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ORIGINAL ARTICLE

# Experience with the PINQ-PHONE telephone questionnaire for detection of recurrences after endoscopic inguinal hernia repair

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## Abstract

**Purpose** The PINQ-PHONE is a 4-question telephone questionnaire designed and validated as a recurrence detection method after laparo-endoscopic inguinal hernia repair. The study aim was to evaluate the PINQ-PHONE by describing our experience with the questionnaire in a high-volume randomized-controlled trial.

**Methods** The PINQ-PHONE was performed 5 years postoperatively after endoscopic totally extraperitoneal (TEP) repair. Positive PINQ-PHONE responses were compared with clinical assessments for a recurrence. An "experience with the PINQ-PHONE"-survey was conducted among the executing researchers. Furthermore, positive predictive values (PPV) for the separate questions and overall PINQ-PHONE were determined.

**Results** Fifty-two of 769 responding patients (6.8%) had positive PINQ-PHONE responses and were invited to visit the outpatient clinic, thus preventing follow-up visits in 93.2% of included patients. Two recurrences were detected (0.3%). The overall PPV of the PINQ-PHONE was low (0.057). The PPV of question 1 (0.040) and 2 (0.100) was lower than that of question 3 (0.222) and 4 (0.286). The PPV of only question 3 and 4 combined was 0.183, and no recurrence would have been missed. The researcher survey unanimously produced that the PINQ-PHONE was user-friendly and executed in $<5$ min, and questions 3 and 4 were considered adequate for recurrence detection. The majority found questions 1 and 2 to be inadequate questions.

**Conclusions** The PINQ-PHONE proved to be a valuable tool in TEP repair follow-up for recurrences. Enhancement of the PINQ-PHONE using only question 3 and 4 is recommended, since more patients refrain from outpatient clinic visits, and nevertheless, recurrences are safely detected.

**Keywords** PINQ-PHONE · Experience · Follow-up · Recurrences · Inguinal hernia · TEP

## Introduction

The quality of inguinal hernia surgery is predominantly determined by chronic groin pain, recurrences, and patient satisfaction [1]. Investigating recurrence rates is only valuable if follow-up is at least 2 years after inguinal hernia surgery [2]. Many have stated that, for an adequate measurement of recurrence rates, all patients need to be routinely examined at the outpatient clinic by a hernia surgeon [3, 4]. This method of follow-up is time-consuming, expensive, and patient unfriendly.

In 2014, a telephone questionnaire was designed and validated as a method of follow-up for the detection of recurrences after laparo-endoscopic inguinal hernia repair; the Post-INguinal-repair-Questionnaire by telephone (PINQ-PHONE) [5]. In its validation study, the PINQ-PHONE proved to be a reliable, practical, and simple method of follow-up.

To our knowledge, the PINQ-PHONE has not been used for any clinical studies after it was validated. Therefore, the aim of this study was to evaluate the PINQ-PHONE by describing our experience with the questionnaire in a high-volume randomized-controlled trial (RCT) with 5-year follow-up after endoscopic totally extraperitoneal (TEP) inguinal hernia repair.

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## Materials and methods

### Design

Five-year follow-up by means of the PINQ-PHONE in a double-blind RCT (TULP-trial) comparing lightweight and heavyweight mesh in patients that underwent endoscopic TEP inguinal hernia repair was previously conducted [2]. The study was carried out in a high-volume hospital with extensive experience in the endoscopic TEP hernia repair technique (Hernia Clinic Diakonessenhuis Utrecht/Zeist). Patient enrollment commenced in March 2010 and ended in October 2012. Patient inclusion and exclusion criteria were published previously [2, 6, 7]. At the start of the trial, 949 patients were included and TEP inguinal hernia repairs were performed by hernia surgeons who completed the learning curve (> 500 procedures). The primary outcomes were development of (chronic) pain and recurrences. In this study, all patients were assessed in whom a 5-year follow-up for recurrences by means of the PINQ-PHONE was completed. Attempts to reach patients for 5-year follow-up were made by five independent researchers between August 2016 and April 2017. The trial was approved by the regional Medical Ethics Committee (VCMO, Nieuwegein, The Netherlands) and the local ethics board of the Hospital.

