

Original Article

Nurse-Led Follow-Up at Home vs. Conventional Medical Outpatient Clinic Follow-Up in Patients With Incurable Upper Gastrointestinal Cancer: A Randomized Study

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Abstract

Context. Upper gastrointestinal cancer is associated with a poor prognosis. The multidimensional problems of incurable patients require close monitoring and frequent support, which cannot sufficiently be provided during conventional one to two month follow-up visits to the outpatient clinic.

Objectives. To compare nurse-led follow-up at home with conventional medical follow-up in the outpatient clinic for patients with incurable primary or recurrent esophageal, pancreatic, or hepatobiliary cancer.

Methods. Patients were randomized to nurse-led follow-up at home or conventional medical follow-up in the outpatient clinic. Outcome parameters were quality of life (QoL), patient satisfaction, and health care consumption, measured by different questionnaires at one and a half and four months after randomization. As well, cost analyses were done for both follow-up strategies in the first four months.

Results. In total, 138 patients were randomized, of which 66 (48%) were evaluable. At baseline, both groups were similar with respect to clinical and sociodemographic characteristics and health-related QoL. Patients in the nurse-led follow-up group were significantly more satisfied with the visits, whereas QoL and health care consumption within the first four months were comparable between the two groups. Nurse-led follow-up was less expensive than conventional medical follow-up. However, the total costs for the first four months of follow-up in this study were higher in the nurse-led follow-up group because of a higher frequency of visits.

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Conclusion. The results suggest that conventional medical follow-up is interchangeable with nurse-led follow-up. A cost utility study is necessary to determine the preferred frequency and duration of the home visits. J Pain Symptom Manage 2014;47:518–530. © 2014 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care, advanced cancer, nurse-led, follow-up studies, patient satisfaction, quality of life, health care costs, esophageal cancer, pancreatic cancer, hepatobiliary cancer, gastrointestinal

Introduction

Symptoms of upper gastrointestinal (GI) cancer tend to appear at a relatively late stage of the disease.^{1–3} This explains why these cancers are generally associated with a poor prognosis. Moreover, many patients develop recurrent disease after surgical resection. When curative options are no longer available, one year survival rates are less than 15%.^{4,5} For patients with unresectable or recurrent esophageal, pancreatic, or hepatobiliary cancer, no curative options are available. Median survival of these patients is less than 10 months. Palliative treatment aims to improve the quality of life (QoL) of patients and their families by the prevention, early identification, and treatment of pain and other physical, psychosocial, and spiritual problems.⁶ The high prevalence of these multiple problems in patients at a palliative stage of their disease underlines the need for close monitoring and support.^{7–10} The interval between follow-up visits, therefore, depends on the adequacy of controlling these multidimensional symptoms. Currently, patients are usually followed by means of regular visits to the outpatient clinic. The frequency of these visits is low in our hospital, with an average of once every one to three months, or even no follow-up. Outpatient clinic visits are a burden for many palliative care patients, among others, in terms of traveling distance while physically unfit. In addition, the short contact during these visits often leaves little time to deal with all issues and concerns.^{11,12} We performed a study in which 109 patients, after intentionally curative surgery for esophageal or gastric cardia cancer, were randomized to standard follow-up by surgeons at the outpatient clinic or by regular home visits

of a specialist nurse.¹³ We found that nurses were able to perform follow-up of patients in their homes, and we found positive effects on QoL and satisfaction of patients and spouses. In addition, this follow-up strategy seemed to be cost-effective compared with standard follow-up at the outpatient clinic.¹⁴ Based on these results, we hypothesized that nurse-led home visits could have the same positive effects for patients in the palliative stage of the disease. This study, therefore, evaluated whether nurse-led follow-up by home visits could be an acceptable alternative to our standard medical follow-up at the outpatient clinic by a physician for upper GI cancer patients and their relatives receiving palliative care.

