The Breast 46 (2019) 157–162

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Original article

Utility of diagnostic breast excision biopsies during two decades of screening mammography

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ARTICLE INFO

Article history:
Received 9 May 2019
Received in revised form
28 May 2019
Accepted 31 May 2019
Available online 1 June 2019

Keywords:
Breast cancer screening
Excision biopsy
Diagnostics
Surgery

ABSTRACT

Introduction: We evaluated the use and value of breast surgical excision biopsies for diagnostic purposes over the last decades in women undergoing mammographic screening, either as a primary procedure or following an inconclusive percutaneous biopsy.
Methods: All women with an excision biopsy among 817,656 screens, obtained from January 1997 to January 2017, were included.
Results: Of 18,593 recalled women (recall rate, 2.3%) with screen-detected abnormalities, 908 (4.9%) underwent excision biopsy. Of these, 411 (45.3%) were performed as first diagnostic intervention, decreasing from 4.3 per 1000 screens in 1997–1998 to 0 per 1000 screens in 2015–2016. The remaining 497 (54.7%) excision biopsies were performed secondary to pathologic findings at percutaneous biopsy. During 1997–1998, 1.0 secondary biopsies per 1000 screens were performed, decreasing to 0.3 per 1000 in 2005–2006 and afterwards increased to 0.6 per 1000 in 2015–2016 ($p = 0.003$). Of all 487 secondary biopsies, 303 (61.0%) had a benign pathology outcome, increasing from 40.4% in 1997–1998 to 70.2% in 2015–2016. Of all 211 biopsies in the three most recent cohorts (2011–2016) the overall upgrade rate was 26.5%, consisting of 39 (18.5%) DCIS (27 low grade) and 17 (8.1%) invasive carcinomas.
Conclusions: Although the use of excision biopsy significantly decreased over the past two decades, we observed a significant increased rate in more recent years. Since the vast majority of currently performed excision biopsies reveals a benign diagnosis or shows low grade DCIS, a secondary excision biopsy should only be considered if radiologic surveillance and repeated percutaneous biopsy continues to yield indeterminate results.

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1. Introduction

In the Netherlands, all women aged 50–75 years are invited to attend the nation-wide biennial screening mammography program, which was implemented between 1989 and 1996. In 1998 the upper age limit of the program was extended to 75 years of age and during 2009–2010 screen-film mammography was replaced by full field digital mammography [1–3].

Adequate biopsy of a suspicious abnormality detected at screening mammography is required to obtain a definitive pathology result. A simple biopsy technique that can be used is fine-needle aspiration (FNA). FNA was first described in 1847 for head and neck cancers [4]. During the 1960s FNA became more widely used and was considered as the gold-standard for the pre-operative

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https://doi.org/10.1016/j.breast.2019.05.018
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diagnosis of breast cancer [5]. However, due the fact that FNA only collects cells, core biopsy evolved as an alternative to harvest tissue. Core biopsy enabled pathologists to make a more reliable diagnosis as it delivers full tissue structure instead of separate cells only. In addition, more reliable testing of hormone receptor and HER2 status is hereby feasible [6,7]. Considering the fact that nowadays most breast lesions are non-palpable at the time of initial diagnosis, biopsies are usually performed under guidance of ultrasound or mammography. The core biopsy technique was first described in 1977 and in the 1990s large core biopsies gradually replaced FNA [8]. Core biopsy was also an adequate alternative for surgical excision biopsy.

Surgical excision biopsy is an invasive technique and used to be the most reliable method to obtain a conclusive diagnosis of a potentially malignant breast lesion, with a diagnostic accuracy of 94%–99% [9]. However, surgical excision biopsies are maximal invasive procedures, are usually performed under general anesthesia and have been found to hamper the assessment of future screening mammography [10,11]. Therefore, the use of excision biopsy, next to fine needle aspiration and core biopsy, has become a matter of debate. In a systematic review, published in 2002, Crowe et al. already reported a decline in the use of excisional biopsies between 1995 and 2002 [12]. Later, a population-based study by van Breest Smallenburg et al., in 2013 reported a decline in the use of excision biopsy between 1997 and 2010 and showed that it was gradually replaced by large percutaneous core biopsy [13]. However, percutaneous core biopsies do not always provide a definite histopathological diagnosis, especially in the current era of digital mammography, which is characterized by the detection of many small lesions. This persistent uncertainty may cause physicians at the multidisciplinary board meetings to opt for an excision biopsy. Furthermore, we distinguished between excision biopsies performed as first biopsy method (primary excision biopsies) and excision biopsies performed secondary to a preceding percutaneous biopsy with no classifying diagnosis (secondary excision biopsies).