### PINQ-PHONE

The PINQ-PHONE includes the following four elements: three questions concerning the operated groin of the patient and instructions for a Valsalva maneuver performed by the patient on the operated groin (Fig. 1). If all four questions are answered negatively, a recurrence can reliably be excluded [5]. If one or more of the four questions is answered positively, the PINQ-PHONE is scored positive and the patient should be invited for clinical assessment of a possible recurrent inguinal hernia.

Patients with a positive PINQ-PHONE were invited for consultation and examination by an experienced hernia surgeon at the outpatient clinic. The outcomes of the PINQ-PHONE questionnaire were compared with the clinical assessment for a recurrence. A recurrence was defined as a symptomatic or asymptomatic bulge or weakness in the abdominal wall of the operated groin with herniation of abdominal contents exacerbated by the Valsalva maneuver. In case of complaints without clear findings of an inguinal hernia on physical examination, imaging was offered [X-ray of the pelvis and/or ultrasonography and/or magnetic resonance imaging (MRI) of the groin].

A survey in Dutch on the practicality and ease of use of the questionnaire was conducted independent from each other among the five researchers who executed the PINQ-PHONE in the TULP-trial. The survey consisted of questions regarding the average time for execution and the experience of the researcher with the overall questionnaire and the separate questions (Fig. 2). Furthermore, the positive predictive value (PPV) for each separate question of the PINQ-PHONE, and subsequently for the overall questionnaire, was determined.

### Statistical analysis

Analyses were performed using SPSS statistical software, version 24 (IBM Corp, Armonk, NY, USA). Descriptive statistics were used for baseline data.

## Results

At 5-year follow-up, execution of the PINQ-PHONE was attempted in 875 patients and completed in 769 patients (87.9%) (Fig. 3). The 5-year study population had a median age of 55 years (IQR 44–64) (Table 1). Fifty-two patients (6.8%) responded positively to one or more of the four questions, and were invited to visit the outpatient clinic. Thirty-five of the positive respondents were examined for a clinical recurrent inguinal hernia. Seventeen positive respondents were not scheduled for assessment.

### Experience of the researchers with the PINQ-PHONE

All five independent researchers (R1 until R5) completed the survey. Three out of five researchers executed the questionnaire (entire phone call) in 0–3 min and two researchers in 3–5 min on average. It was unanimously agreed that overall the questionnaire is a user-friendly method of follow-up.

**Fig. 1** PINQ-PHONE questionnaire

1. Do you have any symptoms at your operated groin?
2. Have you noticed anything at your operated groin?
3. Have you noticed something at the operated groin when coughing, sneezing or squeezing?
4. Could you please stand up and put your other hand flat in your operated groin. Now please put the phone down and put this hand to your mouth and blow. Do you feel something in your operated groin?

Q1: How long on average did it take you to execute the PINQ-PHONE questionnaire?
A: 0-3 minutes B: 3-5 minutes C: 5-7 minutes D: 7-10 minutes

Q2: In general, did you think of the PINQ-PHONE as a user-friendly questionnaire?
A: Yes B: No If 'No', why not? *Free text.*

Q3: With respect to detecting an inguinal hernia recurrence, do you think question 1 of the PINQ-PHONE is an adequate question? A: Yes B: No If 'No', why not? *Free text.*

