

Questionnaire Versus Telephone Follow-up to Detect Postdischarge Complications in Surgical Patients: Randomized Clinical Trial

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Abstract

Background Postdischarge complications in surgical patients are usually recorded only when readmission is required, a method that likely underestimates the overall complication rate. Our aim was to determine which method—telephone interview or questionnaire by mail—collects the most postdischarge complications.

Methods We performed a randomized clinical equivalence trial. From December 2008 until August 2009, all adult surgical patients admitted to a university hospital were randomized to be approached by mail or by phone 30 days after discharge to collect information about postdischarge complications. Primary outcome was the total number of reported complications after discharge. Secondary outcome was the severity of the complications.

Results In all, 1595 patients were reached: 890 by means of a telephone interview and 705 through a questionnaire. Response

rate was higher in the telephone group than in the questionnaire group (63.8 % vs. 51.3 %). The percentage of patients reporting one or more complications did not differ significantly between the groups: 43.3 % in the telephone group versus 39.6 % in the questionnaire group. Length of stay, American Society of Anesthesiologist class, and type of surgery—but not the survey techniques compared here—significantly influenced the number of complications reported. The percentage of patient-reported complications requiring treatment did not differ significantly between the groups.

Conclusions The two survey methods did not differ in their ability to appreciate postdischarge complications as reported by the patients. The decision to use either method may be determined by the institution, costs involved, and labor requirement.

Introduction

Postoperative complications can lead to unfavorable health outcomes for the patient, requiring a change in therapy or even causing irreversible damage [1]. This in turn can result in prolonged hospital stay and increased costs [2–4]. Nowadays, most hospitals record the occurrence of postoperative complications during hospitalization. Such information can be useful for anticipating and counteracting the occurrence of preventable complications, which in turn is helpful for optimizing performance of the medical staff, thereby increasing the quality of patient care [5]. The most common definition of a postoperative surgical complication comprises an adverse outcome that occurs within 30 days after discharge [6, 7]. Hence, postdischarge complications should be recorded as well. After discharge, a patient is generally monitored by surgeons in the outpatient clinic, where it is common practice (at least in our hospital) to

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record only severe complications in patients that result in readmission, which likely underestimates the overall complication rate. However, this may vary substantially depending on the surgeon, nursing staff, and even the method by which it is recorded (paper-based or electronic).

A recent study showed that if all complications are taken into account 58 % of the surgical complications occur after discharge [8]. Another study showed that 25 % of all patients from a general surgical practice suffer from a postdischarge complication [9].

Information about postdischarge complications is important for comprehensive registration of postoperative complications because it can help improve the quality of surgical care. Also, it enhances the communication between surgeon and patient as well as between surgeon and general practitioners about what to expect and how to avoid or deal with postdischarge complications.

Most studies have used telephone follow-up to detect postdischarge complications during the 30-day period after discharge [8–11], but there is no gold standard regarding how to acquire the data that can determine the complication rate after discharge. Because telephone interviews seem more time-consuming and labor-intensive, questionnaires are a possible alternative for reporting postdischarge complications—but only if this method is equally effective for determining the number of these complications [12]. On the other hand, depending on the institution, a written questionnaire or survey could be more labor-intensive because of the preparation of the questionnaire and the materials, postage, and data entry required.

The aim of this randomized clinical trial was to compare two survey methods—follow-up interview by telephone or a questionnaire by mail—to determine the number of postdischarge complications in surgical patients during the 30-day period after discharge.

Patients and methods

This randomized clinical equivalence trial was a Health Innovation Project performed at the Department of Surgery of the Academic Medical Center, a university hospital in Amsterdam, The Netherlands. This trial is described according to the revised CONSORT statement [13]. Because this trial was not regarded as a medical intervention, it was not registered in a trial register, and our institutional review board waived the need for their approval.