The aim of this study was to analyze the more recent trends in the use and added value of excision biopsies in screen-detected breast abnormalities and how these trends compare to those observed until 2010.

2. Methods

2.1. Study population

All women who attended the breast cancer screening program at four specialized screening units in the southern part of the Netherlands between January 1997 to January 2017 were asked to give written informed consent to use their screening and follow-up data for evaluation purpose. Three recalled women refused to give permission. Subsequently, a total of 817,656 screens were included in this study. According to the Dutch Central Committee on Research involving Human Subjects (CCMO) ethical approval was not required for the current study.

2.2. Screening procedure

In the Dutch national screening program screening mammograms are taken biennially by dedicated screening mammography radiographers. Certified screening radiologists double read all mammograms and classify the results according to the Breast Imaging Reporting and Data System (BI-RADS) [14,15]. Women with a BI-RADS 0, 4 or 5 screening result are recalled to a dedicated breast unit. The Dutch breast cancer screening program has been described in detail in previous studies [2,16,17].

2.3. Follow up

All women with a suspicious abnormality on screening mammograms (BIRADS 4–5, classified as; suspicious mass, suspicious calcifications, suspicious mass in combination with calcifications, architectural distortion, asymmetry, or other abnormality) are recalled to specialized breast cancer units for further analysis via their general practitioner. Additional breast radiology examinations will be performed, with or without biopsy. Women are recalled directly to the radiology department in case of an uncertain finding at screening mammography (BIRADS 0). If additional analysis does not reveal a suspicious lesion, women are discharged and the general practitioner is informed.

The available diagnostic biopsy procedures include fine needle aspiration (FNA) cytology, or histologic analysis, carried out by either core needle biopsy (14–18 Gauge), vacuum assisted needle biopsy (9–11 Gauge) or excision biopsy. In this study we focused on excision biopsies. Excision biopsies – primary biopsy method or secondary to percutaneous core needle biopsies, in case of persistent uncertainty (secondary excision biopsies) – were analyzed separately, assuming that the trends in use could differ.

Screening and follow up data of all recalled women were collected in a database kept up to date by one of the screening radiologists (LD).

2.4. Statistical analysis

The main outcome of this study was the incidence of the use of excision biopsy, where we especially focused on the difference between primary and secondary excision biopsy and the proportion of benign and malignant excision biopsy outcomes. Statistical analyses were performed using SPSS, version 24.0 (SPSS, Inc., Chicago, USA). The mean differences with standard deviation (SD) were calculated for continuous variables. Trends over time and variations between subgroups were expressed using proportions and percentiles. 95% confidence intervals (95% CI) and chi-square analyses were performed to compare proportional differences between categorical groups and Fischer Exact Test was employed when sample sizes were small, causing the expected values to be smaller than ten. *P* values less than 0.05 were considered statistically significant.

3. Results

3.1. Excision biopsy over time

An excision biopsy was carried out in 908 recalled women (4.9% of recalls), which decreased from 214 (39.9%; 1997–1998) to 84 (2.3%; 2015–2016; $p < 0.001$).

The overall excision biopsy rate was 1.1 per 1000 screened women. This rate initially decreased from 4.4 in 1997–1998 to 0.4 per 1000 screens in 2005–2006 ($p < 0.001$) and subsequently increased once again to 0.6 per 1000 screens in 2015–2016 ($p = 0.04$, Fig. 1).

