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Diagnosing non-palpable breast disease: short-term impact on quality of life of large-core needle biopsy versus open breast biopsy

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Abstract

Background: One of the alleged advantages of stereotactic large-core needle biopsy of non-palpable breast lesions is that it entails less inconvenience for the patient. In this prospective study, the quality of life of patients undergoing large-core needle biopsy was compared with that of patients undergoing open breast biopsy prior to learning the definitive diagnosis.

Methods: Thirty patients with non-palpable breast lesions underwent stereotactic large-core needle biopsy as initial diagnostic procedure (needle biopsy group). Quality of life as perceived by these patients was compared with that of 27 patients who underwent open breast biopsy as initial diagnostic procedure (control group). Both groups completed quality of life questionnaires (EuroQol and SF-36) 1 day before and 4 days after the diagnostic intervention.

Results: One day before the diagnostic procedure, the overall estimate for quality of life (measured with the EuroQol) was slightly higher in the needle biopsy group than in the control group (73 versus 69 resp.). Four days after the diagnostic procedure, the quality of life score remained approximately unchanged in the needle biopsy group, but was reduced in the control group (71 versus 61 resp.). Results of the SF-36 questionnaire demonstrated that patients in the needle biopsy group had higher quality of life scores on physical functioning, physical performance, pain and social performance after the diagnostic intervention.

Conclusion: Stereotactic large-core needle biopsy seems to affect quality of life to a lesser extent than open breast biopsy. This difference is mainly attributable to a reduction of physical discomfort and pain.

Keywords: Breast neoplasms; Breast biopsy; Biopsy; Needle; Diagnosis; Breast diseases; Quality of life

1. Introduction

Advantages of stereotactic large-core needle biopsy for non-palpable breast disease are reduction of open biopsies for benign disease, lower costs and reduction of surgical procedures for non-palpable breast cancer [1–4]. Another alleged advantage is that patients undergoing large-core needle biopsy experience less physical inconvenience, leading to better quality of life during the diagnostic period. However, to our knowledge, no studies have ever been conducted to substantiate this hypothesis.

We set out to assess the quality of life of patients undergoing stereotactic large-core needle biopsy for non-palpable breast disease and compare it to the quality of life of patients undergoing needle localised open breast biopsy, prior to learning the definite histological diagnosis.

2. Patients and methods

This study is part of the multi-institutional COBRA study (COre Biopsy after RAdiological localisation),

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which has been described elsewhere [5]. Briefly, the aim of the COBRA study was to assess the diagnostic accuracy and cost-effectiveness of stereotactic large-core needle biopsy compared to that of open breast biopsy for the diagnosis of non-palpable breast disease. The study was executed according to the Helsinki Declaration. The Dutch National Insurance Council and all local Institutional Review Boards approved the study protocol. Between April 1997 and February 2000, 826 consecutive patients with 871 non-palpable breast lesions underwent stereotactic large-core needle biopsy, after having given informed consent. Patients were referred from 19 hospitals to undergo stereotactic large-core needle biopsy in one of five centres (University Medical Center Utrecht, Antoni van Leeuwenhoek Hospital Amsterdam, Dr Daniel den Hoed Clinic Rotterdam, Bosch Medicentrum Den Bosch and Martini Hospital Groningen). Biopsies were performed according to a standardised protocol using prone biopsy tables (Fisher Imaging Denver and Lorad Stereoguide Danbury) and a 14-gauge core needle long throw (2.2 cm excursion) automated biopsy device (C.R. Bard Inc., Covington, Ga). Per lesion, at least five needle biopsy specimens were obtained. Based on the large-core needle biopsy diagnosis, further diagnostic or therapeutic strategy was planned. If large-core needle biopsy revealed invasive breast cancer, we performed definitive surgical therapy (breast conserving therapy or mastectomy with axillary dissection or sentinel node biopsy). In case of large-core needle biopsy containing ductal carcinoma in situ (DCIS), breast conserving therapy or mastectomy (in case of extensive DCIS) was executed. According to the study protocol, all patients with a non-malignant large-core needle biopsy result underwent needle localised open breast biopsy.

