

Original Article

# Surgical treatment of breast fibroadenomas

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## ABSTRACT

**INTRODUCTION.** Fibroadenoma is a benign tumour with a prevalence of 9-22% and the third most common palpable breast tumour. Management is primarily conservative, but treatment varies due to a lack of national guidelines. We aimed to estimate the proportion of women diagnosed with fibroadenoma who underwent surgical excision in Denmark between 2011 and 2014, including regional differences in age, tumour size and year of surgery.

**METHODS.** In this nationwide registry-based cohort study, we identified all patients who underwent surgical excision of a fibroadenoma from 1 January 2011 to 31 December 2014, using the Danish National Register of Pathology. This registry provided information on age and region. Operation rates were calculated using population data from Statistics Denmark.

**RESULTS.** We identified 1,843 patients. The mean size of surgically removed fibroadenomas was 25.5 mm, and the mean age at surgery was 37 years. Patients > 50 years had a significantly higher proportion of small fibroadenomas (< 20 mm) removed than younger patients ( $p < 0.01$ ). The overall operation rate was 20.6 per 100,000 women per year, highest in the 18-25-year age group (56.8 per 100,000 per year). Significant regional variation was found ( $p < 0.01$ ), with the North Denmark Region having the highest operation rate (43.6 per 100,000 per year).

**CONCLUSIONS.** Despite conservative management being recommended in Denmark during the study period, many fibroadenomas were surgically removed, and considerable regional variations were recorded. National guidelines are needed to ensure uniform, evidence-based treatment and reduce overtreatment.

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Fibroadenomas are benign tumours, with a prevalence of 9-22% in autopsied cases [1-5]. They are the third most common palpable tumours in the breast. Fibroadenomas primarily occur in women of reproductive age, with an incidence peaking at 50-60% in the third decade of life. They are typically small (2-3 cm) but may vary in size over time due to hormonal influence [5-11]. In adolescence or early adulthood, fibroadenomas clinically present as a smooth, round, firm, highly mobile and non-tender tumour upon palpation of the breast. On mammography, fibroadenomas are often well-defined, round, iso- or hyperdense lesions [5, 11, 12].

In older women, fibroadenomas tend to be smaller, firmer and may contain calcifications, making it more challenging to distinguish them from malignant tumours. In Denmark, clinical examination, mammography and/or ultrasonography, along with biopsy, are required for women over the age of 25 years to exclude breast cancer [13]. In women under 30 years, ultrasonography is the preferred first-line diagnostic tool, which may be supplemented by mammography. In women under 25 years, a biopsy can be omitted if ultrasound findings are typical of a fibroadenoma [5, 13].

Simple fibroadenomas are considered a normal overgrowth of connective tissue stroma, originating from the lobular units of the breast [5, 14]. However, distinguishing fibroadenomas from phyllodes tumours can be challenging. Phyllodes tumours are rare, accounting for 0.3-1% of all primary breast tumours and occur primarily in older women (average: 40-50 years) [9, 11, 14]. Phyllodes tumours have metastatic and/or recurrent potential and are graded based on histological features and clinical behaviour as benign, borderline or malignant. Therefore, accurate diagnosis and surgical removal are essential [15].

In Denmark, the primary management of fibroadenomas is conservative unless there is uncertainty regarding the diagnosis or if the tumour causes discomfort due to size. The indications and size limits for surgical excision vary widely due to a lack of evidence and guidelines, potentially causing overuse of surgical intervention. Surgical treatment imposes stress on patients, carries a risk of complications and strains surgical capacity. There are few studies and clinical guidelines on fibroadenoma management, and no national Danish guidelines are available [11, 12, 15].

This study aimed to estimate the proportion of women diagnosed with fibroadenomas who underwent surgical excision in Denmark between 2011 and 2014. Furthermore, it sought to investigate regional differences in age, tumour size and year of surgery.

## Methods

In this nationwide, register-based cohort study, we identified all patients who underwent surgical excision of a fibroadenoma between 1 January 2011 and 31 December 2014, using the Danish National Register of Pathology. The DNRP is a national database containing detailed information on all tissue and cell examinations made by the Danish healthcare system [16]. We retrieved data on the diagnosis and size of the fibroadenomas from the DNRP [17]. Patients who only had a core needle biopsy and no surgical excision were excluded from the study. Similarly, patients with invasive cancer, carcinoma in situ, mastectomy or sentinel lymph node procedures were excluded, as the primary indication for their surgical treatment was unlikely to be the fibroadenoma.