Patients

From December 2008 until August 2009 all adult surgical patients admitted to and discharged from six surgical wards (one general, one vascular, one trauma, two gastrointestinal)

of a university hospital were eligible for this randomized clinical trial (RCT). Patients who died, had a foreign address, or had been readmitted after a previous hospitalization within 30 days were excluded from the trial. All patients were informed about the trial at discharge and received a dedicated information brochure from the ward nurse stating that they would be approached after 30 days by phone or by mail to collect information about any complications they may have sustained during that period. The patients approached were informed about the definition of a complication and the relevant period during which the complications should have occurred (between discharge and 30 days after discharge) before starting the interview. The definition of a complication as used in our hospital was an unintended and unwanted outcome or state occurring during or following medical care that is so harmful to the patients' health that it requires (adjustment of) treatment or leads to permanent damage during the period from discharge to 30 days after discharge.

Sample size calculation

The trial sample size was based on an expected complication rate of 25 % in the telephone group, which was based on the postdischarge complication rate as found by Marang et al. [9]. With a sample size in each group of 761 patients, a two-group large-sample normal approximation test of proportions with a one-sided significance level of 0.05 would have 90 % power to reject the null hypothesis that the telephone and questionnaire interviews are not equivalent. This is defined as a difference in complication rates of at least 6 % from zero, in favor of the alternative hypothesis that the complication rates in the two groups are equivalent. Thus, we needed a total sample size of 1522 patients. With an anticipated limited response rate of about 55 %, we aimed to include at least 2750 patients.

Randomization

On each weekday of the study period, the list of discharged patients was reviewed for eligibility. Patient randomization was performed after discharge by using a random number sequence generator as provided by a computer program to ensure allocation concealment.

Telephone interview

Patients randomized for the telephone interview received a written announcement 30 days after discharge that they could expect a call for an interview within a few days. The telephone interview was held using a standard questionnaire. This interview covered questions about the type, localization, and severity of the complications and if the

patient had sought medical help. Furthermore, some questions addressed whether and how the complication was treated and if the complication had resulted in readmission or (re)operation. The questions were based on the classification system of the Dutch national surgical complication registration system (LHCR) as developed by the Dutch Bar of Medical Specialists. It is based on national and international standards [6].

The questions were presented to the patient or to a close relative if the patient was incapable of answering. If the patient could not be reached, the research assistant tried to call the patient up to five times, at different times during the day, each time using all available numbers.

Questionnaire

Patients randomized for the questionnaire were approached, in writing, 30 days after discharge. The patients were asked to complete the standard questionnaire (the same as the one used for the telephone interview) on paper. The questionnaire was sent once because of costs and labor. Also, we assumed that the patients who did not respond the first time did not want to participate. All completed questionnaires received within 8 weeks after dispatch were included.

Outcomes assessment

The researcher who performed the telephone calls and sent the questionnaires was unaware of the patient's medical condition and of the treatment given. Postdischarge complications were recorded if they matched the following definition: an unintended and unwanted event or state occurring during or following medical care that is so harmful to the patient's health that (adjustment of) treatment is required or that permanent damage results [9].

The primary outcome was the complication rate in each study arm, which was expressed as the total number of complications reported and the mean number of complications per admitted patient. The secondary outcome was the severity of the complications reported. They were categorized using the four-level severity scale as developed and described by Clavien et al. [14]: 0, temporary health disadvantage without treatment; 1, recovering without (re)operation; 2, recovery after (re)operation; 3, (probably) permanent damage or function loss; 4, death. Complications requiring an interventional radiologic treatment (e.g., percutaneous drainage) were categorized as nonoperative treatment (severity 1) rather than a true reoperation in the operating room (severity 2). Although complications were compared by severity, this study did not aim to compare which types of complications were reported.

In addition, relevant patient characteristics were retrieved from the medical dossiers and electronic hospital databases. They included age, sex, day-care clinic versus clinical admission, American Society of Anesthesiologists (ASA) classification, in-hospital complications, length of hospital stay, type of surgery, complexity of the surgery—defined according to the Dutch Surgical Association on a scale from 1 (simple) to 7 (complex) [9]. For each admission with a surgical intervention, we marked the procedure with the highest surgical complexity as the main operation.