Methods

Participants and Allocation

Consecutive patients with unresectable or recurrent upper GI cancer were recruited from the Departments of Oncology, Gastroenterology and Surgery of the Erasmus MC—University Medical Center Rotterdam between June 2006 and August 2009. The Erasmus MC is a large university-affiliated tertiary referral center in The Netherlands for patients with esophageal, pancreatic, and hepatobiliary cancer. Patients were eligible when a multidisciplinary panel concluded that a curative modality or disease modifying anti-tumor therapy (i.e., palliative chemotherapy, radiotherapy, or surgery) was not or no longer possible. Excluded were patients who were admitted to a nursing home or hospice, patients who could not be followed by a physician at the outpatient clinic of the Erasmus MC, and patients who were unable to understand the

Dutch language or to complete questionnaires. Patients were followed for a maximum period of 13 months from inclusion to either death or loss to follow-up. The institutional review board of the hospital approved this study, and written informed consent was obtained from all patients.

After obtaining informed consent, patients were randomized to conventional medical follow-up at the outpatient clinic or to nurse-led follow-up at home. Randomization was performed using permuted blocks of size 4 and 6, in random order, and stratified by group of esophageal or gastric cancer, duodenal or pancreatic cancer, and hepatobiliary cancer. Patients were assigned to their randomized allocation by the study coordinator using a central telephone or fax number. Patients were asked to nominate a relative who was most involved in their care. If available, this relative also was contacted by the study coordinator and asked for additional informed consent.

Interventions

Nurse-Led Follow-Up. Nurse-led follow-up was performed by home visits of a specialist nurse, with more than 10 years' experience in oncology nursing care. Follow-up was done at 14 days and then monthly after randomization, up to 13 months or death. If necessary, telephone contact was possible between visits. The protocol for the nurse-led follow-up is shown in the [Appendix](#).

The nurse-led care focused primarily on relief of patients' suffering and complaints. For repeated assessment of the actual situation, the nurse used a modified version of the Edmonton Symptom Assessment System questionnaire.¹⁵ The nurse worked under the guidance of the attending medical specialist(s) at the Erasmus MC and had regular contact with both the attending physician and the patient's general practitioner (GP).

Conventional Medical Follow-Up. Conventional medical follow-up comprised scheduled appointments at the outpatient clinic of the Erasmus MC. Follow-up was performed one month and then every two months after randomization, up to 13 months or death. If patients were unable to come to the hospital, appointments could be done by telephone.

Nurse-led care was different as compared with conventional medical follow-up. Patients in this group were only referred back to the medical specialist when a medical intervention was indicated that could not be done by the GP ([Appendix](#)). In both patient groups, in case of symptoms and a subsequent palliative treatment, visits were frequently made to evaluate the effect of this treatment on symptom burden.

Questionnaires

At baseline, patient sociodemographics, clinical characteristics, and preference for follow-up were assessed. Outcome measures were based on structured questionnaires assessing patient (and relative) satisfaction, health-related QoL (HRQoL), and health care consumption (use of GP and hospital admission).

HRQoL. HRQoL was assessed using two measures. The first was the generic EuroQoL-5D,¹⁶ which contains a five-item classifier plus a visual analogue scale of overall health status. The second was the generic European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) measure,¹⁷ which incorporates nine multi-item scales: five functional scales (physical, role, emotional, cognitive, social), three symptom scales (nausea/vomiting, fatigue, pain), six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties), and a global health/QoL scale. In addition to these QoL measurements, the degrees of anxiety and depression were assessed with the Hospital Anxiety and Depression Scale,^{18,19} and pain intensity was measured on a numerical rating scale from 0 (no pain) to 10 (maximum pain imaginable).

Patient Satisfaction. As no specific validated Dutch questionnaire was available to assess patient satisfaction in this setting, a satisfaction questionnaire was developed for patients as well as their relatives, based on the questionnaire of Verschuur et al.¹³ The questionnaire in the present study contained three general propositions related to the follow-up procedure (rated as agree, neutral, not agree), nine questions with regard to satisfaction with the content of the visit (rated as being

very satisfied, satisfied, neutral, dissatisfied, very dissatisfied), and a rating from 1 to 10 for overall satisfaction and the burden of the visit.

Health Care Consumption. Patients or their relatives provided a monthly overview by means of a questionnaire regarding all contacts with GP and (re)admissions to the hospital.

Data Collection

The initial assessment at randomization was performed in the outpatient clinic or on the hospital ward. HRQoL and satisfaction questionnaires for patients, and the latter for relatives as well, were completed at one and a half, four, seven, 10, and 13 months after randomization (postal mailing). GP visits and hospital admissions were assessed monthly, also by postal mailing. Patients or relatives were contacted by telephone if the questionnaires were not returned on time. If desired, the questionnaires were completed with the help of the study coordinator at home or in the outpatient clinic.