In the DNRP, the size of the fibroadenomas is typically recorded, but in some cases, the measurement refers to the entire tissue sample removed rather than to the fibroadenoma. These cases, as well as those with missing size, were excluded.

Patient age at the time of surgery was calculated using the unique Danish social security number. The patients were divided into groups based on five-year intervals, with additional groups for those under 25 and over 70 years. Operation rates per 100,000 women annually were calculated for the entire female Danish population and separately for each of Denmark's five regions. Rates were also calculated according to smaller age groups. Information on population size for different age groups and regions, by year, was retrieved from Statistics Denmark and used to calculate age-adjusted operation rates [18].

ANOVA was used to investigate differences in operation rates between regions and across years. A significance level of  $p < 0.05$  was applied. The  $\chi^2$  test of independence was used to assess the association between age and the size of the excised fibroadenomas, with a significance level of  $p < 0.05$ . Additionally, linear regression was used to examine trends between patient age and the size of the excised fibroadenoma.

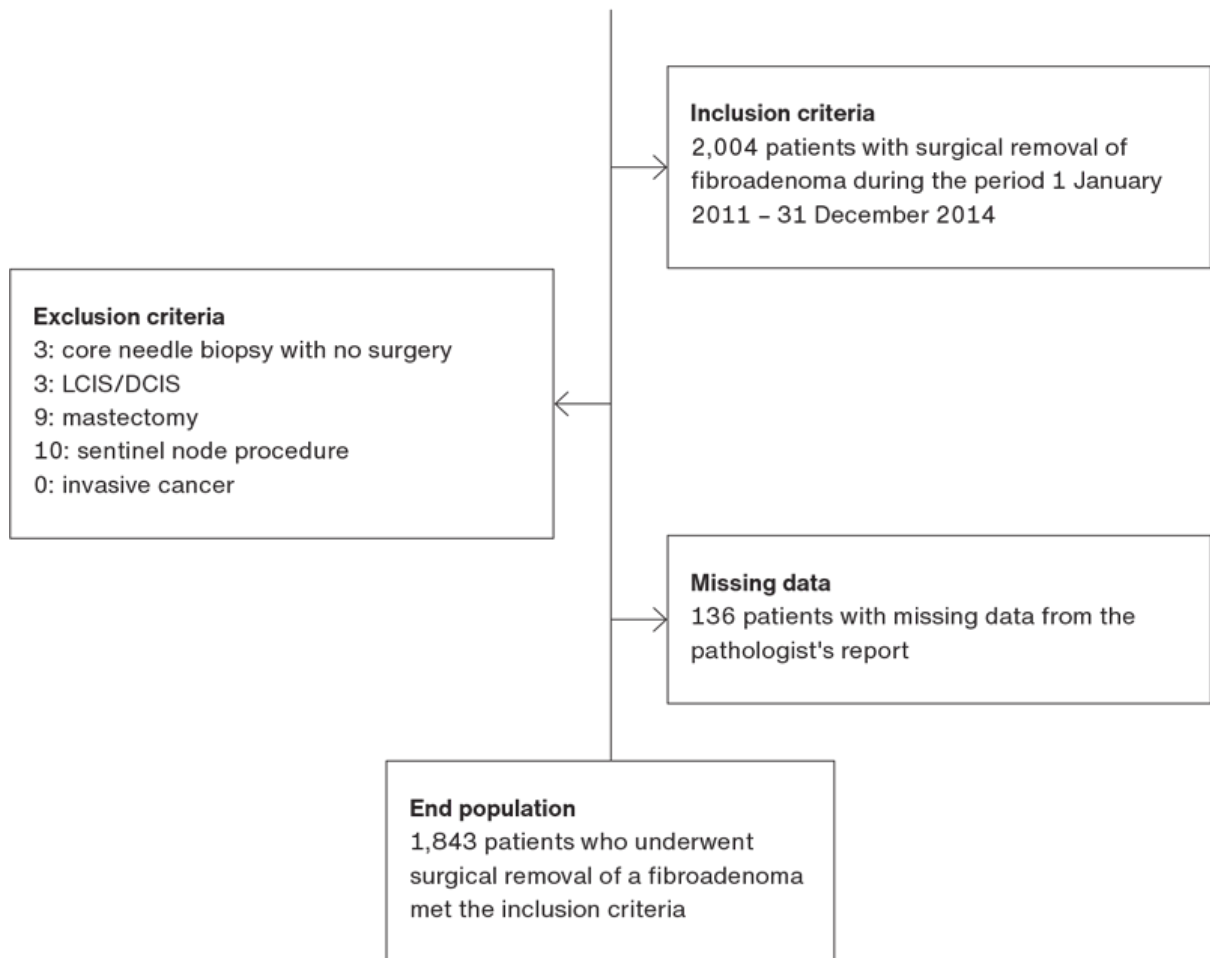
The study was approved by the Danish Data Protection Agency, the Danish Health Authority and the DNRP in accordance with Danish law at the time of data collection in 2015 (SABN 3-3013-1306/1). This study is reported in compliance with the reporting of studies conducted using observational routinely-collected health data (RECORD) statement.