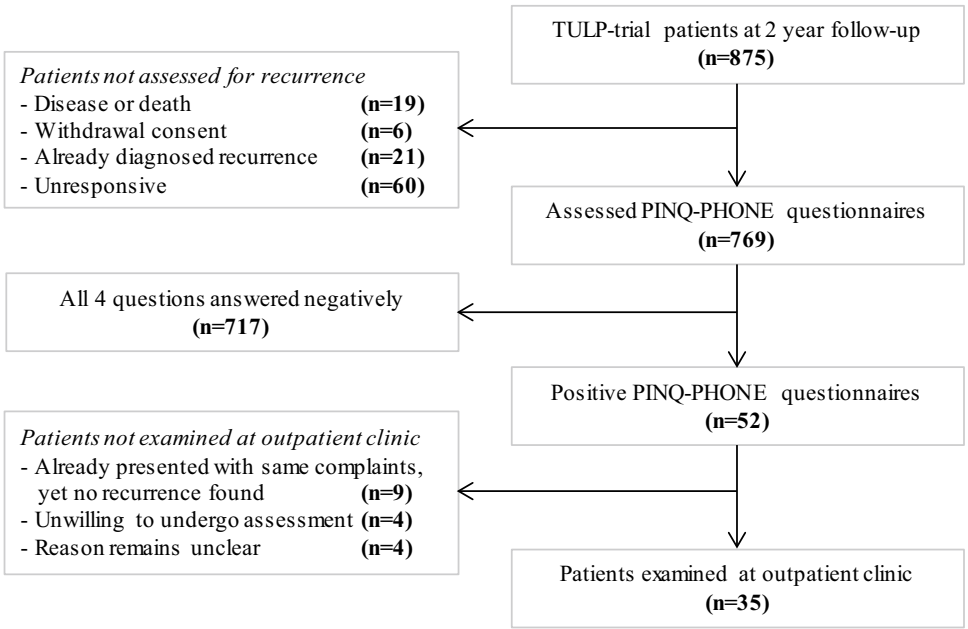
Q4: With respect to detecting an inguinal hernia recurrence, do you think question 2 of the PINQ-PHONE is an adequate question? A: Yes B: No If 'No', why not? *Free text.*

Q5: With respect to detecting an inguinal hernia recurrence, do you think question 3 of the PINQ-PHONE is an adequate question? A: Yes B: No If 'No', why not? *Free text.*

Q6: With respect to detecting an inguinal hernia recurrence, do you think question 4 of the PINQ-PHONE is an adequate question? A: Yes B: No If 'No', why not? *Free text.*

**Fig. 2** Survey among researchers regarding ease of use of PINQ-PHONE

**Fig. 3** Flowchart




Three researchers did not think of question (Q) 1 as an adequate question for the detection of inguinal hernia recurrences. R1 remarked: "Q1 detects a lot of noise because of the wide range of irrelevant complaints patients address. Nevertheless, it is a better question than question 2". R4 comparably states: "'Any symptoms' is too widely interpretable, resulting in many unnecessary and irrelevant responses". R5 proclaimed: "The word 'symptoms' is a very broad concept. Moreover, if pain symptoms existed after placement of the mesh, the question did not distinguish between a recurrence and chronic pain after surgery".

Four out of five researchers did not think of question 2 as an adequate question. R1 commented: "The concept 'noticed anything' is too vague. If the patient means 'symptoms' Q1 addresses this. If the patient means the only other notion of relevance 'inguinal swelling' or 'complaints with increased intra-abdominal pressure', Q3 or Q4 tackles the notion. This broad concept does not enhance the questionnaire". R3 remarked: "Q1 encompasses the objective of Q2, therefore making Q2 irrelevant. 'No symptoms' probably means 'nothing noticed' and if something is noticed patients will address this in Q1. I often received this as a response from patients, as well". R4 stated: "Q2 is too vague and has no added value, since any of the other three questions will always be answered positively if Q2 is answered positively. Moreover, Q2 makes surgeons unnecessarily see many patients at the outpatient clinic with irrelevant complaints". R5 commented: "'Noticed anything' is too vague, furthermore the question to the utmost extent overlaps with Q1. Many typical 'foreign body feeling' patients, but clearly no recurrence, would respond positively to this question. This question can be left out".

