

## How distressing is referral to colposcopy in cervical cancer screening? A prospective quality of life study



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### HIGHLIGHTS

- Distress following abnormal Pap test results was assessed prospectively.
- Anxiety – and not the physical burden of management – seemed to be the most bothersome.
- Distress washed out, suggesting reassuring effects of gynecological management.

### ARTICLE INFO

#### Article history:

Received 12 September 2013

Accepted 3 November 2013

Available online 9 November 2013

#### Keywords:

Cervical cancer

Longitudinal

Quality of life

Screening

CIN

Abnormal Pap

### ABSTRACT

**Objective.** Referral for colposcopy because of abnormal Pap test results is likely to be distressing, but the extent and duration of these effects are unknown. We aimed to fill this gap.

**Methods.** We conducted a prospective observational study at two departments of Obstetrics and Gynecology (an academic and a non-academic setting). Women referred for colposcopy completed questionnaires before colposcopy, and at 1, 3, and 6 months afterwards. A reference group of 706 screen participants, aged 29–60 years old, was included and completed questionnaires once. Main outcome measures were generic health-related quality of life (HRQoL), assessed through the EQ-5D and the SF-12 physical and mental scores (PCS-12 and MCS-12); anxiety as assessed by STAI-6, and screen-specific anxiety as assessed by the psychological consequences questionnaire (PCQ).

**Results.** 154 women responded to the questionnaire, of whom 132 were included in the analyses. Histological results were CIN 1 in 17/115 women (15%) and CIN 2+ in 62 (54%). In 36 women (31%) there was no histologically confirmed neoplasia. Before colposcopy physical HRQoL scores were similar or slightly better than in the reference group, while mental HRQoL (MCS-12) and (screen-specific) anxiety were worse ( $p < 0.001$ ). Irrespective of CIN-grades, anxiety washed out during follow-up ( $p < 0.001$ ), with changes being clinically relevant.

**Conclusions.** Referral for gynecological evaluation because of abnormal PAP-test results was distressing. Anxiety – and not the physical burden of management – seemed to be the most bothersome to women. For all CIN-grades, distress disappeared over six months following colposcopy, suggesting a reassuring effect of gynecological management.

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### Introduction

Screening for cervical cancer aims to reduce disease-specific mortality by early detection and treatment of pre-invasive (cervical intraepithelial neoplasia, CIN) or early invasive disease. Screen participants with abnormal Pap tests are generally referred for gynecological evaluation including colposcopy. Previous studies found that colposcopy

was stressful for most women [1]. Not the procedure itself but the prospect of having cancer and risk of dying were the biggest sources of distress [2].

Cervical cancer screening is aimed at preventing the disease by finding and treating precursor lesions, but these precursors are known to often regress [3]. The number of treated precursors will thus be considerably larger than the number of prevented cases of cervical cancer. Screening policy thus requires balancing the benefits of preventing cancer by treatment of lesions that are likely to resolve against the harms of screening. Distress and anxiety due to screening are such harms. Until 2004 there had been little research on how short-term effects of screening

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interventions affect quality of life [4]. While roughly half of the adult women in Europe are invited to have a smear test at least once every 5 years, of whom between 0.8 and 4.4% are referred to colposcopy every screening round [5], the extent and duration of adverse quality of life effects after abnormal Pap test results are still unknown.

We aimed to prospectively assess the effects of colposcopy referral on women's generic health-related quality of life (HRQoL) and on (screen-specific) anxiety levels. A female reference group of screen participants was included as a proxy of HRQoL levels preceding referral. We compared HRQoL and anxiety outcomes of the study group, referred to as 'colposcopy group', to those of the reference group.

## Methods

### Cervical cancer screening in the Netherlands

In the Dutch national cervical cancer screening program, women aged 30–60 are invited once every 5 years to have a Pap test. Participation does not entail costs. At the time this study was conducted, the national uptake rate was 65% [6], and neither primary HPV screening nor HPV vaccination had been introduced. In 2009, 96.7% of women who participated had normal cytological smear results and in 1% Pap tests were of inadequate quality requiring repeat smears. High-grade cytological abnormalities, including moderately dyskaryotic (Pap 3a2 [7]) or worse, were found in 0.5% to 0.7% and low grade abnormalities, including borderline or mildly dyskaryotic (Pap 2/3a1) smear results, were found in 1.8% of screen participants [6–8].