Data analysis

Data were entered in a Microsoft Access (2003) database (Microsoft, Seattle, WA, USA) and transferred into PASW Statistics version 18 (IBM, Armonk, NY, USA) for further analysis. A possible difference in complication rates between the two survey methods was analyzed using a χ^2 test and expressed as the risk difference (RD) including the 95 % confidence interval (CI). Differences between continuous variables were analyzed using the unpaired Student's *t* test or the Mann–Whitney *U* test, depending on the variables' normal distribution.

Because other factors apart from the survey technique might be unequally distributed between the two techniques, we applied regression analysis to adjust for it and to determine which factors were independently associated with the number of reported complications. Because this number was not normally distributed, we performed a log transformation of the number of reported complications as dependent-variable. Variables showing a substantial ($p < 0.20$) difference in number of complications between the trial groups were subsequently entered into the multi-variable linear regression model.

Results

During the 8-month period of this trial, 2768 clinical admissions were registered. Among them, 1395 patients were randomized for a telephone interview and 1373 for the questionnaire (Fig. 1). In both groups, several patients were excluded from analysis, mostly because of an unknown address or phone number or readmission during the 30 days after discharge. Details on trial flow and reasons for exclusion are shown in Fig. 1.

Eventually, 1595 patients responded and were analyzed, 890 by means of a telephone interview and 705 through the questionnaire. Thus, the response rate in the telephone group was higher than in the questionnaire group (63.8% vs. 51.3%).