2.1. Study groups

The quality of life during the diagnostic work up of patients with non-palpable breast lesions was studied in two groups. The needle biopsy group consisted of 30 consecutive patients that were enrolled in the COBRA study between March and June 1999 in Utrecht University Medical Center, Martini Hospital Groningen, Rijnstate Hospital Arnhem and Antoni van Leeuwenhoek Hospital Amsterdam. These patients underwent stereotactic large-core needle biopsy as initial diagnostic procedure for non-palpable breast disease.

The control group consisted of 27 consecutive patients with non-palpable breast disease undergoing needle localised open breast biopsy as initial diagnostic procedure. These patients were included during the same period in the following hospitals: Canicius Hospital Nijmegen, Leyenburg Hospital Den Haag, Antoniushove Hospital Leidschendam and Ruwaard van Putte Hospital Spijkenisse. In these hospitals, needle localised open breast biopsy is used as the initial procedure for the diagnosis of non-palpable breast disease. None of these hospitals participated in the COBRA study. All patients underwent needle localisation at the local department of radiology prior to surgical biopsy. Surgical biopsies were obtained under general anaesthesia.

2.2. Quality of life measurement

Quality of life was measured by means of the EuroQol and the SF-36 quality of life questionnaires. The EuroQol instrument consists of a questionnaire that classifies the patient into one of 243 health states (five dimensions, each with three levels: mobility, self-care, usual activities, pain/discomfort and anxiety/depression). This concise questionnaire generates a single numeric index of health status, i.e. a so-called 'utility' measure, between 0 (worst health) and 100 (optimal health) that enables calculation of 'quality adjusted life years' [6]. The societal value of quality of life is obtained. This societal perspective is the preferred perspective in an economic evaluation of health care. The EuroQol also contains a visual analogue scale (VAS) on which patients rate their own health between 0 and 100. This value represents the patients' perspective and is considered as the clinical perspective of quality of life. The EuroQol generates two overall values (utilities) for the quality of life and is recommended for use in combination with other more detailed generic measures.

The SF-36 is such an instrument [7]. It contains 36 questions that cover the following eight dimensions of health: physical performance, social performance, physical functioning, emotional functioning, vitality, general health, pain and mental functioning. It produces a health profile with scores between 0 and 100 for each dimension. A high score indicates good health status from the patient's perspective.

All patients were asked to complete the EuroQol and the SF-36 questionnaires 1 day before and 4 days after the diagnostic procedure (i.e. large-core needle biopsy or open breast biopsy). The questionnaires were always answered prior to obtaining a final diagnosis with regard to the breast lesion.

2.3. Statistical analysis

We used t-test for comparing continuous variables and χ^2 tests to compare dichotomous variables. To assess comparability of the two groups, the (mean) baseline scores were compared. Differences in impact of diagnostic procedures were assessed by comparing mean difference in score values across groups.

3. Results

The mean age in the needle biopsy group was 57 years and practically similar in the control group (58 years, $p = \text{NS}$). Also, there was no difference in the proportion of malignant (i.e. invasive or in situ) lesions (66% in the needle biopsy group and 65% in the control group).

Quality of life results, measured with the EuroQol questionnaire, are presented in Fig 1. Using societal score values, quality of life was slightly better among patients planned for needle biopsy than among patients planned for open biopsy 1 day before the diagnostic intervention (73 versus 69, respectively, $p = 0.05$). Four days after, the mean score on the EuroQol questionnaire was significantly more reduced in the control group than in the needle biopsy group (61 versus 71 respectively, $p < 0.001$), reflecting a lower quality of life in the control group. A similar trend was observed for quality of life as valued by the patients themselves using the VAS, although the absolute differences were smaller and not significant (Fig. 1).