Statistical Analysis

Analyses were performed on an intention-to-treat basis. Patients could be evaluated if they completed at least one questionnaire regarding QoL. First, we estimated the number of patients at each point of data collection because we expected a decline as a result of death before the endpoint of the study (13 months). Furthermore, we analyzed the differences in scores between baseline and each point of data collection.

We ignored missing items on QoL and satisfaction questionnaires when making the calculations, whenever at least half the items for multi-item scales were completed. The assumption was that these likely occurred at random. Otherwise, we registered the scores as missing. To investigate the robustness of the conclusions, we performed a sensitivity analysis on the results of EORTC QLQ-C30 (primary outcome) with two other datasets: 1) dataset including missing values analysis, in which missing values are replaced with the mean of all other values in the same group (nurse-led or conventional follow-up) and 2) dataset excluding missing values from analysis, by

deleting the patient with one or more missing values on a questionnaire.

The results were expressed as mean \pm SD and medians and interquartile range (IQR) if the scores were not normally distributed. Survival time from inclusion to death was calculated by using the Kaplan-Meier method. Comparisons of nominal variables were made using the Chi-square test, whereas comparisons of ordinal variables were made using the Mann-Whitney *U* test. Numerical variables were compared with Student's *t*-test (normal distribution) or the Mann-Whitney *U* test (no normal distribution). For calculating costs of both follow-up strategies, we estimated time and travel prices for one visit and for the actual costs incurred in this study for four months' follow-up. Standard costs as determined for cost research in health care²⁰ were used as the basis for these calculations, with all costs reported in Euros. For all analyses, to minimize the impact of multiple comparisons, a two-sided *P*-value of less than 0.01 was considered statistically significant. Calculations were performed with SPSS, version 14.0 (SPSS Inc., Chicago, IL). According to a power calculation in advance, we calculated that two groups of 50 patients would be sufficient for a difference of approximately .56 SD on the standardized EuroQoL-5D, with a two-sided Type 1 error rate of 0.05 and a statistical power of 80%. Taking into account the loss to follow-up, a total of 150 patients was considered to be sufficient.

Results

Patient Demographics

Patients Who Refused vs. Consented. In total, 204 patients were eligible and informed about the study, and 68% ($n = 138$) agreed to participate (Fig. 1). Reasons for refusal to participate were that the study was considered too burdensome (53%), there was no need for hospital-based follow-up (33%), and the patient preferred a doctor-led follow-up (14%).

Patients With vs. Without Follow-Up Data. Of the 138 patients allocated to either nurse-led follow-up or outpatient clinic follow-up, 66 (48%) completed at least one questionnaire regarding QoL and satisfaction within four

