European Radiology
https://doi.org/10.1007/s00330-017-5219-8

BREAST

Prospective study aiming to compare 2D mammography and tomosynthesis + synthesized mammography in terms of cancer detection and recall. From double reading of 2D mammography to single reading of tomosynthesis

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Received: 20 June 2017 / Revised: 19 November 2017 / Accepted: 28 November 2017

Abstract

Objectives To evaluate tomosynthesis compared with 2D-mammography in cancer detection and recalls in a screening-programme, and assess performing synthesized instead of 2D, and compare double reading of 2D with single reading of tomosynthesis.

Methods Women (age 50–69 years) participating in the screening-programme were included. 2D-mammography and tomosynthesis were performed. There were four reading models: 2D-mammography (first); 2D-mammography (second); tomosynthesis + synthesized (third); tomosynthesis + synthesized + 2D (fourth reading). Paired double reading of 2D (first+second) and tomosynthesis (third+fourth) were analysed.

Results In 16,067 participants, there were 98 cancers and 1,196 recalls. Comparing double reading of 2D with single reading of tomosynthesis, there was an increase of 12.6 % in cancer detection with the third reading (p= 0.043) and 6.9 % with the fourth reading (p=0.210), and a decrease in recalls of 40.5 % (p<0.001) and 44.4 % (p<0.001), respectively. With double reading of both techniques, there was an increase in cancer detection of 17.4 % (p = 0.004) and a decrease in recalls of 12.5 % (p = 0.001) with tomosynthesis.

Conclusion Single reading of tomosynthesis plus synthesized increased cancer detection and decreased recalls compared with double reading 2D. 2D did not improve results when added to tomosynthesis.

Key Points

- *Tomosynthesis increases cancer detection and decreases recall rates versus 2D mammography.*
- *Synthesized-mammography avoids performing 2D, showing higher cancer detection.*
- *Single reading of tomosynthesis + synthesized is feasible as a new practice.*

Keywords Mammography · Digital breast tomosynthesis · Screening · Breast cancer · Radiology

Abbreviations and acronyms

DCIS	Ductal carcinoma in situ
IDC	Invasive ductal carcinoma
ILC	Invasive lobular carcinoma
MGD	Mean glandular dose
PPV	Positive predictive value

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Introduction

Conventional 2D mammography is the standard breast cancer screening technique, as it is the only technique that has been shown to decrease mortality in large studies [1, 2]. However, it has limitations, such as false negatives (20–30 %) and a high recall rate, of about 11%, most of which are false positive [3].

Published online: 02 January 2018

Tomosynthesis allows visualization of the breast as a 3D structure in different planes [4, 5]. In the screening setting, it improves the limitations of 2D mammography [6] with published results of increasing detection up to 43 % [7] and decreasing the recall rate up to 18 % [8].

The implementation of tomosynthesis in breast cancer screening programmes also has limitations. Firstly, the radiation dose is increased when added to 2D [9]. Secondly, tomosynthesis remains a limited resource that is not currently offered to all women because of the cost involved. Finally, the interpretation time is longer for tomosynthesis than for 2D mammography.

The use of a synthesized image (obtained from the tomosynthesis data) avoids the need for performing 2D and reduces the radiation dose [10], although published data are limited.

In a recent publication [11], Houssami proposes the possibility of changing the strategy of readings with the incorporation of tomosynthesis since a single reading may not be inferior to a 2D double reading. This new strategy of reading is a more effective and efficient approach, due to the decrease in cost per reading and in the cost associated with negative recalls.

This study, performed on a population-based breast cancer screening programme, firstly compares tomosynthesis plus synthesized image with digital 2D mammography in terms of cancer detection and recalls; secondly it assesses whether a synthesized image would avoid the performance of 2D mammography and finally explore the value of a single reading of tomosynthesis versus double reading of 2D mammography as a reading strategy in screening.