3.2. Trends in primary and secondary excision biopsies

During the past two decades, 411 (45.3%) excision biopsies were performed as first diagnostic intervention (primary excision biopsy), compared to 497 (54.7%) performed following previous percutaneous biopsies (secondary excision biopsy).

During the first screening period 1997–1998, a primary excision biopsy was performed in 167 (78.0%) of all 214 patients who underwent excision biopsy, which decreased to 0 out of 84 in the last cohort ($p < 0.001$). In the last decade, only 24 recalled women

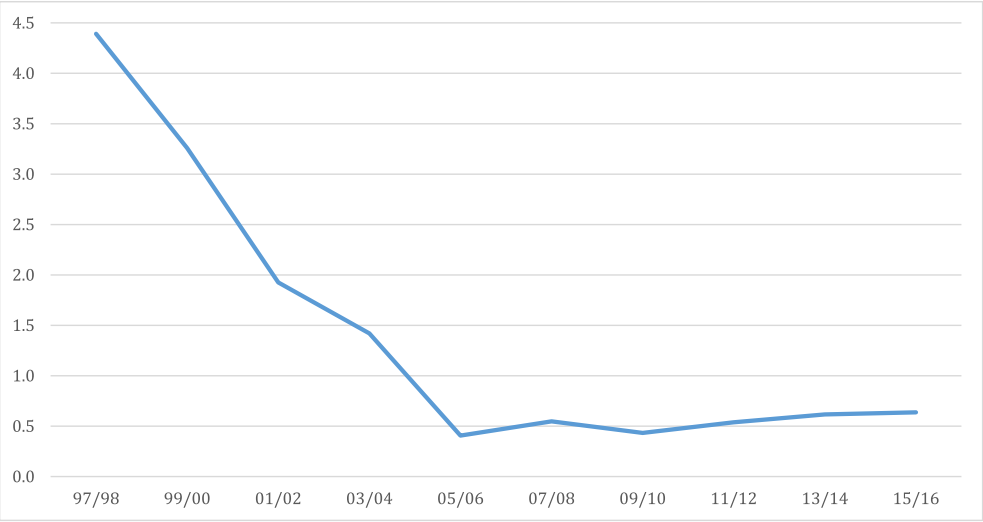

Fig. 1. Number of women undergoing surgical biopsy per 1000 screens.

underwent a surgical excision biopsy as the first diagnostic intervention, mostly due to inability to perform a stereotactic core needle biopsy (SCNB).

The use of secondary excision biopsies among the patients undergoing an excision biopsy increased from 22.0% (47 out of 214) in 1997–1998, to 100% (84 out of 84) in 2015–2016. The majority (286, 57.8%) of the 495 secondary excision biopsies were performed because of pathologic findings at percutaneous biopsy for which pathologists were unable to guarantee a benign disorder. Discordance between radiologic findings and the result of percutaneous biopsy was the reason to perform an excision biopsy secondary to percutaneous biopsy in 109 patients (22.0%); other indications for a secondary excision biopsy are specified in Table 1. The observed increase in secondary excision biopsies was mostly due to an increase in suspicious findings at percutaneous biopsy, while the other reasons for secondary excision showed no increase or other trend during this period (Table 1).

The rate of primary excision biopsies per 1000 screens decreased over the years from 3.4 in 1997–1998 to 0 per 1000 screens in 2015–2016 ($p < 0.001$, Fig. 3).

The rate of secondary excision biopsies per 1000 screens decreased initially from 1.0 performed in 1997–1998 to 0.3 per 1000 screens in 2005–2006 ($p < 0.001$). After that period a significant increase to 0.6 per 1000 screens was observed in 2015–2016 ($p = 0.003$, Fig. 3).

3.3. Histological diagnosis of excision biopsies

The final histopathological diagnosis was benign in 442 (48.7%) of the 908 women who underwent an excision biopsy. The percentage of benign excision biopsy results increased from 32.2% (69/214 patients), in 1997–1998, to 70.2% (59/84 patients) in 2015–2016 ($p < 0.001$). Fig. 2 shows the benign versus (pre-)malignant ratio in excision biopsies per 1000 screens. The benign versus (pre-)malignant biopsy ratio increased from 0.5 (1997–1998) to 2.4 in (2015–2016; $p < 0.001$, Table 1).