Women can be referred to gynecological evaluation through two different routes. Following the screening protocol women whose smear results are moderately dyskaryotic (Pap 3a2) or worse are immediately referred for colposcopy by a gynecologist. Women with borderline or mild dyskaryotic smear results (Pap2/3a1) are advised to have triage smears made by their GP [7]. If these are once again abnormal women are also referred for colposcopy.

If histology results of biopsies taken at colposcopy indicate CIN-grade 2 or worse further treatment is performed. A more conservative approach is recommended for women diagnosed with CIN 1 since the

majority of these lesions will regress. After two or three consecutive negative smears women with CIN 1 will return to the national screening program.

### Study design

Between February 2006 and April 2008 a prospective longitudinal cohort study was conducted in two Dutch hospitals. We aimed at including all women who were referred for gynecological evaluation because of abnormal Pap test results in the screening program. Women whose patient files later showed that they were ineligible were excluded (see Fig. 1.)

Women scheduled for colposcopy after abnormal smear results were sent a letter, in which they were asked for written informed consent to participate in the study, which involved completion of the attached questionnaire (see below), and 3 following ones after 1, 3 and 6 months (return envelopes were provided). Women were also asked for permission to consult their patient files and/or the gynecologist for clinical data about colposcopy follow-up. They were assured that not completing the questionnaires would not have any consequences for their medical care. No reminders were sent after the initial questionnaire. Once women had consented in participation in the study we sent reminders for follow-up questionnaires. A group of screen participants was included as a reference (see below). Both groups were 29–60 years old.

This study was part of a comprehensive evaluation of the Dutch cervical cancer-screening program. The medical ethics review committees of the Erasmus University Medical Center Rotterdam (MEC-2004-099) and the Medical Center Alkmaar (M04-051) approved the research protocol.

### Respondents' characteristics

Questions on education, employment, marital status, and having children or not were part of the initial questionnaire. Educational level was classified as low (primary school or lower technical education), intermediate or high (college/university degree).

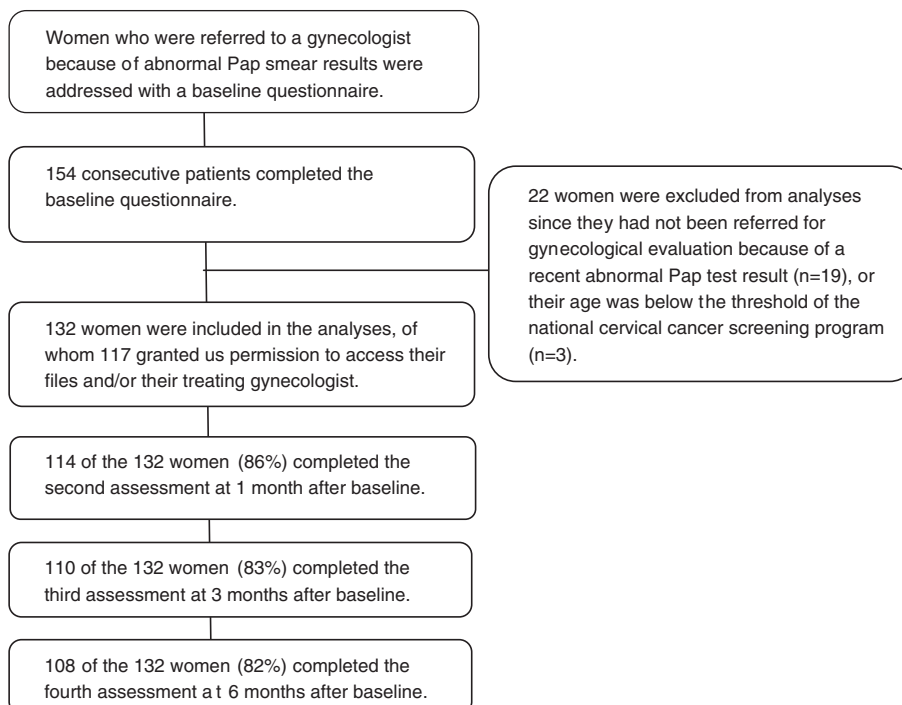


Fig. 1. Flowchart of study population.

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