Material and methods

Study group and image techniques

The Cordoba Screening Programme is part of the Breast Cancer Screening Programme of Andalucía. Women aged 50–69 years are invited to undergo routine biennial screening mammography. Independent double reading, without consensus or arbitration, is the standard of practice. Women are recalled for diagnostic work-up if one or both readers consider the mammography as suspicious for malignancy.

Tomosynthesis (Dimensions; Hologic; Bedford, MA, USA and C-View 2D-software) was incorporated into our breast screening programme in November 2014 and from January 2015 to December 2016; women were invited to participate in this prospective-transversal study and written informed consent was provided. Those who agreed underwent combined mammography plus tomosynthesis at the same time, receiving 2D mammography (mediolateral oblique and craniocaudal of each breast) and tomosynthesis (also four views), with a single breast compression per view. The synthesized image was created from the stack of tomosynthesis images.

The only exclusion criterion was the refusal to take part in the study. The study was approved by the research ethics committee of the Reina Sofia Hospital.

Image interpretation

Five radiologists with 3–15 years of exclusive dedication to breast imaging and experience in breast cancer screening programme of a minimum of 5,000 screening cases per year participated in this study. The experience with tomosynthesis consisted of an intensive personal training of approximately 8 h and 3 months of screening practice with this new technology.

The four reading models included were (Fig. 1): (1) 2D mammography (first reading); (2) 2D mammography (second reading); (3) tomosynthesis plus synthesized mammography (third reading); (4) tomosynthesis plus synthesized mammography plus 2D mammography (fourth reading).

Each participant had four blind readings. No reader performed more than one reading per participant. Comparison with previous mammograms was made whenever previous studies were available at the time of screening interpretation.

In our study, we compare double reading of 2D mammography (positive if the participant was recalled by the first reading, second reading or both, referred to as 'double 2D') with the third reading, with the fourth reading and, finally, with double reading of tomosynthesis (positive if the participant was recalled by the third reading, fourth reading or both). Furthermore, we also explored the comparison between single readings of tomosynthesis (third reading vs. fourth reading).

Summary measures

We collected data regarding age, breast density, radiological findings and recall indication for each participant.

For assessment of breast density, we used the Breast Imaging Reporting and Data System (BI-RADS) classification [12]. Each participant was given a single breast density according to the most frequently granted category value in the four readings.

The radiological findings were classified as mass, architectural distortion, calcifications or asymmetric density. In case of discrepancy between readings, we opted for the most frequently found. The size of the finding was measured in millimetres.

For each reading, double reading and every radiologist, we obtained absolute and relative data of recalls (women who after the reading of the screening test were recalled for further evaluation) and cancers detected (women in whom a malignant lesion is demonstrated by anatomopathological study, in situ and/or invasive).

From women recalled we collected the number of percutaneous biopsies; and from cancers detected the histological type (in situ or invasive), grade and size.

