy aggressively treating low-grade, low-volume disease, but unfortunately we don't have the data yet to say which groups we can safely observe. So I'm very much looking forward to those studies ... " (S_F_12 YE) "I think there's going to be a lot more challenging conversations ahead, if and when we're able to offer that. But it'll be good if we can say, look ... we've got trials and we know that this is ... all very safe." (P_F_20 YE) "Only research will actually be able to demonstrate the true results of that [active monitoring] for the future. I think at the end of the day all approaches should be looked at and then the individual should be allowed to go away and make an informed decision." (N_F_12 YE)

S = surgeon; P = breast physician; R = radiation oncologist; N = nurse.
F = female; M = male.
YE = years of experience with DCIS management.

" ... small size, low-grade, no personal or family risk factors ... certainly poor health: I wouldn't advocate treatment in a woman ... who was on renal dialysis or had multi-system disease or was on immunosuppressant medication or anything for which the risks of having surgery and treatment outweigh the risk of the disease progressing." (P_F_11YE)

There was also some discussion around breast density, with some HCPs commenting that they could be more confident in the mammography imaging in older women because they have less dense breast tissue than younger women. They also mentioned that the pathology in older women tends to be less aggressive.

However, many HCPs stressed that their management conversations are not simply age-dependent but rather involve considering individuals on a case-by-case basis and weighing risks of treatment versus expected benefits.

"I wouldn't change my management for women above the age of 70 with DCIS if they don't have significant past medical history or medical co-morbidities and I would expect them to live at least 10 years." (S_F_8YE)

3.3. Views about and potential issues with active monitoring

3.3.1. Where things currently stand in relation to monitoring

Many HCPs felt uncomfortable recommending active

monitoring to their own patients with low-grade DCIS. Their main reason seemed to be the lack of evidence that monitoring is safe and effective.

"Observation is currently an unproven strategy. So, I would certainly not feel comfortable with observing high-grade DCIS or larger intermediate-grade DCIS. But for older women with smaller-volume low-grade or intermediate-grade DCIS then, yeah, I think it's something that desperately needs some more evidence." (S_X_26YE)

HCPs said that DCIS patients infrequently ask about active monitoring.

"Occasionally a patient may not want to have anything done, but I don't feel that observation is an appropriate option for the patient, so I would discourage them from not wishing to do anything." (S_M_22YE)

The HCPs who did present active monitoring as a management option said that, in their experience, patients invariably opt for surgery wherever possible.

"In most situations if I see that either option is fair and reasonable then I'll give the patient the choice, and 100% of those women will opt to have surgery." (S_M_10YE)

A small number of HCPs did however acknowledge that “the landscape is changing” around monitoring for low-grade DCIS “quite a bit”. They noted the increasing diagnosis of small screen-detected lesions (with fewer local recurrences) and said they are therefore starting to feel it may be safe to offer monitoring.

3.3.2. Uncertainty confirming DCIS diagnosis without surgery

No participant felt fully comfortable recommending monitoring with no surgical treatment for all cases of low-risk DCIS. This hesitation stemmed from a lack of confidence in imaging, concerns about sampling error, and the current absence of an appropriate biomarker to reliably indicate which disease will progress.

“I don’t agree with it ... because I think with sampling techniques there can be sampling error and for that reason one may only have biopsied a less aggressive part of a process. So, I think complete excision is appropriate.” (S_M_18YE)

HCPs pointed out that surgery and examination of the excised lesion provide a better understanding of the entire histology, thereby reducing uncertainty and enhancing confidence in the diagnosis.

“The question is you don’t know for sure until you take it out that it is truly all DCIS. And are you willing to take that chance?” (R_M_6YE)

3.3.3. Feasibility of active monitoring in DCIS

HCPs voiced a number of concerns over the challenges of carrying out monitoring trials. Some felt that trials are difficult due to the disease pathology, as discussed above, and that being able to ensure studies only include low-risk cases really depends on pathologist expertise. Others mentioned issues around maintaining adequate and vigilant monitoring of patients, and a few discussed the difficulty with the number of biopsies required during monitoring.

“My concern would be if we conservatively managed them and then they for some reason, whether they forget or other things are happening, they drop off the radar to follow-up and don’t continue the screening process ... ” (N_F_5YE)

There was some discussion around the feasibility of monitoring particularly for patients in rural locations, and a few HCPs expressed concern about added burden on the health system. A few also highlighted that monitoring might prove more psychologically distressing for patients, committing them to more imaging, more biopsies and more unknowns.

“I guess the downside of that is that you’re committing them to increased surveillance and possibly to increased anxiety around ... that known risk of invasive cancer developing that would be higher than if it was treated.” (P_F_8YE)

Some HCPs acknowledged that patient perspectives regarding the necessity of active treatment may be shifting, suggesting that a few patients indicate awareness of or interest in monitoring.