**Table 1** Patient characteristics

| | All patients ($n=769$) | Patients examined at outpatient clinic ($n=35$) |
|---|---|---|
| Age (years), median (IQR) | 55 (44–64) | 53 (43–63) |
| BMI (kg/m$^2$), mean (SD) | 24.8 (2.6) | 25.9 (3.3) |
| Side, *n* (%) | | |
| Left | 336 (43.7) | 14 (40.0) |
| Right | 433 (56.3) | 21 (60.0) |
| Hernia type, *n* (%) | | |
| Medial | 186 (24.2) | 7 (20.0) |
| Lateral | 578 (75.2) | 28 (80.0) |
| Femoral | 4 (0.5) | 0 (0.0) |
| Mesh, *n* (%) | | |
| Ultrapro | 386 (50.2) | 21 (60.0) |
| Prolene | 383 (48.8) | 14 (40.0) |
| Operation time (min), median (IQR) | 19 (15–23) | 20 (16–22) |

*BMI* body mass index, *IQR* inter-quartile range, *SD* standard deviation

**Table 2** Positive PINQ-PHONE results

| | Positive response (%) | Recurrences detected (%) | PPV |
|---|---|---|---|
| Question 1 | 25/35 (71.4) | 1/2 (50.0) | 0.040 |
| Question 2 | 20/35 (57.1) | 2/2 (100) | 0.100 |
| Question 3 | 9/35 (25.7) | 2/2 (100) | 0.222 |
| Question 4 | 7/33 (21.2) | 2/2 (100) | 0.286 |

All researchers agreed that Q3 and Q4 of the PINQ-PHONE were adequate questions for the detection of inguinal hernia recurrences.

## Contribution of separate PINQ-PHONE questions

The first question of the PINQ-PHONE concerning the presence of any symptoms in the operated groin was answered positively in 36 out of 769 patients (4.7%) (Table 2). Of the patients with a positive PINQ-PHONE seen at the outpatient clinic ($n=35$), 71.4% of patients responded positively to the first question (Fig. 4). The second question referring to whether the patient noticed anything in the operated groin was answered positively in 29 patients (3.8%). Of the 35 patients seen at the outpatient clinic 57.1% of patients answered positively to the second question. The third question inquiring whether the patient noticed anything in the operated groin upon moments of sneezing, coughing or squeezing (increased abdominal pressure) was answered positively in nine patients (1.2%). All nine were seen, and thus, the contribution to patients seen at the outpatient clinic was 25.7%. The fourth question contained instructions for the do-it-yourself Valsalva maneuver. Two patients were unwilling to perform the maneuver. Upon self-examination in seven patients (0.9%) something was felt in the operated groin, therefore, accounting for 21.2% of the examined patients.

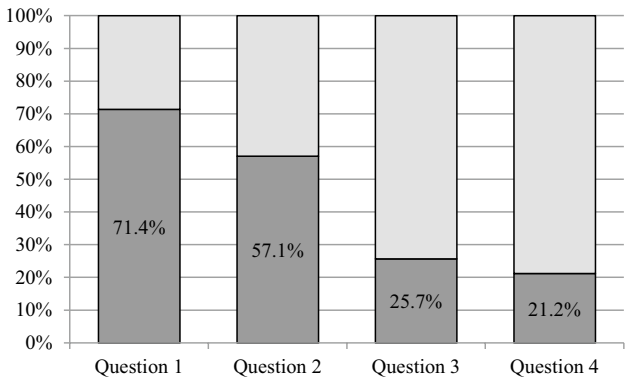



**Fig. 4** Contribution of separate questions to positive PINQ-PHONEs

In two patients (0.3%), an inguinal hernia recurrence was detected on physical examination. In four doubtful cases, an additional imaging was performed, yet no additional recurrences were detected. Both patients were minimally symptomatic; therefore, a watchful waiting approach was decided for and instructions on what to do if symptoms would increase were given. One patient requested surgery 3 months later and a Lichtenstein repair was performed.

Question 1 of the PINQ-PHONE detected one of two inguinal hernia recurrences. Thus, the first question had a PPV of 0.040. Both recurrences were detected in the patients evaluated with a positive second, third, and fourth question. The questions, therefore, had a PPV of 0.100, 0.222, and 0.286, respectively (Table 2).

The overall PPV of the PINQ-PHONE was 0.057.