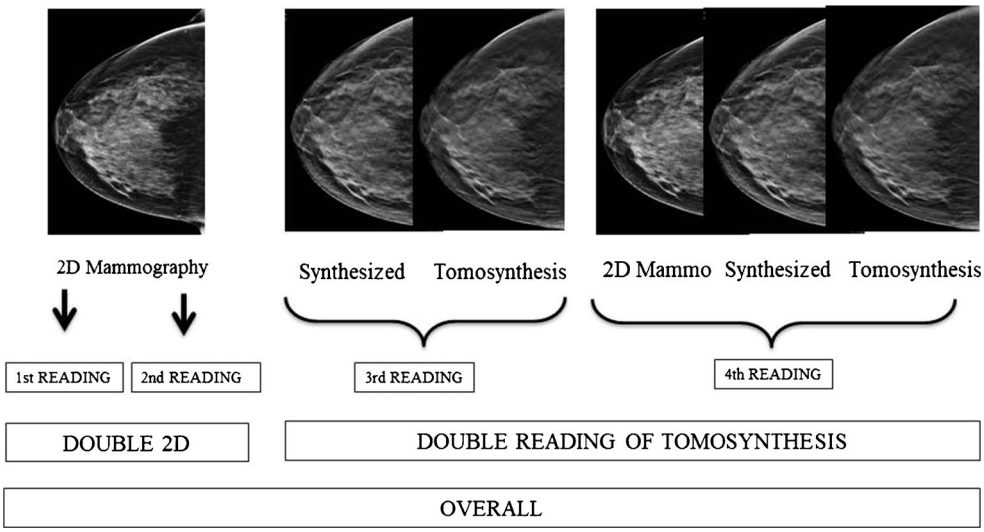

Fig. 1 Interpretation models

We cannot estimate sensitivity and specificity because this study was carried out for 2 years and interval cancers were not considered.

Positive predictive values (PPVs) were calculated as follows: PPV_1, the number of cancers per number of recalls × 100; PPV_2, the number of cancers per biopsy performed × 100.

The mean glandular dose (MGD) was found by adding the radiation dose of the four views of each technique related to the compressed breast thickness in a set of 149 randomly selected participants.

The interpretation time (in seconds) for each reader in each of the three reading models was recorded from a set of 3,341 women.

Statistical analyses

The analysis was carried out with SPSS version 17 (IBM,Chicago, IL, USA) and a p-value of less than 0.05 was considered statistically significant. For a description of the qualitative variables, numbers (n) and percentages (%) were calculated. The comparison of cancers detected and recalls between 2D mammography and tomosynthesis were considered paired binary data, using McNemar's test for analysis. The remaining comparisons between qualitative variables were performed using the Chi-squared test or Fisher's exact test. For the quantitative variables, we calculated the arithmetic mean, standard deviation, minimum and maximum values. The confidence intervals were calculated with 95 % confidence.

Results

Out of the 18,665 women appointed to the tomosynthesis device, 2,598 refused to participate in this study to undergo 2D mammography. A total of 16,067 women were thus enrolled in the study (median age 57.59 ± 5.9, range 50–70 years). 3,341 women were appointed for the first time (baseline-screened women) and 12,727 were previously screened. We detected 98 breast cancers in 97 participants (one bilateral cancer), so we present data for 16,068 screens.

Table 1 shows the number of cancers, cancer detection rate, recalls number, recall rates, percutaneous biopsies performed and PPV for each reading, double 2D, double reading of tomosynthesis and overall.

Table 2 compares detected cancers and recalls the number between double 2D and single reading of tomosynthesis (third and fourth readings) to assess the single reading as a new screening strategy; between double 2D and double reading of tomosynthesis and between the third reading and fourth reading to evaluate whether or not the availability of 2D mammography improves the outcomes of tomosynthesis.

Regarding cancer detection, comparing double 2D with the third reading, 69 cancers were detected at both 2D and the third reading. Seven cancers were detected only at double 2D compared with 18 detected only at the third reading. The increase in cancer detection was 12.6 % (95 % CI 7.2–21.2, p= 0.043) at the third reading. Comparing double 2D with the fourth reading, 65 cancers were detected with both techniques, 11 cancers were detected only at double 2D compared with 16 detected at the fourth reading, meaning an increase in cancer detection of 6.2 % (95 % CI 2.7–13.6, p=0.442). Comparing double 2D with double reading of tomosynthesis, 70 cancers were detected with both techniques, six cancers were detected only at double 2D compared with 22 cancers detected only at double reading of tomosynthesis, which means an increase in cancer detection of 17.4 % (95 % CI 11.0–26.4, p=0.004). Finally, comparing the fourth reading with the third reading, 76 cancers were detected at both readings, five cancers were detected only at the fourth