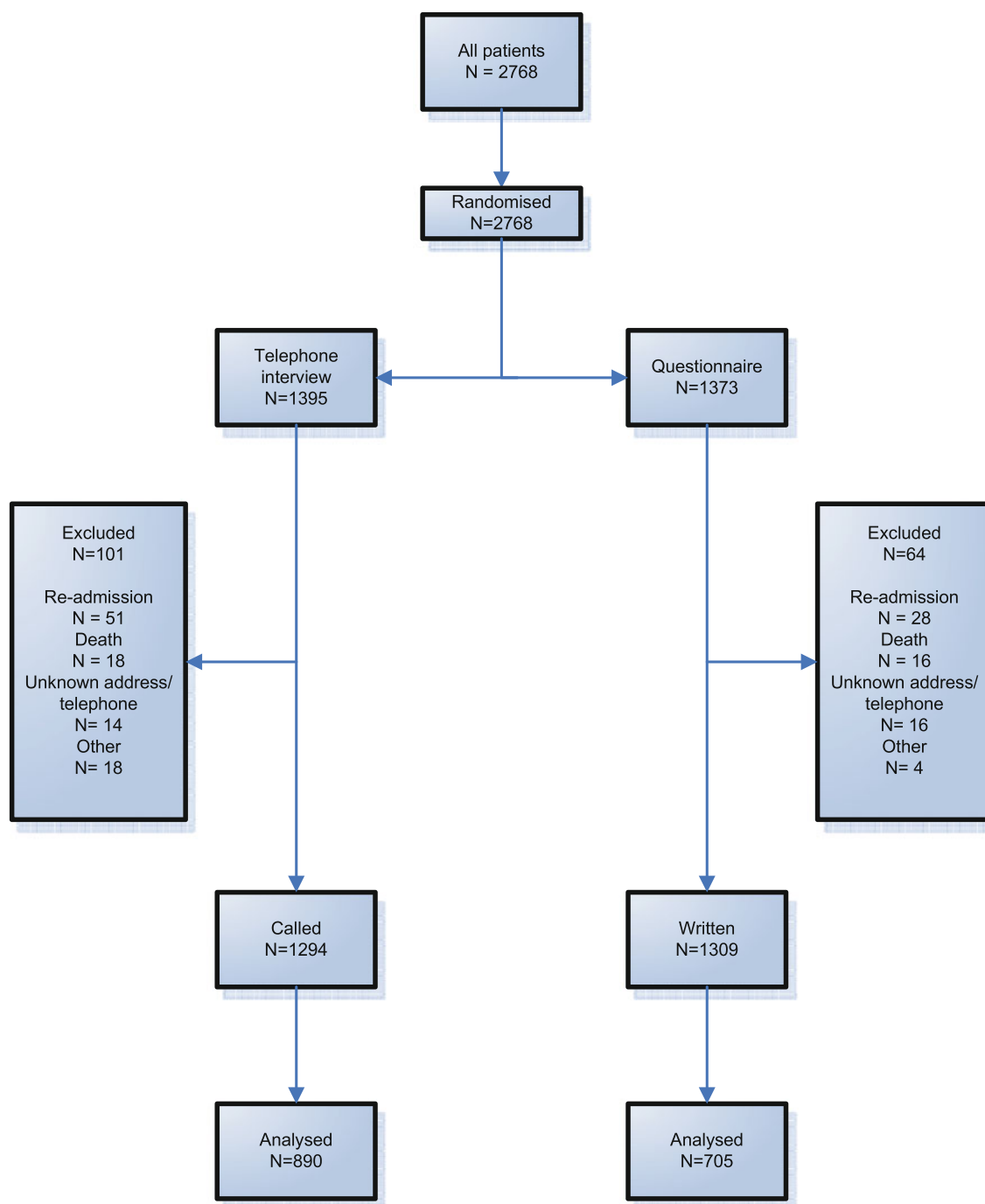


Fig. 1 Flow diagram of patient inclusion and analysis

Patient characteristics

Table 1 summarizes the characteristics of included patients in the two groups. Respondents in the groups were similar, except for their mean age, which was significantly lower in the telephone group (53 years) than in the questionnaire group (58 years) ($p < 0.001$). The median length of hospital stay in patients in the telephone group was slightly but significantly shorter than in the questionnaire group (5 vs.

6 days, respectively; $p = 0.013$). The distribution of the types of surgery was significantly different between the groups ($p = 0.023$): Patients in the questionnaire group underwent more vascular surgical interventions.

Complications after discharge

Complication rates did not differ between the groups: 43.3% of all respondents in the telephone group and 39.6 %

Table 1 Patient characteristics of respondents in telephone interview vs. questionnaire groups

Characteristic	Telephone interview (<i>n</i> = 890)	Questionnaire (<i>n</i> = 705)	<i>p</i>
Age (years), mean	53	58	<0.001
Male sex	54 %	5 %	0.786
Day care	17 %	15 %	0.202
Complications during hospital stay	14 %	16 %	0.369
Hospital stay (days), median and IQR)	4.0 (2.0–9.0)	5.0 (2.0–9.0)	0.013
Underwent surgery	651 (73.1%)	530 (75.2%)	0.213
Types of surgery performed			
Gastrointestinal	284 (43.6%)	221 (41.7%)	0.023
Vascular	76 (11.7%)	90 (17.0%)	
Trauma	113 (17.4%)	101 (19.1%)	
Other	178 (27.3%)	118 (22.2%)	
Complexity > 6	25 %	29 %	0.149
Missing (no.)	69	50	
ASA score at first operation ≥ 3	15 %	15 %	0.99
Missing (no.)	280	204	

Bold values indicates significant *p*-values *p* < 0.05

IQR interquartile range, ASA American Society of Anesthesiologists

in the questionnaire group reported to have suffered from one or more complications after discharge (RD 3.7 %, 95 % CI 1.2–8.5 %; *p* = 0.138). Table 2 shows that significantly (*p* = 0.003) more complications were reported by the patients who completed the questionnaire (mean rate 1.53 complications per patient) than by those who were questioned on the telephone (mean rate 1.26).

The severity of the complications was significantly different between patients who returned the questionnaire and those reached by telephone (Table 2). The latter reported significantly more severity 1 complications, which required only conservative treatment (RD 6.7 %, 95 % CI 1.1–12.2 %). The percentage of patient-reported complications that needed any treatment (severity 1 or 2) was not significantly different between the telephone group and the questionnaire group.