Quality of life results, subdivided over eight dimensions of the SF-36 are shown in Table 1. One day before the diagnostic procedure, patients in the needle biopsy group had a significantly higher score on physical functioning. On all other domains, quality of life was not significantly different between both groups. Four days after the diagnostic procedures, patients in the needle biopsy group had higher quality of life scores for physical performance, social performance, physical functioning and pain. In Fig. 2 the differences in quality of life scores before and after the diagnostic procedure for all domains are presented for both groups. The large-core needle biopsy procedure had less negative impact on quality of life scores on physical performance, social performance, physical functioning and pain than the open breast biopsy. Both diagnostic procedures had approximately the same impact on the emotional and mental functioning, the general health state and vitality.

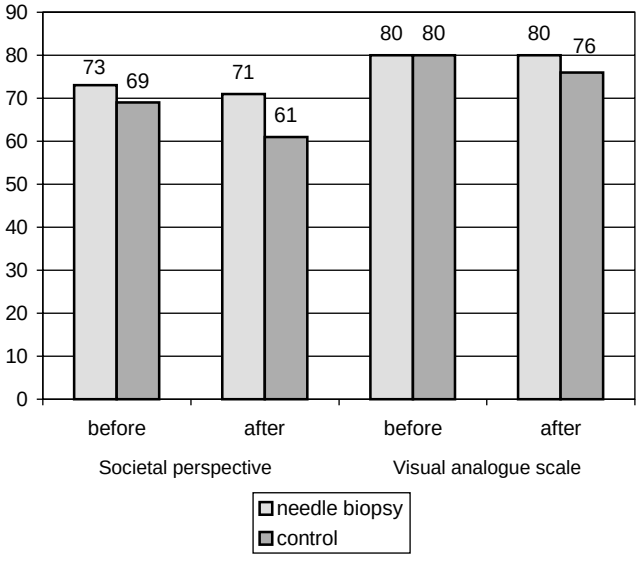

Fig. 1. Mean values of EuroQol score 1 day before and 4 days after large-core needle biopsy or open breast biopsy.

4. Discussion

This study was conducted to evaluate the impact of the diagnostic intervention on the quality of life perceived by patients with impalpable breast disease who are still ignorant of the ultimate histological diagnosis. As expected, stereotactic large-core needle biopsy affected quality of life to a lesser extent than needle localised open breast biopsy.

Quality of life scores, measured 1 day before the diagnostic procedures, were comparable to the quality of life scores of the healthy population, which has scores ranging from 71 (general) to 84 (social functioning) [7]. This can be explained by the fact that non-palpable breast lesions are generally detected by screening mammography performed in predominantly healthy women.

For open breast biopsy, an operation under general anaesthesia is required, while for large-core needle

Table 1
SF-36 scores 1 day before and 4 days after the diagnostic procedure

	Before			After		
	Needle biopsy group	Control group	p	Needle biopsy group	Control group	p
Physical performance	86.7	77.1	NS	85.3	66.3	<0.001
Social performance	78.3	75.0	NS	78.3	65.5	0.04
Physical functioning	96.7	75.0	0.003	81.9	48.0	0.001
Emotional functioning	65.5	65.2	NS	54.4	53.3	NS
Vitality	69.8	66.8	NS	65.4	58.3	NS
General health	63.7	68.6	NS	65.9	68.8	NS
Pain	93.1	87.8	NS	86.9	70.6	0.006
Mental functioning	68.6	65.8	NS	66.2	62.8	NS