Table 1 Measures for each reading and double reading

	2D mammography (1st reading)	2D mammography (2nd reading)	Double 2D	Tomo+synthesized (3rd reading)	Tomo+synthesized+ 2d (4th reading)	Double reading of tomosynthesis	Overall
Cancers detected	63	66	76	87	81	92	98
Cancer detection rate (%)	3.9	4.1	4.7	5.4	5.0	5.7	6.1
Recalls	556	499	810	482	450	709	1196
Recall rate (%)	3.5	3.1	5.0	2.9	2.8	4.4	7.4
Percutaneous biopsies	150	149	193	189	181	235	280
PPV_1 (%)	11.3	13.2	9.4	18.0	18.0	13.0	8.2
PPV_2 (%)	42.0	44.3	39.4	46.0	44.8	39.1	35.0

Cancer detection is given as number and rate

Recalls are given as number and rate

Percutaneous biopsies are given as number

PPV_1 positive-predictive value of recalls, *PPV_2* positive-predictive value of biopsies

reading compared with 11 detected at the third reading, meaning an increase of 6.9 % (95 % CI 3.2–14.2, p=0.210) (Table 2).

As for recalls, 1,196 women were recalled (7.4 %). Comparing double 2D with the third reading, 250 occurred at both double 2D and the third reading, 560 occurred only at double 2D compared with 232 at the third reading, showing a decrease of 40.5 % (95 % CI 37.2–43.9, p<0.001). Comparing double 2D with the fourth reading, 234 occurred with both techniques and 576 occurred only at double 2D compared

Table 2 Comparison of cancer detection and recall between double 2D and double 3D; double 2D and 3rd reading; double 2D and 4th reading; third reading and fourth reading

	Cancers detected			Recalls		
	3rd reading positive	3rd reading negative	Total	3rd reading positive	3rd reading negative	Total
Double 2D positive	69	7	76	250	560	810
Double 2D negative	18	15,974	15,992	232	15,026	15,258
Total	87	15,981	16,068	482	15,586	16,068
P-value	0.043			<0.001		
	Cancers detected			Recalls		
	4th reading positive	4th reading negative	Total	4th reading positive	4th reading negative	Total
Double 2D positive	65	11	76	234	576	810
Double 2D negative	16	15,976	15,992	216	15,042	15,258
Total	81	15,987	16,068	450	15,618	16,068
P value	0.442			<0.001		
	Cancers detected			Recalls		
	Double reading of tomo positive	Double reading of tomo negative	Total	Double reading of tomo positive	Double Reading of tomo negative	Total
Double 2D positive	70	6	76	323	487	810
Double 2D negative	22	15,970	15,992	386	14,872	15,258
Total	92	15,976	16,068	709	15,359	16,068
P-value	0.004			0.001		
	Cancers detected			Recalls		
	3rd reading positive	3rd reading negative	Total	3rd reading positive	3rd reading negative	Total
4th reading positive	76	5	81	223	227	450
4th reading negative	11	15,976	15,987	259	15,359	15,618
Total	87	15,981	16,068	482	15,586	16,068
P-value	0.210			0.160		

McNemar's test was used for paired binary data and p-values

with 216 at the fourth reading, showing a decrease of 44.4 % (95 % CI 41.1–47.8, p<0.001). Comparing double 2D and double reading of tomosynthesis, 323 occurred with both techniques and 487 occurred only at double 2D compared with 386 only at double reading of tomosynthesis, showing a decrease in recalls of 12.5 % (95 % CI 10.4–14.9, p=0.001). Finally, comparing the third reading with the fourth reading, 223 occurred at both readings, 259 occurred only at the third reading compared with 227 at the fourth reading, resulting in a decrease of 6.6 % (95 % CI 4.74–9.22, p=0.160) (Table 2).

Interaction between tomosynthesis use and baseline status was explored but it was not statistically significant. Twenty-eight cancers were detected in 3,341 baseline-screened women, 23 cancers were detected at double 2D compared with 24 detected at double reading of tomosynthesis, leading an increase of 4.2 % (95 % CI 0.7–20.2, p=1.00). Regarding recalls, 460 baseline screened women were recalled, 310 occurred at double 2D compared with 294 at double reading of tomosynthesis (leading a decrease of 5.2 %; 95 % CI 3.2–8.2, p=0.399).