*Trial registration:* nr. SABN 3-3013-1306/1.

## Results

We identified 2,004 patients in the DNPR who underwent surgical excision of a fibroadenoma. After excluding patients who were not eligible, we ended up with 1,843 patients who met the inclusion criteria (**Figure 1**). Patient and tumour characteristics are shown in **Table 1**. The mean age at the time of fibroadenoma excision was 37 years (range: 18-87 years). 30% of all excisions were performed in patients aged 18-25 years (Table 1), whereas only 15% were performed in patients older than 50 years.

**FIGURE 1** CONSORT diagram of patients eligible for analysis of operation rate.



DCIS = ductal carcinoma in situ; LCIS = lobular carcinoma in situ.

**TABLE 1** Demographics, and patient and tumour characteristics, for 1,843 Danish female patients with surgically removed fibroadenomas between 2011 and 2014 (N = 1,843).

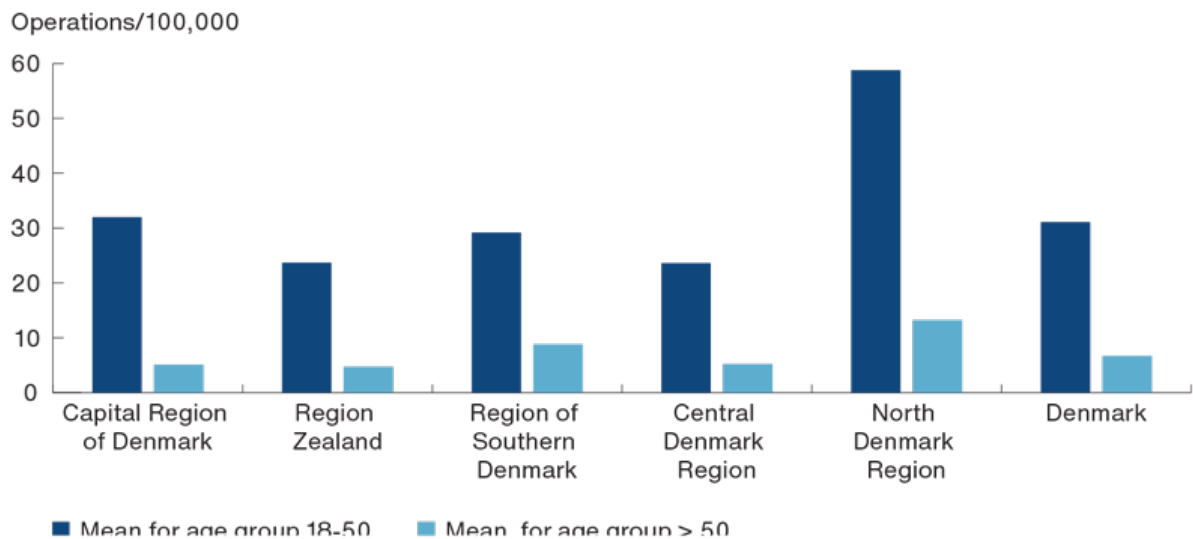
	Operation rate: n/100,000/yr	Average (min.-max)	n (overall %)	Average age, 2011-2014, yrs	Average population ≥ 18 yrs 2011-2014, n
<i>Total</i>					
Average operation rate	20.6				
Age, yrs		37 (18-87)			
<i>Operations</i>					
<i>Age group:</i>					
18-25 yrs	56.8		549 (29.9)		
26-30 yrs	30.6		189 (10.3)		
31-35 yrs	23.1		154 (8.4)		
36-40 yrs	28.8		208 (11.3)		
41-45 yrs	33.5		242 (13.2)		
46-50 yrs	28		216 (11.8)		
51-55 yrs	17.5		128 (6.9)		
56-60 yrs	7.9		55 (2.9)		
61-65 yrs	5.7		41 (2.2)		
66-70 yrs	6.1		40 (2.2)		
> 70 yrs	1.6		21 (1.1)		
<i>Region of Denmark:</i>					
Capital Region of Denmark	23		606 (33.0)		
Region Zealand	17.4		182 (9.9)		
Region of Southern Denmark	22.4		377 (20.6)		
Central Denmark Region	17.5		314 (17.1)		