## Discussion

This study gave a clear insight into the practicality of the PINQ-PHONE by sharing our experience and demonstrating the value of the instrument as a method of follow-up by telephone for inguinal hernia recurrence detection. The PINQ-PHONE proved to be a simple and practical tool in a high-volume RCT with 5 years of follow-up, which prevented unnecessary and time-consuming follow-up visits in 93.2% of included patients [2]. The researcher survey unanimously produced that the PINQ-PHONE was user-friendly and executed in < 5 min. Questions 3 and 4 were considered adequate for recurrence detection; however, the majority of researchers found questions 1 and 2 to be inadequate. Evaluation of the separate PINQ-PHONE questions showed a much lower PPV of question 1 (0.040) and 2 (0.100) compared to the PPV of question 3 (0.222) and 4 (0.286). To our knowledge, this is the first study that performed follow-up using the PINQ-PHONE in a clinical trial since the design and validation of the questionnaire.

We applaud the work done by van den Heuvel et al. in designing and validating the PINQ-PHONE; however, through our experience in a large sample of patients, we see opportunities to enhance the PINQ-PHONE [5]. Pragmatically, we would like to suggest to use only questions 3 and 4 of the questionnaire as they were. The PPV of question 3 and 4 combined is 0.183, and is, therefore, over three times higher than the PPV of 0.057 of the original PINQ-PHONE. Furthermore, only question 3 and 4 would not have missed an inguinal hernia recurrence. Although we realize, in the validation study of the PINQ-PHONE, the negative predictive value was a more decisive outcome, the PPV as an objective outcome does substantiate the experience of the researchers and, thus, our idea for modification. The suggestion for enhancement has a practical nature, since it would allow clinics to schedule fewer outpatient clinic visits; in our sample group, this would imply clinically evaluating only 11 out 769 patients (1.4%) instead of 52 patients (6.8%), while still being able to detect all recurrences.

We can only relate our findings to the study of van den Heuvel et al. [5]. In their validation study, they found an overall PPV of 0.100, which is slightly higher than our PPV of 0.057. Nevertheless, their PPV remains considerably lower than 0.183 of our suggestion for a renewed PINQ-PHONE. Van den Heuvel et al. stated that if a patient responds negatively to all questions of the PINQ-PHONE, from their findings, the physician can be 100% sure that the patient has no recurrence. Among the positive respondents, they found five recurrences in 300 patients (1.7%) of which one recurrence in their opinion, and, to our agreement, should not be taken into account for the reason that progressive dementia made the outcomes unreliable. In their sample of patients, all recurrences would have also been detected with only questions 3 and 4, and thus, the overall sensitivity of the renewed PINQ-PHONE is still 1.00. From these provided results of van den Heuvel et al., the conclusion can be drawn that our suggestion for enhancement is safe. Furthermore, similarly as in our sample of patients, the first question of the PINQ-PHONE is only answered positively in 50.0% of recurrences, while, at the same time, it is evidently the biggest contributor to have schedule patients at the outpatient clinic due to false-positive responses. In the study of van den Heuvel et al., 48 out of 300 patients (16.0%) were invited to the outpatient clinic because of a positive PINQ-PHONE, and 1.7% turned out to have a recurrence. Thirty-nine patients answered question 1 positively; therefore, 81.3% of patients are seen at the outpatient clinic due to question 1, even though it misses 50.0% of recurrences. This finding was substantiated by the experience of three of our researchers. The suggestion to leave out the second question is solemnly based on our findings and the experience of four of the researchers. Van den Heuvel et al. found 7 out of 300 positive responses (2.3%) to question 2 of the PINQ-PHONE, while, in our study, the question was a big contributor to having to see patients at the outpatient clinic due to false-positive responses. Possibly, this question is, therefore, ambiguous for both patient and researcher. Unfortunately, from their provided results, we were unable to extract whether patients answered positively to only one question or more, and thus, a negative predictive value could not be calculated.