For previously screened women, there was a significant increase in cancer detection of 22.1 % (95 % CI 13.8–33.2, p=0.001). Seventy cancers were detected in 12,727 women, 53 cancers were detected at double 2D compared with 68 detected at double reading of tomosynthesis. The number of recalls was 736,500 at double 2D compared with 415 at double reading of tomosynthesis, which resulted in a significant decrease in recalls of 26.5 % (95 % CI 21.9–31.5, p<0.001).

Cancer detection and recall rates according to individual radiologists are shown in Table 3. Four of the five radiologists detected more cancers with the use of tomosynthesis, with a significant increase for reader 4. Regarding recalls, there was a decrease for four radiologists, which was a significant decrease in readers 2 and 5.

Among the women recalled, PPV_1 was 9.4 % by double 2D (76 cancers/810 recalls) and 18 % at both single readings of tomosynthesis (third reading, 87 cancers/482 recalls; fourth reading, 81 cancers/450 recalls), leading to an increase of 47.8 % (95 % CI 27.2–69.1, p<0.001). There was an increase in PPV_1 of 27.7 % at double reading of tomosynthesis (13 %, 92 cancers/709 recalls) compared with double 2D (95 % CI 11.0–54.7, p=0.026). Although there was an increase in PPV2 when tomosynthesis was compared with double 2D, this difference was not statistically significant (14.4 % for third reading, p=0.189; 12.4 % for fourth reading, p=0.293 and 0.8 % for double reading, p=0.961) (Table 1).

Breast density was: 22.8 % almost entirely fatty (3,663 participants), 51.0 % scattered fibroglandular densities (8,198 participants), 23.5 % heterogeneously dense (3,768 participants) and 2.7 % extremely dense (439 participants). Table 4 shows the number of cancers detected by breast density. In almost entirely fatty breasts, both techniques detected the same number of cancers. Tomosynthesis detected twice as many cancers as 2D mammography in extremely dense breasts. There was an increase in cancer detection of 14.9 % in scattered fibroglandular densities breasts (95 % CI 7.4–27.7, p=0.092) and 21.6 % in heterogeneously dense breast (95 % CI 11.4–37.2, p=0.039).

As shown in Table 4, there were 72 invasive cancers (72/98, 73.5 %) and 26 in situ cancers (26/98, 26.5 %). Fifty-six invasive cancers were detected with both techniques, one cancer was detected only at double 2D compared with 15 detected

Table 3 Cancer detection and recall rates according to individual radiologists

Readers		Mammography		Tomosynthesis		p
		N°	%	N°	%	
Reader 1	Recalls/readings	248/7,631	3.2	229/6,567	3.5	0.434
	Detected cancers/readings	31/7,631	0.4	37/6,567	0.5	0.176
	Detected cancers/total cancers (s)	31/48	64′6	37/42	88′1	0.010
Reader 2	Recalls/readings	103/2,857	3.6	131/5,807	2.2	<0.001
	Detected cancers/readings	12/2,857	0.4	27/5,807	0.5	0.769
	Detected cancers/total cancers (s)	12/24	50.0	27/32	88.4	0.006
Reader 3	Recalls/readings	167/6,985	2.4	131/6,812	1.9	0.059
	Detected cancers/readings	25/6,985	0.3	38/6,812	0.5	0.082
	Detected cancers/total cancers (s)	25/40	62.5	38/40	95.0	<0.001
Reader 4	Recalls/readings	249/6,781	3.7	238/6,973	3.4	0.411
	Detected cancers/readings	21/6781	0.3	45/6,973	0.6	0.004
	Detected cancers/total cancers (s)	21/32	65.6	45/53	84.9	0.039
Reader 5	Recalls/readings	288/7,895	3.6	173/5,976	2.9	0.014
	Detected cancers/readings	39/7,895	0.5	22/5,976	0.4	0.267
	Detected cancers/total cancers (s)	39/51	76.5	22/29	75.9	0.951