North Denmark Region	43.6		364 (19.8)		
<i>Year:</i>					
2011	22.7		503 (27.4)		
2012	19.7		439 (23.9)		
2013	20.8		467 (25.5)		
2014	19.2		434 (23.7)		
<i>Fibroadenoma size, mm</i>					
<i>Size:</i>					
		25.5 (1.2-150)			
≥ 20 mm			1,169 (63.4)		
< 20 mm			674 (36.6)		
<i>Age group:</i>					
18-25 yrs		30.2 (3-135)			
26-30 yrs		27.1 (4-130)			
31-35 yrs		23.8 (3-85)			
36-40 yrs		24.8 (1-85)			
41-45 yrs		23.5 (2-118)			
46-50 yrs		23.1 (1.2-150)			
51-55 yrs		20.1 (3 -80)			
56-60 yrs		22.2 (5-80)			
61-65 yrs		16.1 (4-50)			
66-70 yrs		24.3 (6-142)			
> 70 yrs		21.5 (2-75)			
<i>Population</i>					
<i>Region of Denmark:</i>					
Capital Region of Denmark				40.6	705,900
Region Zealand				43.3	381,140
Region of Southern Region				42.3	475,709
Central Denmark Region				40.8	498,282
North Denmark Region				42.6	229,779
Denmark				41.6	2,290,811

The overall operation rate in Denmark for fibroadenomas during the study period was 20.6 per 100,000 women per year, without variations between years of surgery ( $p = 0.94$ ). The highest operation rate was observed in the 18-25-year age group, with a rate of 56.8 per 100,000 women per year (Table 1). The distribution of operations by age group is shown in Table 1.

A significant variation in operation rates was observed between regions ( $p < 0.01$ ). The highest operation rate was seen in the North Denmark Region, with an operation rate of 43.6 per 100,000 women per year, which was significantly higher than the national average of 20.6 per 100,000 women per year ( $p = 0.002$ ) (Figure 2 and Table 1). The North Denmark Region had a significantly older population than the national average ( $p < 0.01$ ) (Table 1).