Of all 411 primary excision biopsies, 134 (32.6%) were benign. Of all 497 secondary biopsies, 303 (61.0%) showed a benign histopathological diagnosis. This percentage increased from 40.4% (19 out of 47) in 1997–1998 to 70.2% (59 out of 84) in 2015–2016 (Table 1). The (pre-)malignant histopathological results of secondary excision biopsies in the three most recent cohorts (2011–2012, 2013–2014 and 2015–2016) were further analyzed. Of all 211 biopsies, only 56 showed a (pre-)malignant histopathological result, resulting in an overall upgrade rate of 26.5%. Of all secondary biopsies 18.5% showed DCIS (27 low grade, 12.8%; 10 intermediate grade, 4.7%; 2 high grade, 0.9%) and 8.1% invasive carcinomas (11 low grade, 5.2%; 4 intermediate grade, 1.9%; 2 high grade, 0.9%; Fig. 4).

4. Discussion

This population-based study describes the changes in use and evaluates the added value of excision biopsies of screen-detected mammographic suspicious breast lesions in the southern part of the Netherlands from January 1997 to January 2017. A sharp decline in the use of primary excision biopsy was observed over the past two decades. Currently, primary excision biopsy has been replaced by percutaneous core biopsy in almost all patients, which was also demonstrated in this study [15–17].

Although it has been postulated that, with the introduction and widespread use of (S)CNB, an excisional biopsy would become an obsolete procedure, an ongoing significant increase was observed over the last few years, comprising mainly secondary excisional biopsies due to an increase in the number of suspicious findings at percutaneous biopsy. In daily practice, most secondary biopsies are performed if percutaneous biopsy yields an inconclusive histopathologic diagnosis, implying malignancy cannot be ruled out completely or when a discordance between radiologic and histopathologic findings persists after (repeated) percutaneous biopsy. This discordance is known to be related to an increased likelihood of upgrading to carcinoma [18].

The recent increase in secondary excision biopsies is probably related to the introduction of full-field digital mammography, revealing smaller breast lesions due to the higher sensitivity of digital mammography compared to screen-film mammography [19,20]. These changes in imaging techniques and diagnosis revealing lesions of unknown significance have had an impact on the types of specimens in which radiologists and pathologists encounter high-risk lesions [21]. This poses clinicians for therapeutic dilemmas for which either subsequent need for additional secondary excision biopsy or mammographic surveillance is imposed depending on the level of agreement in multidisciplinary tumor boards [22,23]. These lesions include, for example, atypical