The complication type was classified according to the LHCR system (Table 3). In both groups, almost 40% of the reported complications were symptoms rather than diagnoses (e.g. pain, fever, nausea). Two categories showed a difference in percentage. Complications categorized as a “functional disorder” (e.g., ileus, gastroparesis, weight loss) were reported twice as much in the telephone group. In the questionnaire group, the most frequently (19 %) reported complication belonged to the category “other” (e.g., mental disorder).

Regression analyses

Univariable analysis showed that, apart from the survey technique, sex, age, length of hospital stay, day care, ASA classification, whether an operation was performed, and

Table 2 Complication numbers and severity in patients reporting complications after discharge, by telephone interview and questionnaire groups

Parameter	Telephone interview (<i>n</i> = 890)	Questionnaire (<i>n</i> = 705)	<i>p</i>
Reporting at least one complication	385 (43.3 %)	279 (39.6 %)	0.138
In-hospital complications	123 (14 %)	105 (15 %)	–
Complications reported (total)	485	426	
Complications per patient reporting at least one complication (mean)	1.26	1.53	0.003
Severity of complications			
0	160 (33%)	159 (37%)	0.067
1	311 (64%)	244 (57%)	0.004
2	14 (3%)	23 (6%)	0.605

Bold values indicates significant *p*-values *p* < 0.05

Results are the number of patients or complications

Table 3 Complication types in patients reporting complications after discharge, by telephone interview and questionnaire groups

Parameter	Telephone interview (<i>n</i> = 890)	Questionnaire (<i>n</i> = 705)
No. of complications	485	426
Symptoms without diagnosis: pain, fever, nausea	179 (37 %)	151 (36 %)
Functional disorders: bowel problems, weight loss, numbness, insomnia, cardiac problems	106 (22 %)	41 (10 %)
Inflammation/infection: abscess, (wound) infection	90 (19 %)	89 (21 %)
Accumulation/leakage of body fluids: gallbladder/chyle leakage or accumulation	33 (7 %)	34 (6 %)
Bleeding/hematoma: abdominal, anal, limbs, groin	28 (6 %)	27 (6 %)
Other: depression, dehiscence, others	49 (10 %)	84 (19 %)

type of surgery substantially differed between the telephone and questionnaire groups.

Multivariable regression analysis showed that using the questionnaire instead of the telephone interview increased the number of reported complications by 4%, but the difference was not statistically significant (95 % CI −0.1 % to 2.6 %). There was a significant increase in the number of reported complications of 0.4 % per day of additional hospitalization. This means that if the patient's hospital stay was prolonged 1 day the chance of developing complications would increase by 0.4 % (95 % CI 0.1–0.8 %). Day care was associated with a reduction in the complication rate of 9.2 % (95 % CI −0.3% to 17.5 %), whereas the ASA class increased the complication rate by 6.4 % (95 % CI 1.3–11.9 %). Finally, the type of surgery was significantly associated with a change in complication rates.

Discussion

This trial shows that about 40 % of surgical patients report experiencing one or more complications during the 30-day period after discharge, most of which require additional nonoperative or surgical treatment. The two survey methods—telephone interviews and mailed questionnaires—showed a significant difference in number, type, and severity of reported complications after discharge. However, the two groups also showed differences in patient characteristics: number of days in the hospital, sex, and type of surgery. Multivariable analyses showed that factors other than the survey method (e.g., hospital stay) are strongly associated with a larger number of postdischarge complications. Taking this into account, we assume that the two survey methods do not differ in their ability to identify postdischarge complications as reported by the patients, in particular the complications that require further treatment. The reporting of these complications was associated with ASA class, clinical admissions, length of hospital stay, and type of surgery. Because the percentages of in-hospital complications in the two groups were similar, we did not

further analyze the influence of in-hospital complications (e.g., type and number) to complications as reported by the patients after discharge. The differences in types of complications may be related to the differences in patient characteristics in both groups. For example, the higher percentage of bowel-related complications might well be correlated with the number of gastrointestinal procedures in this group [15, 16].