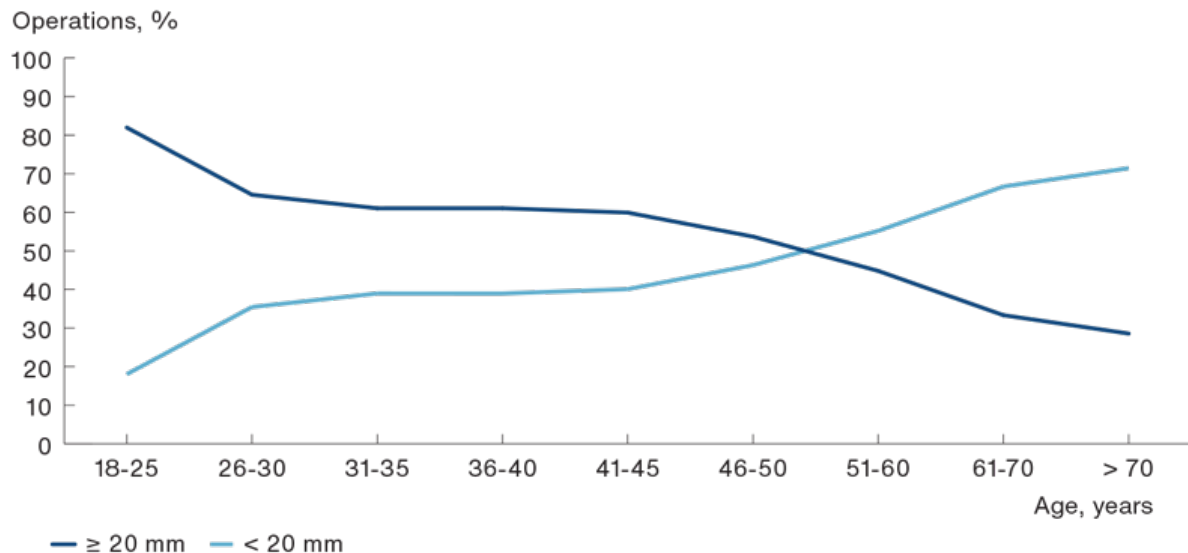
Still, the average age for removal of a fibroadenoma in the North Denmark region was only 36 years.

**FIGURE 2** Mean operation rates per 100,000 women, for the period from 2011 to 2014, in the following age groups: 18-50 years and above 50 years, across the five regions of Denmark and the national average.



The mean size of the surgically excised fibroadenomas was 25.5 mm (Table 1). In 36% of cases, the excised fibroadenoma was smaller than 20 mm, and only 7.3% of the cohort (135 patients) had a fibroadenoma larger than 50 mm surgically removed, of which 83% were under 50 years of age. Patients above the age of 50 years underwent surgery for a significantly higher proportion of small fibroadenomas (< 20 mm) than patients aged 50 years or younger ( $p < 0.01$ ). In the 18-25-year age group, less than 20% of the removed fibroadenomas were smaller than 20 mm, whereas in the groups of women older than 50 years, 50-70% of fibroadenomas were smaller than 20 mm (Figure 3).

**FIGURE 3** Percentage distribution of fibroadenomas larger and smaller than 20 mm, categorised by age, in Denmark from 2011 to 2014.



## Discussion

In this nationwide registry-based study, we investigated the incidence of patients with surgically removed fibroadenoma. Despite recommendations for conservative management, more than 2,000 excisions were performed from 2011 to 2014, corresponding to an operation rate of 20.6 per 100,000 women. As expected, younger women had the highest operation rate, reflecting the higher incidence of fibroadenomas in this group [9].

Fibroadenomas have characteristic clinical and imaging features. Excision is generally unnecessary unless diagnostic discordance exists or if the tumour causes discomfort. In our study, we found that 36% of the excised fibroadenomas were smaller than 20 mm, making discomfort less likely to be the primary reason for excision, which may indicate surgical overtreatment. Giant fibroadenomas (> 5 cm), which account for 0.5-2% of all fibroadenomas, should be surgically removed due to the increased risk of a phyllodes tumour. In our cohort, 7.3% of excised fibroadenomas were > 5 cm, primarily in women below 50 years of age.

Fibroadenomas may regress over time owing to hormonal changes [5, 8]. In this study, removed fibroadenomas tended to decrease in size with increasing age (Figure 3), possibly because of regression or increased diagnostic uncertainty in older women with a higher risk of malignancy.

We found the highest operation rate in younger women despite their low risk of malignancy and the limited potential for atypia [7, 9, 10, 19]. Patients with fibroadenomas and without a family history of breast cancer do not seem to have an independently increased risk of breast cancer [7, 12]. This suggests overtreatment in younger patients.

To our knowledge, a few studies have investigated the frequency of surgical removal of fibroadenomas. A retrospective study from Egypt in 2022, which included 1,392 patients with a clinical/radiological provisional diagnosis of fibroadenoma, reported an operation rate of 59.2% [15]. A retrospective study conducted in South Africa in 2021, with a five-year follow-up, examined the conservative management of confirmed fibroadenomas

and included 306 women under 35 years old. In this group, 23.2% were surgically removed during the observation period [8]. International variation may stem from demographic differences and inconsistencies in diagnostic guidelines, underscoring the need for standardised, evidence-based recommendations.