Table 1

Screening year	97/98	99/00	01/02	03/04	05/06	07/08	09/10	11/12	13/14	15/16	Total
Screens	48,721	53,718	53,489	61,251	66,300	67,530	90,128	113,335	131,427	131,757	817,656
Excisional biopsy	214	175	103	87	27	37	39	61	81	84	908
Benign (%)	69 (32.2)	47 (26.9)	41 (39.8)	53 (60.9)	17 (63.0)	22 (59.5)	29 (74.4)	44 (72.1)	61 (75.3)	59 (70.2)	442 (48.7)
(pre) Malignant (%)	145 (67.8)	128 (73.1)	62 (60.2)	34 (39.1)	10 (37.0)	15 (40.5)	10 (25.6)	17 (27.9)	20 (24.7)	25 (29.8)	466 (51.3)
Per 1000 screens	4.4	3.3	1.9	1.4	0.4	0.5	0.4	0.5	0.6	0.6	1.1
Benign	1.4	0.9	0.8	0.9	0.3	0.3	0.3	0.4	0.5	0.4	0.5
(pre) Malignant	3.0	2.4	1.2	0.5	0.2	0.2	0.1	0.1	0.2	0.2	0.6
Benign/(pre)malignant ratio	0.48	0.37	0.66	1.6	1.7	1.5	2.9	2.6	3.1	2.4	0.95
Excisional biopsy and outcome											
Primary excisional biopsy (%^)	167 (78.0)	132 (75.4)	59 (57.3)	25 (28.7)	6 (22.2)	6 (16.2)	3 (7.7)	6 (9.8)	9 (11.1)	–	413 (45.5)
Benign (%)	52 (31.1)	32 (24.2)	25 (42.4)	14 (56.0)	1 (16.7)	4 (66.7)	1 (33.3)	3 (50.0)	2 (22.2)	–	134 (32.4)
(pre) Malignant (%)	115 (68.9)	100 (75.8)	34 (57.6)	11 (44.0)	5 (83.3)	2 (33.3)	2 (66.7)	3 (50.0)	7 (77.8)	–	279 (67.6)
Secondary excisional biopsy (%^)	47 (22.0)	43 (24.6)	44 (42.7)	62 (71.3)	21 (77.8)	31 (83.8)	36 (92.3)	55 (90.2)	72 (88.9)	84 (100)	495 (54.5)
Benign (%)	19 (40.4)	15 (34.9)	16 (36.4)	39 (62.9)	13 (61.9)		28 (77.8)	41 (74.5)	55 (76.4)	59 (70.2)	303 (61.2)
(pre) Malignant (%)	28 (59.6)	28 (65.1)	28 (63.6)	23 (37.1)	8 (38.1)	18 (58.1) 13 (41.9)	8 (22.2)	14 (25.5)	17 (23.6)	25 (29.8)	192 (38.8)
Indication for secondary excisional biopsy											
Suspicious findings at percutaneous biopsy[a]											
Benign (%°)	5 (10.6)	5 (11.6)	4 (9.1)	16 (25.8)	5 (23.8)	6 (19.4)	24 (66.7)	33 (60.0)	51 (70.8)	44 (65.8)	193 (39.0)
(pre) Malignant (%°)	6 (12.8)	7 (16.3)	11 (25.0)	9 (14.5)	4 (19.0)	7 (22.6)	3 (8.3)	11 (20.0)	13 (18.1)	22 (23.7)	93 (18.2)
Discordance[b]											
Benign (%°)	7 (14.9)	8 (18.6)	12 (19.4)	12 (19.4)	4 (19.0)	11 (35.5)	1 (2.8)	2 (3.6)	2 (2.8)	9 (10.7)	61 (12.3)
(pre) Malignant (%°)	8 (17.0)	11 (25.6)	8 (12.9)	8 (12.9)	1 (4.8)	1 (3.2)	2 (5.6)	2 (3.6)	2 (2.8)	1 (1.2)	48 (9.7)
Inadequate percutaneous biopsy[c]											
Benign (%°)	3 (6.4)	2 (4.7)	8 (12.9)	8 (12.9)	2 (9.5)	1 (3.2)	3 (8.3)	3 (5.5)	–	5 (6.0)	28 (5.7)
(pre) Malignant (%°)	14 (29.8)	10 (23.3)	6 (9.7)	6 (9.7)	2 (9.5)	5 (16.1)	1 (2.8)	1 (1.8)	2 (2.8)	2 (2.4)	48 (9.7)
Patient related[e]											
Benign (%°)	2 (4.3)	–	3 (6.8)		1 (4.8)		–	2 (3.6)	2 (2.8)	1 (1.2)	13 (2.6)
(pre) Malignant (%°)	–	–		2 (3.2)	1 (4.8)	–	2 (5.6)	–	–	–	3 (0.6)
Other[d]											
Benign (%°)	2 (4.3)	–	3 (6.8)	1 (6.1)	1 (4.8)	–	–	1 (1.8)	–	–	8 (1.6)

°percentage of secondary excision biopsies.
^percentage out of all excision biopsies.
[a] Borderline lesion for which the pathologist is unable to guarantee benign disorder.
[b] Benign percutaneous biopsy but suspicious radiological findings.
[c] Inadequate tissue sample and or uncertainty of representativeness.
[d] Patient anxiety or other patient related factors for which excision was decided upon.
[e] Persistent uncertainty despite adequate tissue sample.