To ensure correct reporting of complications by patients using any method, its definition must be clear and strict. Although the definition was explained to every patient interviewed, in a telephone follow-up the interviewer can ask if the definition is clear and explain it if necessary. Answers obtained through a questionnaire might be biased when given by person other than the patient. However, this also happened during some telephone interviews because of the health status of the patient or language barriers. Furthermore, telephone interviews may lead to more socially acceptable answers, whereas patients may answer more freely if approached by questionnaire [12]. Also, patients may have difficulty determining whether their complaint fits the definition of a complication. Even among specialists, this can be ambiguous [7]. Further research should compare the answers of patients during the follow-up with the information in the outpatient record as recorded by the specialist to establish if there is a difference between the interpretation of a complication by a patient or a specialist and whether patient-reported complications can be considered valid and useful information.

The response rate of telephone follow-up is likely to be higher than that by questionnaire because a letter is easier to ignore. This was also apparent in our trial, which recorded a 15 % higher response rate in the telephone group. The difference in this trial may also have been due to the fact that questionnaires were sent only once, whereas phone calls were repeated if unanswered. Nevertheless, the effectiveness and costs of telephone interviews seem much less profitable than the questionnaires. Clearly, most studies have used a telephone follow-up because of the better response rate [8–11]. Several studies have presented methods to increase

the response rate to questionnaires; for example, contacting people before sending a questionnaire, providing a stamped self-addressed envelope, keeping the questionnaire short, and making it more personal [17, 18]. In our study, we called the patient up to five times, but the questionnaire was sent only once. Had we used these methods we probably could have further increased the response rate for the questionnaires. Unfortunately, sending the questionnaire more than once means higher costs and more labor, which might make it as expensive and labor-intensive as a telephone follow-up. Finally, although patients appreciate follow-up by telephone, there is no evidence of its effectiveness in preventing complications or readmissions [10, 11].

The considerable dropout rate, resulting in differences in patient numbers and characteristics between the two groups in our trial, was due to the fact that randomization of patients took place before making sure the patients had a valid address or telephone number and checking if they had died. This might have led to attrition bias, although it is unlikely that being unable to reach the patients was related to the number of complications they may have had. This could also explain the complication rate of almost 40 %, whereas the expected complication rate based on previous research [9] was only 25 %.

The dropout rate after randomization may have led to the differences found in patient characteristics in the two randomized groups. After correcting for these differences, the two groups showed no significant difference in the number of reported complications. These characteristics can also be useful for developing triggers [19] to search for complications, which might imply for sending a questionnaire or to check the medical file or other sources. An alternative is to check only the patient records of the patients with a high risk of complications.

Although postdischarge complications tend to be missed, the question remains whether hospitals are willing to invest time and money in registering all complications, including those that occur after discharge. It may require the use of more resources to detect such complications. Complications after discharge that lead to readmission, reoperation, or death are generally recorded with the current registration methods. On the other hand, missed complications are usually those that require conservative treatment (e.g., medical treatment from their general practitioner), which are nevertheless adverse outcomes patients perceive as important and undesirable. Moreover, the information registered is usually part of a quality measure that aims at preventing complications. To optimize this stratagem, as many complications as possible should be included because they may ultimately prevent the need for additional care.

Wound infection is one of the national indicators for quality of care and patient safety [Dutch Inspectorate of Health Care, www.igz.nl]. Hospitals are obliged to register

wound infections and report their numbers to national health care institutions. A reliable, complete complication registration can be useful not only to improve quality of care but also as a benchmark on a national level.

Conclusions

The two survey methods did not differ in their ability to identify postdischarge complications as reported by patients. The decision to use either method may be determined by the institution, costs involved, and labor requirement. Information about complications after discharge is valuable for improving the quality of care and for informing the patient about the benefits and risks of a treatment.

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Conflict of interest None.

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