Chapter 8

Is it too early to move to full electronic PROM data collection?

A randomized clinical trial comparing PROM’s after hallux valgus captured by e-mail, traditional mail and telephone.

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ABSTRACT

Background: Patient reported outcome measures (PROM’s) after hallux valgus surgery are used to rate the effectiveness as perceived by the patient. The interpretability of these PROM’s is highly dependent on participation rate. Data capture method may be an important factor contributing to the response rate. We investigated the effect on response rate of traditional paper mail, telephone and e-mail PROM’s after hallux valgus surgery.

Methods: All consecutive patients operated between January and September 2013, were identified. Included patients were randomized by envelope in three groups: traditional pen and paper mail, e-mail and telephone. They were asked to fill in a FFI and EQ-5D. Two weeks later non-responders were sent a reminder.

Results: Of the 73 included patients, 25 were approached by mail, 24 by e-mail and 24 patients by telephone. The response rate on traditional mail was highest (88%), while response on e-mail was lowest (33%). Response rate on telephone was also high (79%). Response rate on traditional mail and telephone was significantly higher ($p < 0.001$) than response on e-mail.

Conclusions: Though electronic data collection has enormous potential, this study shows that e-mail yields unacceptable low response rates. It is too early to replace traditional pen-and-paper PROM’s by electronic questionnaires.
1. INTRODUCTION

Patient reported outcome measures (PROM's) collect information on the effectiveness of care as perceived by the patients and are critical to assess whether surgery really improves the health of patients. Patients are usually invited to complete standardized PROM’s before surgery and at regular times postoperatively. The success of conducting a survey depends on the participation rate. A suboptimal participation rate gives rise to a possible selection bias and decreases the validity and interpretability of PROM’s considerably [1,2]. Previous studies identified multiple patient characteristics associated with non-response: a language barrier, substance abuse, cognitive limitations, psychiatric diagnosis, sight deficiency, low socioeconomic status, non-white patients and patients living alone [3–5].

Data capture method may be an important factor contributing to the response rate, and various distinct methods for contacting patients are in use. Typical capture methods of PROMs include contacting patients by telephone, by e-mail, by traditional paper mail or through an appointment in the outpatient clinic.

Possible advantages of web-based PROMs are numerous: faster response, efficient data collection and management, and cost-efficiency. However, literature comparing response rate of different capture methods is scarce and current available evidence is inconclusive.

Older studies, in non-orthopedic patient groups, showed equivalent scores in pen-and-paper and computerized PROMS [6] or higher response rates in traditional pen-and-paper methods [7,8]. More recent non-orthopedic studies confirm this [9,10]. A meta-analysis by Shih [11] in 2009 described 35 studies, performed between 1992 and 2006 in all kind of scientific fields, that directly compared the response rates of traditional mail versus e-mail surveys. Shih concluded that mail survey was still superior to e-mail survey with higher response rate.

In orthopedic studies, data capture methods are compared in patient groups needing joint replacement surgery. Gakhar [12] reported no difference in response between electronic capture methods and pen-and-paper methods, while Rolfson [13] found a higher response rate on traditional pen-and-paper PROM’s. Schamber [5] found that a switch from paper surveys to electronic capture methods resulted in a significant increase in PROM participation rate.

Few studies compared obtaining PROM’s by telephone with other capture methods. Harris [14] compared mailed surveys and telephone interviews. He found a higher response in the telephone group and reported less missing data. Harewood [15] found a slightly higher response rate when comparing telephone with e-mail, but his study also shows that e-mail was the most cost-efficient. A recent study by Nota [16] compared mail, e-mail and telephone in terms of response rate in younger orthopedic patients after hand surgery. Nota found the highest response rate in the group of people that were interviewed by telephone; response on e-mail was lowest.

Other studies only used telephone contact as a reminder to patients that did not respond initially [17] or to identify the reason for non-response [12].
We focused on the use of PROM’s in patients after hallux valgus surgery. Standardized evaluation with PROM’s will help to compare different surgical techniques and help to improve patient satisfaction. Response rates in patients receiving hallux valgus surgery may differ from orthopedic patients requiring joint replacement, since patients are typically younger and the operation is less invasive, and have not been investigated before.

In this study we aim to investigate the effect of three different data capture methods on the response to PROM’s used after hallux valgus surgery: traditional pen-and-paper mail, electronic mail (e-mail) and telephone.