Two additional asymptomatic recurrences (0.3%) were detected in the TULP-trial. The overall 5-year recurrence rate was 2.4%. The low percentage of additional recurrences compared to the literature and a few positive PINQ-PHONE responses compared to van den Heuvel et al. can be explained through the excluded patients with already diagnosed inguinal hernia recurrences ($n = 21$) up until 2 years in the TULP-trial, thus, leaving a sample of patients less prone to develop a recurrence. This does not influence the evaluation of effectiveness of the PINQ-PHONE, although, as a result, the number of patients with a final positive outcome for the questionnaire (recurrence) was smaller. Unfortunately, at the 2-year follow-up point, the PINQ-PHONE was not yet available. Until 2 years of follow-up, all patients that reported pain, discomfort, or swelling were scheduled to visit the surgeon for physical examination. Hence, the PINQ-PHONE provided a substantial practical improvement at 5-year follow-up. Usually, asymptomatic recurrences require no surgical action; however, in a prospective trial with recurrence as an outcome, the value of the PINQ-PHONE was proven by detecting symptomatic and asymptomatic recurrences.

Our experience with using the PINQ-PHONE made us supportive of the questionnaire, since it refrains 84.0% of patients in the study of van den Heuvel et al. and 93.2% of our sample of patients from visiting the outpatient clinic for scheduled follow-up. Especially, in a prospective clinical trial with attempted follow-up in every patient, it proves to be a valuable method. Nevertheless, having to unnecessarily schedule 14.3% (van den Heuvel et al.) and 6.5% (TULP-trial) of all operated inguinal hernia patients for visits at the outpatient clinic to exclude a recurrence remains time-consuming. From our experience, this can relatively easy and safely be improved by eliminating the major sources of false-positive responses.

We advise implementing the PINQ-PHONE for detecting inguinal hernia recurrences. Considering the growing awareness of learning from registration databases in addition to clinical trials, the renewed PINQ-PHONE provides questions that should be part of any registration aimed at detecting inguinal hernia recurrences.

A limitation of this study is that the negative PINQ-PHONE responses were not scheduled for a visit to the outpatient clinic. In this experience study, logically not all patients were scheduled, since the meaning of the PINQ-PHONE is decreasing the burden at the outpatient clinic for both patients and doctors. From our data, (asymptomatic) recurrences (false negatives) might have been missed and it makes us unable to determine a sensitivity or specificity of our suggestion for a renewed PINQ-PHONE with only questions 3 and 4. However, from the original validation data, the renewed PINQ-PHONE, in addition to a higher PPV, shows a sensitivity of 1.00, implying that recurrences can be excluded with 100% reliability in patients with a negative response. Furthermore, a specificity of 0.85 was previously presented, which will only improve after the elimination of the major source of false-positive responses [5]. Therefore, the renewed questionnaire can safely be performed. Nevertheless, ideally, a validation study of the renewed PINQ-PHONE would make the questionnaire even more reliable.

The PINQ-PHONE itself also comes with limitations. The PINQ-PHONE is only reliable when patients comprehend the language and do not suffer from cognitive impairment. Moreover, patients are often unresponsive (6.9% in the current study), in which case patients should be addressed as loss to follow-up.

The PINQ-PHONE was validated for laparo-endoscopic inguinal hernia repair. Van den Heuvel et al. performed TAPP repair in 92.0% and TEP repair in 8.0% of cases. In our study, 100% of cases underwent TEP repair. Future research should validate the PINQ-PHONE in its renewed version after open inguinal hernia repair. In both studies, the questionnaire was executed in Dutch and validation of the PINQ-PHONE in the other languages needs to be undertaken.

In conclusion, the PINQ-PHONE proved to be a valuable tool in TEP repair follow-up for recurrences and prevents time-consuming outpatient clinic visits for both patients and surgeons. However, enhancement of the PINQ-PHONE using only question 3 and 4 is recommended, since more patients refrain from visits to the outpatient clinic and, nevertheless, recurrences are safely detected.

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**Author contributions** WJB: study conception and design, data collection, analysis and interpretation of data, and drafting of manuscript. MMR: study conception and design, data collection, interpretation of data, and critical revision. TK: data collection and critical revision. JPJB: study conception and design, interpretation of data, and critical revision.

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## Compliance with ethical standards

**Conflict of interest** The authors WJB, MMR, TK, and JPJB declare that they have no conflict of interests.

**Ethical approval** Ethical approval was obtained by the Regional Medical Ethics Committee and the hospitals Ethics Board.

**Human and animal rights statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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