We found a significant variation in operation rates between Danish regions, with the highest rate being recorded in the North Denmark Region. Our data do not allow us to draw conclusions regarding the reasons for the removed fibroadenomas in the North Denmark Region or the number of conservatively treated fibroadenomas. We do expect that the higher proportion of fibroadenomas in some regions of Denmark may be due to demographic factors, as younger individuals tend to settle in the larger cities for education and employment opportunities [18]. The North Denmark Region had a significantly older population than the national average. However, the average age of women with a removed fibroadenoma was lower than the average age for women in all of Denmark, indicating overtreatment. When comparing fibroadenoma excisions in the North Denmark Region to the national average, significantly more small fibroadenomas were removed, suggesting that factors other than size-related discomfort influenced surgical decisions. In Denmark, there is easy and free access to imaging, diagnostic biopsies and breast surgery in all regions; therefore, we do not expect that access to treatment has influenced the rate of surgery or diagnosis of fibroadenomas.

Alternative treatments, including heat- and cold-based ultrasonographically guided ablative techniques, such as radiofrequency, laser and cryoablation of fibroadenomas, provide alternatives to surgery, with minimal pain and scarring, but were unavailable in Denmark during the study period [20].

A limitation in this study was the lack of information on the reasons for surgical excision. We did not have access to data on patient symptoms, cosmetic concerns, anxiety or family history of breast cancer. Some resections may have been prompted by other diagnoses, with the fibroadenoma being an incidental finding. In addition, we did not have information on the number of fibroadenomas diagnosed and treated conservatively. The diagnosis of nonpalpable fibroadenomas is not verified by biopsy, and no registration exists in the DNRP. We did not have access to radiological findings for identification of non-palpable fibroadenomas diagnosed on imaging without biopsy. To calculate an operation rate, we therefore used the size of the female population in Danish regions retrieved from Statistics Denmark, despite knowing that the proportion of fibroadenomas varies with the proportion of younger women in the region. Still, differences were found between regions in the average age of women with a removed fibroadenoma. Another limitation is the imprecise measurement of tumour size. Macroscopic and microscopic descriptions were reviewed for each patient to obtain the most accurate size. Even so, the accurate size was unavailable for 7% of patients. Smaller, non-palpable fibroadenomas may be less likely to be measured due to imaging limitations and the pathologist's examination of the breast tissue. In that case, the number of small fibroadenomas removed may be higher. Fibroadenomas found incidentally could also contribute to an increase in the number of small fibroadenomas excised.

The strengths of this study lie in the fact that the entire population could be easily identified using their Danish social security numbers. All excised fibroadenomas were reported to the nationwide DNRP, providing a high level of data completeness and a large nationwide sample size of more than 2,000 patients, ensuring a high likelihood of representative results.

## Conclusions

This study reported a high proportion of surgically removed fibroadenomas in younger women in Denmark, despite their low risk of malignancy. Conservative treatment should be the goal (gold standard) in most cases. More than a third of the excised fibroadenomas were < 20 mm, indicating possible surgical overtreatment. These are typically considered suitable for conservative management, yet the lack of detailed clinical context makes it

difficult to assess whether surgery was clinically justified in each case. This pattern may suggest a potential area of overtreatment, although further research is needed to evaluate the exact reason and indication for surgery. One of the five Danish regions had a higher frequency of excision than the other regions. Regional variation in surgical rates suggests treatment differences based on tradition rather than evidence-based guidelines.

Whereas international guidelines exist for breast cancer, there is a notable lack of standardised recommendations for benign breast conditions. Establishing national and international guidelines may potentially ensure a more uniform, evidence-based treatment while reducing unnecessary surgery. Although a consensus exists on the conservative management of fibroadenomas following a confident diagnosis, considerable variation persists in the surgical removal of fibroadenomas both within regions in Denmark and internationally. There are no universal guidelines regarding the duration of observation or the need for excision in the conservative management of fibroadenomas.

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