As the population of patients receiving hallux valgus surgery is younger compared to those requiring joint replacement, we hypothesize that e-mailed questionnaires will yield the highest rates of response.

2. PATIENTS AND METHODS

2.1. Setting

The study was conducted at the Canisius Wilhelmina Hospital, a 653 bed public hospital located in Nijmegen, The Netherlands.

2.2. Design

All patients receiving hallux valgus corrective surgery between the 1st of January 2013 and the 1st of September 2013 were identified using the hospital’s electronic patient database. Exclusion criteria were people without an e-mail address, age under 16, age above 75 years, a language barrier and inability to reach by phone for collection of the e-mail address after three attempts. Socioeconomic status, comorbidities and complications after surgery were not exclusion criteria.

Patients were contacted by phone by one of three investigators in October 2013 to collect their e-mail addresses. An e-mail in which the purpose of the study was explained, was sent to all patients on in December, 2013. The included patients were randomized by envelope via www.randomisation.com into three groups: (1) traditional pen and paper mail (mail), (2) electronic mail (e-mail) and (3) telephone. These data were recorded in non-transparent envelopes (SNOSE) [18]. The allocation sequence was concealed to the investigators. All patients were asked to fill in the validated Dutch version of the Foot Function Index (FFI) and the EQ-5D health questionnaire. The Foot Function Index (FFI) is a widely applied score, which was developed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction [19,20]. It consists of twenty-three items in three subscales, with a maximum of 100 points. The EQ-5D is a standardized and validated questionnaire, with five subscales (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). It contains a numeric rating scale on general health status [21]. Patients approached by mail
received an envelope containing a cover letter explaining the purpose of the study, the two PROM-questionnaires and a business-reply envelope. The envelopes were posted in December 2013. Two weeks later we sent non-responders a reminder with a new reply envelope. Patients approached electronically received an e-mail in December 2013 in which the purpose of the study was explained with the PROM questionnaires attached. After two weeks a reminder was sent, if necessary. The third group of patients was approached by telephone. The purpose of the phone call was explained and the patients were asked if they would participate. When the patient agreed in taking part, he or she was asked to answer the questions of the PROM questionnaires. The answers were digitalized by the investigator. A maximum of four attempts to reach the patient was made.

Primary outcome measure was response rate. The statistical significance between the participation rate in the three groups was analyzed with a one-way ANOVA by one the investigators.

3. RESULTS

We included 73 patients, see Fig. 1 for a CONSORT flow diagram of the present study. After randomization 25 patients were approached by mail, 24 patients by e-mail and 24 patients by telephone. There was no significant difference between groups with respect to age or PROM score, see Table 1. Twenty-two of 25 patients who were approached by traditional mail sent back the PROM-questionnaires in the reply envelope. A total of six patients did this after receiving a reminder. Nineteen of 24 patients, contacted by telephone, were willing to answer
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The PROM questionnaires. A total of three patients refused to participate in this study, and two patients did not answer the phone after four attempts. A total of eight patients, who were approached by e-mail, returned the PROM-questionnaires, of whom three did this after receiving the reminder e-mail. One of these eight patients had difficulty with her computer and came to the hospital to ask for a paper version to fill in. She sent this paper version to us by mail. See Table 2 for an overview of response rates. Response on traditional pen-and-paper mail \((p < 0.001)\) and telephone \((p < 0.000)\) was significantly higher than response on e-mail. The difference between response on traditional mail and response on telephone was not significant \((p = 0.414)\). The response rates were not influenced by the variables age and gender.

<table>
<thead>
<tr>
<th>Capture method</th>
<th>Participation</th>
<th>Participation percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>19 (24)</td>
<td>79</td>
</tr>
<tr>
<td>Mail</td>
<td>22 (25)</td>
<td>88</td>
</tr>
<tr>
<td>E-mail</td>
<td>8 (24)</td>
<td>33.3</td>
</tr>
</tbody>
</table>

### Table 1. Patient age and PROM scores in the three capture method groups.

<table>
<thead>
<tr>
<th>Capture method</th>
<th>Mean age (years)</th>
<th>Score FFI</th>
<th>Score EQ-5D</th>
<th>EQ VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mail</td>
<td>52.12 (range 17–71)</td>
<td>28.3</td>
<td>6.09</td>
<td>80</td>
</tr>
<tr>
<td>E-mail</td>
<td>50.21 (range 16–73)</td>
<td>26.6</td>
<td>6.0</td>
<td>86.3</td>
</tr>
<tr>
<td>Telephone</td>
<td>49.38 (range 17–73)</td>
<td>21.7</td>
<td>6.05</td>
<td>83</td>
</tr>
</tbody>
</table>