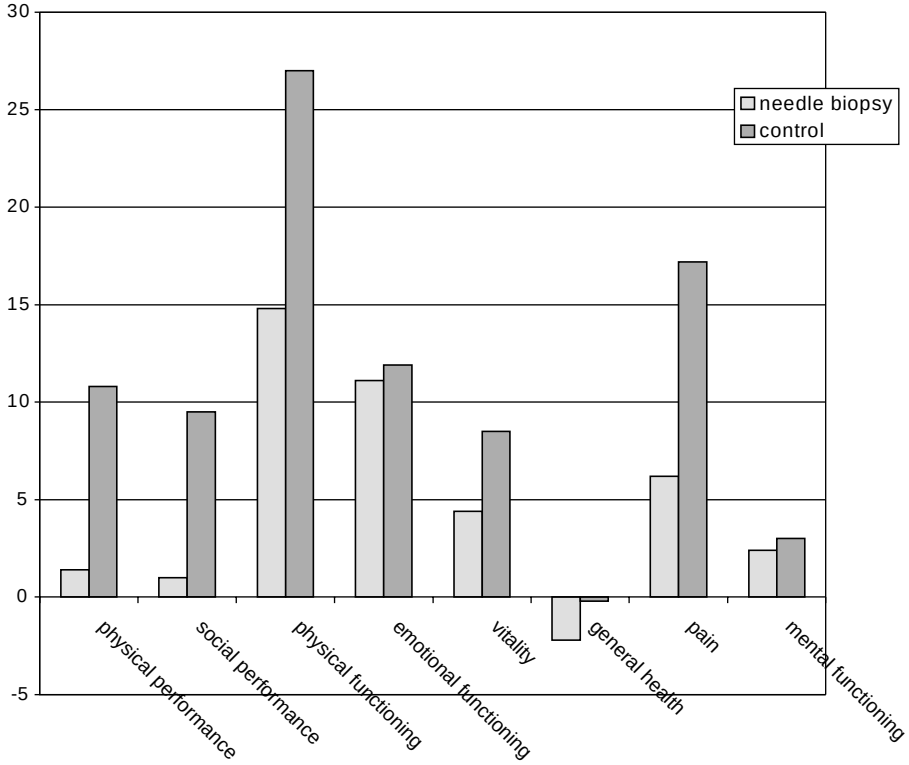

Fig. 2. Differences in quality of life scores on the SF-36 domains between 1 day before and 4 days after large-core needle biopsy or open breast biopsy.

biopsy only local anaesthesia and a minimal incision are necessary. It is therefore understandable that the latter procedure causes less physical problems. In concordance with this presumption, higher quality of life scores for physical performance (profession, housework), physical functioning (walking stairs, running), pain and social performance (visiting family and friends, perform social activities) were observed in the group undergoing large-core needle biopsy.

Conversely, quality of life scores for the emotional and mental domains, vitality and general health were not essentially different between both groups. Obviously, all patients with non-palpable breast disease have to face the fact that there is a considerable chance that they have breast cancer. Apparently, this uncertainty has the same impact on quality of life for the 'non-physical' domains, regardless whether a minimally invasive procedure or an operation is performed.

Patients undergoing large-core needle biopsy had a borderline significantly higher EuroQol (societal perspective) score and a significantly higher SF-36 score on the domain of physical functioning at baseline. We cannot justify this observation, as the mean age and general health status was comparable for both groups. A possible explanation might be that patients who know they will undergo a surgical intervention the day after respond differently than patients who will undergo the surgical procedure somewhat later in the near future.

This baseline difference makes it somewhat difficult to compare SF-36 scores 4 days after the procedure. To circumvent this problem, we used the differences in SF-36 scores at baseline and after 4 days to estimate the impact of the diagnostic procedure on quality of life. We feel this gives a more reliable estimate of the perceived impact of the diagnostic procedure.

We realise that quality of life during the diagnostic period may have very little impact on the quality of life of breast cancer patients in general. On the other hand, approximately 40% of the patients with non-palpable breast disease (requiring histological examination) turn out to have a benign lesion [8]. These patients may experience not only short term benefits (better quality of life during the diagnostic interval) but may also profit of long-term beneficial effects (i.e. large-core needle biopsy gives better cosmetic results). However, as we were not able to observe long-term results in patients undergoing large-core needle biopsy, we can only report on short-term effects.

There will be a number of patients who will not benefit from the introduction of large-core needle biopsy. A small proportion of patients will have a non-diagnostic biopsy result ($<2\%$) or will be diagnosed as 'high risk' (atypical ductal or lobular hyperplasia, lobular carcinoma in situ) ($<5\%$) [5]. In addition, in an unknown proportion of patients there will be discrepancy between mammography and histol-

ogy. These patients need to undergo a second diagnostic intervention, which will interfere with their quality of life. Unfortunately, we were not able to study the effect of this phenomenon in our study.

In conclusion, large-core needle biopsy seems to be perceived as less burdensome than open breast biopsy and might therefore conveniently replace this surgical procedure.

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