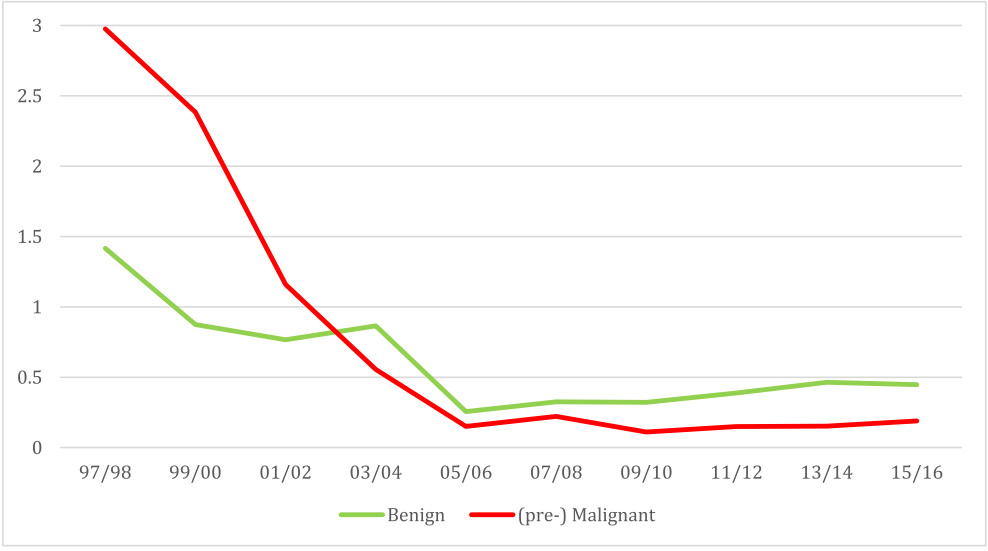

Fig. 2. Benign versus (pre-)malignant excisional biopsies per 1000 screens.

ductal hyperplasia (with the differential diagnosis of ductal carcinoma in-situ), papillary lesions, atypical lobular hyperplasia and flat epithelial atypia [24]. Since surgical excision is still regarded as the gold standard to obtain a definitive histopathologic diagnosis, surgical excision of the these lesions may be considered in order to minimize the risk of missing out malignant disease [22]. However, Mercado et al., in 2006 demonstrated that approximately 80% of all papillary lesions consist of benign pathology at secondary surgical excision [25]. Another study, by Sen et al., in 2016, also demonstrated that 97.6% of all atypical lobular hyperplasia was benign at secondary surgical excision [26]. Consequently, mammographic surveillance can be performed safely for some subtypes of high-risk

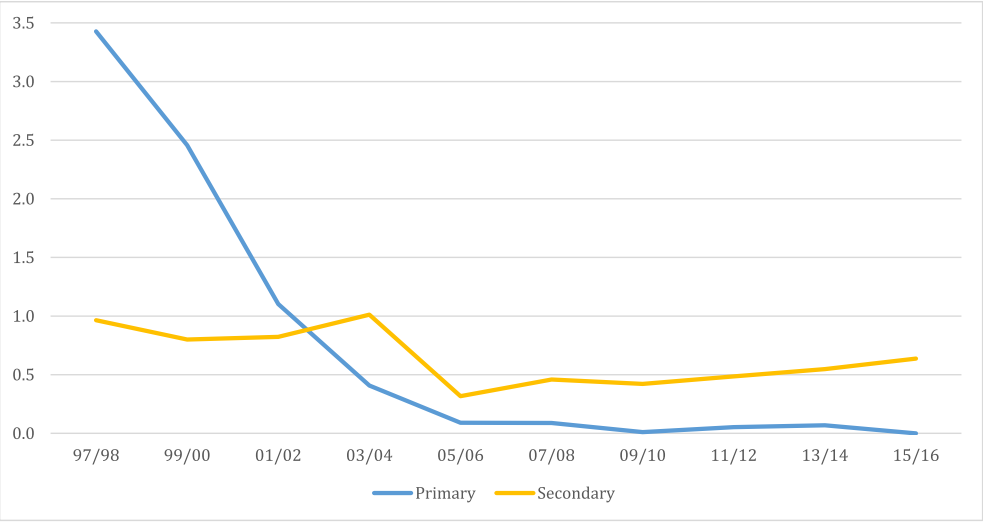

Fig. 3. Primary versus secondary excisional biopsies per 1000 screens.