Chi-squared test and p-values are given

Table 4 Characteristics of cancers detected by 2D mammography and tomosynthesis

Total	Total number of cancers	No. of cancers detected with 2D mammography	No. of cancers detected with tomosynthesis	No. of cancers detected with 2d mammography only	No. of cancers detected with tomosythesis only	P-value
	98	76	92	6	22	0.004
Histological type						
Invasive	72	57	71	1	15	0.001
IDC	68	55	67	1	13	0.001
Grade 1	33	23	33	0	10	0.001
Grade 2	25	23	24	1	2	0.552
Grade 3	10	9	10	0	1	0.305
ILC	4	2	4	0	2	0.102
Grade 1	2	2	2	0	0	1.000
Grade 2	2	0	2	0	2	0.467
In situ	26	19	21	5	7	0.774
Low grade	10	7	7	3	3	0.510
Medium grade	7	5	6	1	2	0.515
High grade	9	7	8	1	2	0.582
Lesion size (mm)						
≤10	26	19	25	1	7	0.021
11–15	16	12	14	2	4	0.365
16–19	14	12	14	0	2	0.142
≥20	42	33	39	3	9	0.061
Breast density						
Fatty	7	6	6	1	1	1.000
Scattered	50	40	47	3	10	0.092
Heterogeneous	39	29	37	2	10	0.039
Extreme	2	1	2	0	1	1.000

Chi-squared test and p-values are given

only at double reading of tomosynthesis. The increase in invasive cancer detection attributable to tomosynthesis was 19.7 % (95 % CI 12.1–30.4, p=0.001). Cancers detected by tomosynthesis were smaller (≤ 10 mm, p=0.021) and of a lower grade at detection. Ten of 15 additional invasive cancers were grade 1, constituting a 66.7% of the total (p=0.001). There was no significant difference in grade 2 or 3 cancer detection and in the detection of in situ cancers between both techniques (p=0.774).

Table 5 shows cancers according to the radiological finding. All cancers presented as a mass or architectural distortion were detected at double reading of tomosynthesis (54/54 and 20/20, respectively) versus the results of double 2D (49/54 and 8/20). This means an increase in detection of 9.3 % of cancers presented as mass (95 % CI 4.0–19.9, p= 0.063) and in 60 % of cancers presented as architectural distortion (95 % CI 38.6–78.1, p<0.01). Detection of calcifications was the same for both techniques (17/21 cancers, 80.9 %).

The mean compressed breast thickness was 62.5 mm ± 12.8. The MGD during 2D mammography and tomosynthesis were 3.27 mGy ± 0.83 and 4.97 mGy ± 1.28, respectively (increase of 34.2 %). The mean interpretation time was 25 s for 2D mammography, 61 s for third reading and 67 s for fourth reading (increase of 59 % and 62.7 %, respectively).

Discussion

This study was performed in a single institution with the participation of 16,067 women, the largest study group in European articles published to date [6, 13–15].

Our study shows methodological differences with respect to the published bibliography. Firstly, we performed double reading of 2D mammography in order to compare tomosynthesis with the standard practice in our screening programme, which is different from the single reading of the study TOMMY [14] and the double reading with the CAD system of Oslo [13]. Four blinded and independent readings for participants prevented the risk of knowing the results of the other techniques, as may happen with the sequential readings

Table 5 Radiological findings according to reading models

Radiological findings		Double 2D	Double 3D	Tomo +C- view (3rd reading)	Tomo + C- view +2D (4th reading)	Overall
Mass	Number	49	54	52	50	54
	% within cancers detected	92.7	100	96.3	92.6	55.1
Architectural distortion	Number	8	20	19	16	20
	% within cancers detected	40.0	100	95.0	80.0	20.4
Calcifications	Number	17	17	15	15	21
	% within cancers detected	80.9	80.9	71.4	71.4	21.4
Asymmetrical density	Number	2	1	1	0	3
	% within cancers detected	66.6	33.3	33.3	0	3.1
Global	Number	76	92	87	81	98
	% within cancers detected	77.5	93.9	88.8	82.6	100

in the study STORM [15]. Secondly, to have the latest version of the reconstruction software of image synthesized has allowed us to assess tomosynthesis plus synthesized mammography as an independent reading versus double 2D. Finally, we were able to evaluate whether adding 2D mammography to tomosynthesis plus synthesized mammography improved the results.