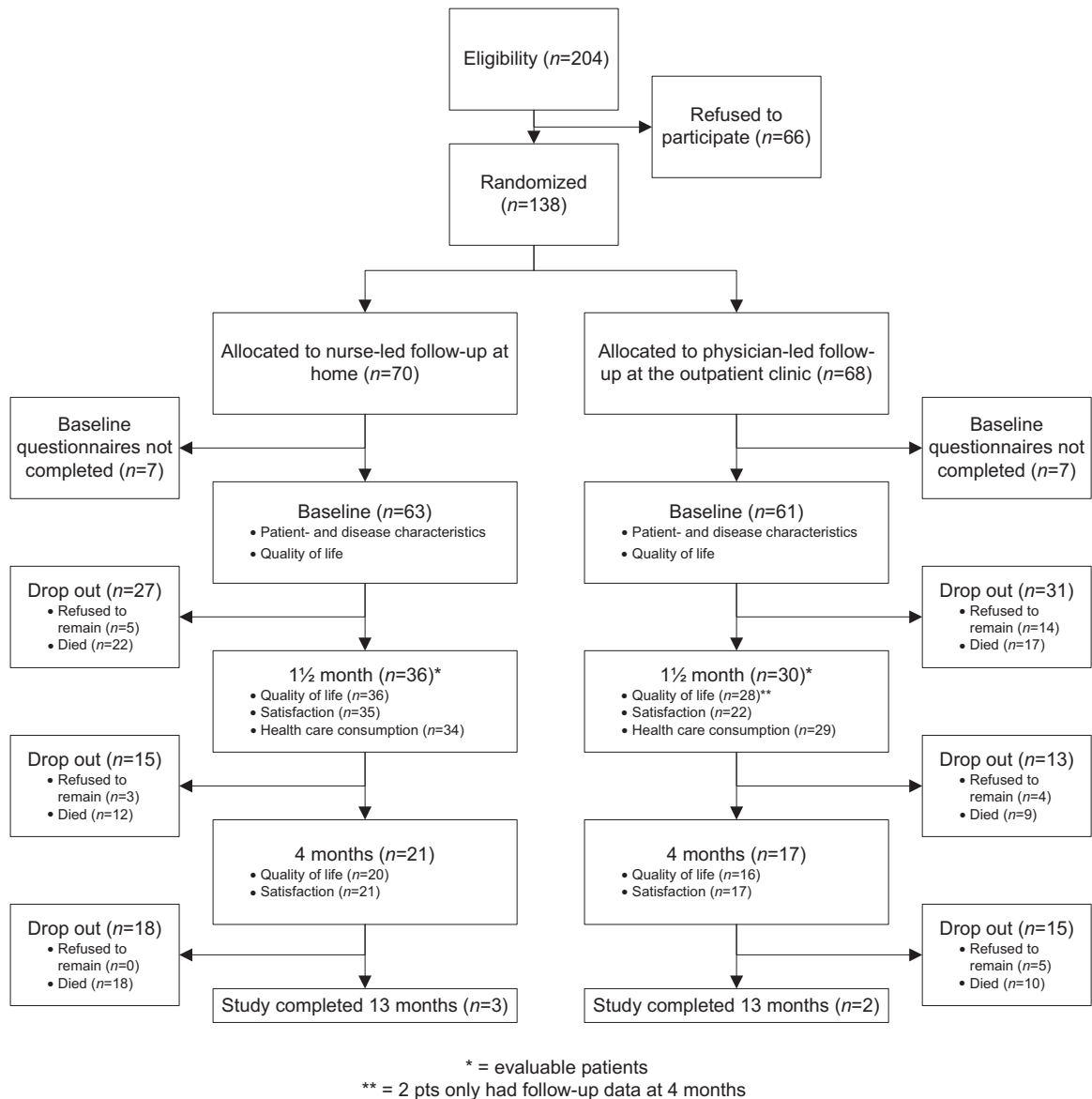


Fig. 1. Flow diagram of recruitment.

months after inclusion (36 nurse-led follow-ups, 30 outpatient clinic follow-ups). The remainder of included patients ($n = 72$) were closer to death at inclusion (median survival 1.6 month [IQR 0.92–3.02] vs. patients with follow-up data, median survival 6.8 months [IQR 3.90–10.50]; $P = 0.00$) and they less often had a relative to provide input for the satisfaction questionnaire (drop-out patients with relative, $n = 38$ [53%] vs. patients with follow-up data with relative, $n = 47$ [71%]; $P = 0.03$). At baseline, the patients without follow-up data scored worse on all QoL items/scales, except

for financial problems, than the patients with follow-up data.

Patients With Nurse-Led Follow-Up vs. Conventional Medical Follow-Up. Our findings reflect patient satisfaction, QoL, and health care consumption in the first four months after inclusion, because at later follow-up, too few patients remained alive to allow for meaningful analyses. Regarding the 66 patients with follow-up data, there was no statistically significant difference between the two follow-up strategy groups according to the demographic or clinical

Table 1
Characteristics of 66 Patients With Unresectable or Recurrent Esophagus, Pancreas, or Hepatobiliary Cancer With Data From at Least Baseline and One Follow-Up^a for All Outcomes