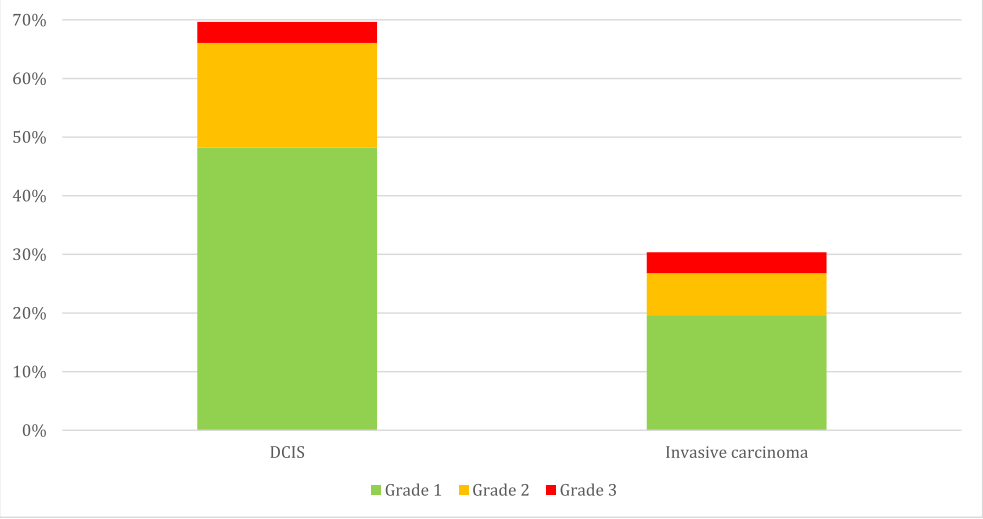

Fig. 4. (Pre-)malignant pathology outcome of secondary excision biopsies divided per grade from 2011 to 2016.

lesions, without the risk of a significant underdiagnoses and -treatment [13,26].

In the Netherlands and many other countries, pathology results of diagnostic core biopsies are discussed in a multidisciplinary tumor board. Secondary excision biopsy, preceded by percutaneous biopsy in almost all cases, appears to be the necessary following step in case of persistent uncertainty. Still, it can be questioned if the increase in the use of these excision biopsies can be considered as an improvement in the diagnostic process. Proponents might prefer to proceed to an excision biopsy to gain a definitive pathology result claiming that over 25% of the high-risk lesions show a (pre-) malignant pathology result after surgical excision. Others might state that these lesions may be safely managed by active radiographic surveillance, knowing that the majority of these lesions are low grade DCIS. Actually, this issue is currently subject of several ongoing studies [27,28].

One may question whether our current approach of high-risk mammographic lesions may be too defensive and results in too many unnecessary surgical excisions. In a recent survey amongst breast pathologists in the United States, almost 90% reported using one or more assurance behaviors, manifesting itself in ordering additional services with marginal or no additional medical value to avoid adverse patient outcomes [29]. This phenomenon is understandable, since a delay in diagnosis of breast cancer is a leading cause of malpractice suits filed in the United States [30].

The rate of excision biopsy procedures is much higher in the United States compared to European countries, including the Netherlands and the United Kingdom. This higher excision biopsy rate may be due to differences in legislation, with a higher rate of malpractice claims for delayed cancer diagnoses in the US than in Europe [11,31]. Unfortunately, we were not able to reliably retrieve the detailed considerations to proceed to a secondary excision biopsy as these were frequently not specified in the multidisciplinary tumor board reports.

In conclusion, following a sharp decline of the overall excision biopsies rate, a significant increase of secondary excision biopsies was noted the last few years.

Since the vast majority of all excision biopsies performed nowadays is benign, secondary excision biopsy should only be considered for women in whom radiologic surveillance and

repeated percutaneous biopsy continues to yield indeterminate result.

The authors declare no conflict of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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