Tomosynthesis plus synthesized mammography (third reading) increased cancer detection significantly compared with double 2D (12.6 %), with an important reduction in recalls (40.5 %) and with an increase in PPV recalls and PPV biopsies. With these outcomes, we think that a single reading of tomosynthesis plus synthesized mammography can be proposed as an alternative to double reading of 2D mammography, a possibility mentioned by Houssami [11].

There were no significant differences in cancer detection or recall rates between tomosynthesis plus synthesized and tomosynthesis plus synthesized plus 2D. We did not observe any improvement when 2D mammography was added to tomosynthesis plus synthesized, which could avoid performing 2D, as also concluded by Skaane [16].

Single reading of tomosynthesis plus synthesized plus 2D (fourth reading) showed a non-significant lower cancer detection than tomosynthesis plus synthesized (6.9 %). We think that this may be due to three main factors. First, synthesized mammography highlights calcifications and architectural distortions improving detection. Second, a greater number of images per study in the fourth reading can produce fatigue for the reader. Finally, our hanging protocol for the fourth reading showed 2D first and, in most cases, the reader obviated the need for looking at the synthesized image.

Double reading of tomosynthesis (third reading + fourth reading) has shown a significant increase in cancer detection of 17.4 % versus double reading of 2D, but lower than the 30–43 % published so far [6, 13]. Also, there was a significant reduction in recalls (12.5 %), similar to Oslo [13] or STORM [15], and a significant increase in PPV recalls (27.7 %) compared with double reading of 2D.

Although most of the additional cancers detected were grade 1, perhaps more important in terms of detection was the significant increase in invasive cancers (19.7 %) without differences among in situ ones. Also, all cancers presented as mass or architectural distortion were detected by tomosynthesis, with a significant increase in detection of architectural distortions versus double 2D (60 %, $p<0.01$). With the use of tomosynthesis, architectural distortions are often seen with greater clarity, including those that may be produced by benign entities, but we have not found significant differences in PPV biopsies between 2D and tomosynthesis.

We also analysed cancer detection stratified by breast density. We found a significant increase in cancer detection in heterogeneously dense breast (21.6 %), which agrees with the data published by McCarthy A., which has an increase of 33 % in dense breast (heterogeneously dense and extremely dense breast) [17].

Tomosynthesis leads to a significant increase in cancer detection and a decrease in recalls in previously screened women. This was not so for baseline-screened women, where there were no significant differences between the two techniques.

The current tomosynthesis plus 2D mammography procedure requires a 40 % greater radiation dose than 2D alone (8.24 mGy tomosynthesis plus 2D vs. 4.97 mGy tomosynthesis). However, tomosynthesis plus synthesized mammography was shown to be better than tomosynthesis plus 2D. Thus, synthesized mammography would replace 2D mammography and avoid the increase in radiation dose.

The interpretation time was significantly longer for tomosynthesis than for 2D mammography. Although there was more than double the interpretation time with tomosynthesis, we think it is acceptable given the significant increase in cancer detection and decrease in recalls. In addition, the implementation of a single reading of tomosynthesis as a screening strategy would reduce this negative effect.

Limitations

Our study had several limitations. Firstly, a breast cancer-screening programme is integrated in our daily practice so we could not completely balance the number of readings performed for each of the readers in the four interpretation models. Secondly, this is a single-institution study, which may prevent a correct extrapolation of the results. Finally, the readers had limited experience in tomosynthesis.