“Probably one in five or one in four of the patients ask, do we really need to treat DCIS and do we have to take it out?” (S_M_8YE)

3.3.4. Need for evidence

The overall sentiment from HCPs was that active monitoring is a strategy that has not yet been proven and currently needs a stronger evidence base. There was support for the ongoing international DCIS trials to inform practice and assist decision making. However, this was only mentioned in the context of low-risk disease.

“I think this is a group of patients that have probably been over-treated in the past. And I think we need to re-evaluate and have some good scientific evidence as a basis for our decision making, and at present I don’t believe we have that evidence.” (S_M_18YE)

Importantly, many HCPs felt that monitoring will be a valid management option for low-risk DCIS in the future and that the consensus opinion amongst their peers may change once high-quality supporting evidence becomes available.

“I know there’s a lot of theories out there saying we’re over-diagnosing DCIS and things like that, and I think the trials will add valuable information to determine whether we are doing the right thing or if we need to change practice.” (N_F_5YE)

4. Discussion

To our knowledge this is the first study to explore in-depth HCPs’ views on active monitoring as a management option for low-risk DCIS. We found that HCPs involved in the management of DCIS in Australia and New Zealand generally felt uncomfortable recommending active monitoring as a management option. They viewed this as outside of standard care. HCPs discussed surgery being the only route to confidence in knowing the true nature of DCIS in terms of its extent and features, and said that for now active monitoring was an unproven strategy in need of an evidence base. This view was fairly consistent across breast surgeons, breast physicians, radiation oncologists and breast care nurses. Many HCPs did acknowledge that active monitoring for low-risk DCIS may be considered for patients with significant co-morbidities or limited life expectancy. Several clinicians reported occasional conversations with patients about this option and, although a few women may find it appealing, they believed that most patients would opt for surgery where possible.

The current situation in low-risk DCIS differs somewhat from other cancers where active monitoring is better established. For example, this management approach has been shown to be safe in RCTs [25,26] and offered as an option in low-grade prostate cancer for a number of years. It is now also a guideline-supported option for some patients with low-risk thyroid cancer [27] based on observational data [28]. Nonetheless, across these cancer types there is significant variability in acceptance and a strong perception from clinicians that surgical treatment is still required [29,30]. While there is acknowledgement of and efforts to reduce over-treatment in both conditions, once there is a confirmed diagnosis of cancer, clinicians and patients tend to perceive that something more than monitoring should be done.

One of the main concerns HCPs expressed in this study was around the uncertainty in accurately diagnosing DCIS based on imaging and core biopsy alone. Studies have estimated that diagnostic core biopsies in non-high grade DCIS underestimate invasive cancer by 8–22% [31–33]. HCPs explained that surgery and the associated full pathology ameliorates uncertainty around the extent and true features of the DCIS. Alongside this, some of our findings raise the question of whether trials of monitoring should

mainly be directed to older women, in whom age or co-morbidities may mean the risks of surgery outweigh the risk of disease progression and may be more open to it. Clinicians may therefore be more receptive to recruiting older patients into trials, and may also feel more comfortable recommending active monitoring to patients in this cohort.

The evolving landscape of DCIS management in recent years means there is an inherent limitation in research like ours which reports retrospectively on current opinions. It is possible that some HCPs' views and perspectives may have already shifted towards active monitoring. However, there are no results yet from the relevant clinical trials [14–16] nor any recent change to relevant guidelines, this seems unlikely. Since there are currently no such trials in Australasia, the experiences of our participants may differ from HCPs in countries where trials are active. With all qualitative research, the views expressed may not be representative, in particular given the self-selected nature of the study sample. The use of telephone interviews may have also caused the loss of some important non-verbal information. However, we interviewed a variety of Australian and New Zealand HCPs with different clinical experience in multiple settings, aiming to capture a diverse range of perspectives. Our study design, materials and analyses incorporated input contributed by a multidisciplinary research team including experienced qualitative researchers, clinical experts (breast surgeons, physician and radiation oncologist), and patient representatives.

Overall, this study highlights the important need for robust RCT data about active monitoring for women with low-risk DCIS to provide HCPs with confidence in their management recommendations and decision making, particularly regarding active monitoring for women with low-risk DCIS. Although it is now acknowledged that DCIS may be overdiagnosed and overtreated [34], the existing observational data that have informed ongoing trials [4,35] do not provide enough confidence to HCPs. It will be some years yet before the trial results are published and new evidence incorporated into clinical guidelines, where upon active monitoring may be accepted into practice. In the meantime, subtle shifts can already be observed in terms of HCPs recommending less invasive management, for example pulling back on adjuvant radiotherapy across all age groups where appropriate, and considering monitoring as an option in older patients with co-morbidities and/or reduced life expectancy. If and when high-quality evidence supports its use, HCPs will need training about the potential benefits and downsides of active monitoring for patients with low-risk DCIS, guidance for how to discuss and offer monitoring safely, and support to facilitate informed decisions incorporating patient preferences.

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Ethical approval

This study was approved by The University of Sydney Human Research Ethics Committee (Project No: 2016/878).

Declaration of competing interest

None to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.breast.2020.09.002>.

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