### 4. DISCUSSION

This study shows that the response rate on mailed PROM questionnaires is highest (88%), while the response of patients who received the questionnaires by e-mail was lowest (33.3%) in patients receiving hallux valgus surgery. The response rate by telephone is relatively high with 79% response. The other variables (age and gender) did not influence the response rate in this study. Although our results are similar to those in older studies [22–24], we were surprised by low response rate by e-mail. Most previous studies were performed in the 1990s, and the use of internet has improved since [25].

A high response rate is crucial for correct evaluation of PROMs because missing data are not random [26]. Results in a study performed by Iman showed that dissatisfied patients were less likely to respond to questionnaires, which suggest that there may be an over-representation of satisfied patients [27]. There is no satisfactory statistical solution to deal with missing data that may not be at random. Moreover, statistical power is stronger with higher response rates [27]. As a rule of thumb, a loss to follow-up of more than 20% probably leads to assessment bias [28,29]. However, a low response rate does not simply mean that the data are inaccurate, they
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may also be less reliable. Prior research showed that a response rate of 20% in some settings may yield the reliability of the data [30,31].

So why do e-mailed questionnaires yield lower response rates than the traditional on paper questionnaires, even with rapidly growing internet demographics?

There are a number of plausible explanations put forward by Palmblad et al. [32]. First, electronic data collection is not suitable for all types of patients. Patient populations might vary in physical and mental health status, age and experience with technology. Secondly, e-mails do not have a physical form and therefore do not physically show up on the patients desk. This makes it less likely for e-mail to receive the patients full attention. Nowadays people receive large numbers of e-mails, which makes a survey e-mail less high-profile, so it can be discarded easily. An additional problem is that e-mail is not always anonymized, which could influence response rate. In our study we asked the patients to fill in their name and date of birth on the paper version of the surveys, but nine patients sent back the surveys anonymously. This could indicate that patients prefer responding to PROM's anonymously. This is surprising, because this prevents the care provider to act upon a bad PROM outcome score.

Electronic surveys do provide a faster reaction time than traditional on paper surveys. Yun [22] collected over 80% of the e-mail responses in his investigation within three days after the initial contact; most responses were received on the day the initial e-mail was sent. Multiple contacts improve response rates, and it is advisable to send a second e-mail one or two weeks after the initial e-mail as a reminder.

This study has its limitations. There was a significant difference between groups in male-female ratio, which might harm the validity of our findings. However, previous authors showed that gender is not associated with non-response to PROM's [4,5]. The included patients represented a narrow range of ethnicities and socioeconomic status. This might limit the generalizability of the study and the results might not be applicable to patients with a language barrier, substance abuse, sight deficiency or psychiatric diagnosis. Another limitation is that our study size is relatively small. We did not perform a power study prior to the start of our study. A greater number of included patients may have improved the robustness of the study. The magnitude of the effect size is such that a larger study probably would not alter the results of the study. In our view, future research should focus on improved ways of electronic data collection in order to facilitate electronic data collection. Perhaps the use of a shorter PROM might facilitate the use of electronic capture methods especially if the participant use handheld devices.

Better ways of data collection are essential for improving quality of care, and this is critical in surgeries like hallux valgus corrective surgery. Although electronic data collection has enormous potential for collecting PROMs, a major drawback of e-mail is its non-physical form which causes patients to discard it. New methods of electronic data collection should have an easy response design, to facilitate a swift response and improve response rates. Roberts et al. [33] showed in a pilot study that the combination of an SMS reminder and access to a
Wi-Fi enabled tablet computer in the clinic setting enabled 94% of elective orthopedic patients to complete a PROM. To our knowledge, there are no studies that compare response rate in web-based PROM's versus e-mailed PROM's.

The current low response rate of PROMs using e-mail in patients receiving hallux valgus surgery suggests that it is too early to replace traditional pen-and-paper PROM's by electronic questionnaires.

Disclosure

Each author has participated in the writing of the manuscript, and assumes full responsibility for the content of the manuscript. There are no conflicts of interest. No funds were received in support of this study.
REFERENCES


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