Conclusion

In conclusion, we found that single reading of tomosynthesis plus synthesized mammography resulted in a significant increase in cancer detection and a decrease in recalls compared with double reading of 2D mammography. The outcomes of tomosynthesis did not improve when 2D was available. The evidence we showed warrants rethinking of the single reading of tomosynthesis plus synthesized as a new screening strategy.

Acknowledgements The data manager who performed the data collection was Cristina Amate Rivas.
Funding This study has received funding by SERAM (Sociedad Española de Radiología Médica).

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Sara Romero Martín.

Conflict of interest The authors of this manuscript declare relationships with the following companies: Hologic (Bedford, MA, USA) sponsored the study by providing the breast tomosynthesis equipment.

Statistics and biometry Dra. Pilar Font Ugarte kindly provided statistical advice for this manuscript.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

Methodology
- prospective
- observational
- performed at one institution

References

1. Acebal M, Álvarez M, Bayo E et al (2011). Proceso Asistencial Integrado. Cáncer de mama. Detección precoz de cáncer de mama. 3rd edn. Junta de Andalucía. Consejería de Salud
2. Colditz G, Bohlke K (2014) Priorities for the Primary Prevention of Breast Cancer. CA Cancer J Clin 64:186–194
3. Rodríguez M, Osa AM (2013) Breast cancer screening: current status. Radiologia 55:305–314
4. Conant E (2014) Clinical implementation of digital breast tomosynthesis. Radiol Clin N Am 52:499–518
5. Houssami N (2013) Digital breast tomosynthesis: the future of mammography screening or much ado about nothing? Expert Rev Med Devices 10:583–585
6. Rafferty E, Park J, Philpotts LE et al (2014) Diagnostic Accuracy and recall rates for digital mammography and digital mammography combined with one-view and two-view tomosynthesis: results of an enriched reader study. AJR Am J Roentgenol 202:273–281
7. Lang K, Andersson I, Rosso A, Tingberg A, Timberg P, Zackrisson S (2016) Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmö Breast Tomosynthesis Screening Trial, a population-based study. Eur Radiol 26:184–190
8. Skaane P, Bandos A, Gullen R et al (2013) Prospective trial comparing full-field digital mammography (FFDM) versus combined FFDM and tomosynthesis in a population-based screening programme using independent double reading with arbitration. Eur Radiol 23:2061–2071
9. Feng S, Sechopoulos I (2012) Clinical Digital Breast Tomosynthesis System: Dosimetric Characterization. Radiology 263:35–42
10. Bernardi D, Macaskill P, Pellegrini M et al (2016) Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study. Lancet Oncol 17:1105–1113
11. Houssami N, Macaskill P, Bernardi D et al (2014) Breast screening using 2D-mammography or integrating digital breast tomosynthesis (3D-mammography) for single-reading or double-reading. Evidence to guide future screening strategies. Eur J Cancer 50: 1799–1807
12. D'Orsi CJ, Sickles EA, Mendelson EB et al (2013) ACR BI-RADS Atlas, breast imaging reporting and data system, 5th edn. Am Coll Radiol, Reston
13. Skaane P, Bando A, Gullien R et al (2013) Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. Radiology 267:47–56
14. Gilbert F, Tucker L, Gillan M et al (2015) The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK NHS Breast Screening Programme – a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. Health Technol Assess. https://doi.org/10.3310/hta19040
15. Ciatto S, Houssami N, Bernardi D et al (2013) Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. Lancet Oncol 14:583–589
16. Skaane P, Bandos A, Eben E et al (2014) Two-view digital breast tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images. Radiolgy 271:655–663
17. McCarthy A, Kontos D, Synnestvedt M et al (2014) Screening outcomes following implementation of Digital Breast Tomosynthesis in a General-Population Screening Program. J Natl Cancer Inst. https://doi.org/10.1093/jnci/dju316