| Characteristics | Nurse-Led Follow-Up (<i>n</i> = 36) | Outpatient Clinic Follow-Up (<i>n</i> = 30) | <i>P</i> -value |
|--|---|---|-------------------|
| | <i>n</i> (%) | <i>n</i> (%) | |
| Age, years; mean (SD) | 67 (10.4) | 64 (12.0) | 0.37 ^b |
| Sex: male | 22 (61) | 18 (60) | 0.93 ^c |
| Primary tumor site | | | 0.52 ^c |
| Esophagus/gastric | 18 (50) | 16 (53) | |
| Pancreatic/duodenum | 10 (28) | 5 (17) | |
| Hepatic/common bile duct | 8 (22) | 9 (30) | |
| Main indication for palliative care | | | 0.88 ^c |
| Unresectable tumor | 5 (14) | 6 (20) | |
| Inoperable disease | 2 (6) | 2 (7) | |
| Distant metastases | 4 (11) | 3 (10) | |
| Recurrence | 3 (8) | 4 (13) | |
| Unknown | 22 (61) | 15 (50) | |
| Preference for follow-up strategy at baseline | | | 0.36 ^c |
| Nurse-led follow-up at home | 27 (75) | 17 (57) | |
| Physician-led follow-up at the outpatient clinic | 1 (3) | 1 (3) | |
| No preference | 8 (22) | 12 (40) | |
| Marital status: single/separated/divorced/widowed | 11 (31) | 7 (23) | 0.51 ^c |
| No religion | 14 (39) | 12 (40) | 0.97 ^c |
| Highest education | | | 0.25 ^d |
| Elementary school | 20 (56) | 11 (37) | |
| Intermediate school (VMBO/MBO) ^e | 7 (19) | 10 (33) | |
| Higher school (HAVO/HBO/VWO/university) ^f | 9 (25) | 7 (23) | |
| Unknown | — | 1 (3) | |
| Travel time to the hospital; km, median (IQR) | 38 (10.3–64.3) | 19 (13.8–29.3) | 0.09 ^d |

IQR = interquartile range.

^aAt one-and-a-half or four-month follow-up.

^bStudent's *t*-test.

^cChi-square test.

^dMann-Whitney *U* test.

^eVMBO = pre-vocational secondary education (VMBO) which is usually an introduction to middle vocational education (MBO).

^fHAVO = Senior general secondary education qualifies students to enter higher professional education (HBO). VWO = Pre-university education prepares students for academic studies at university level (WO) VWO includes Gymnasium (Latin and Greek is compulsory), Atheneum (Latin or Greek is compulsory), Lyceum (Latin and Greek are optional).

characteristics (Table 1). The largest difference was found for travel distance to the hospital. Patients with at least one follow-up allocated to conventional medical follow-up at the outpatient clinic had less travel distance (median 19 km, IQR 13.8–29.3) than patients allocated to the nurse-led follow-up at home (median 38 km, IQR 10.3–64.3). The median follow-up time was 6 months in both groups, and there was no significant difference in survival between both groups.

Patients in the nurse-led follow-up group had an overall median survival of 6.3 months (IQR 4.7–7.9) vs. median 6.8 months (IQR 3.9–9.6) ($P = 0.87$) in the conventional medical follow-up arm. More patients in the conventional medical follow-up group refused further participation in the trial before the official endpoint of the study (death or 13 months): nine patients (8%) in the conventional medical follow-up group vs. three

patients (30%) in the nurse-led follow-up group ($P = 0.02$).

HRQoL

The difference between the median EuroQoL-5D index score in the nurse-led follow-up group and the conventional medical follow-up group was not significant at both time points (0.78, IQR 0.31–0.88 at one and a half months and 0.78, IQR 0.33–0.84 at four months vs. 0.67, IQR 0.33–0.78 at one and a half months and 0.69, IQR 0.31–0.81 at four months, respectively). Results from EORTC QLQ-C30 show that at baseline patients in the nurse-led follow-up group vs. the conventional medical follow-up group had less symptoms of diarrhea (median 0.0, IQR 0.0–0.0 vs. median 0.0, IQR 0.0–33.3; $P = 0.09$), financial difficulties (median 0.0, IQR 0.0–0.0 vs. median 0.0, IQR 0.0–0.0; $P = 0.06$), and had better cognitive

Table 2
Satisfaction of Patients and Relatives With Follow-Up Strategy At One-and-a-Half Month Follow-Up

| Statement/Item from Satisfaction Questionnaire | Mean (SD) Score at One-and-a-Half Month Follow-Up | | | | | |
|--|---|--|------------------------------|--------------------------------------|--|------------------------------|
| | Patients | | | Relatives | | |
| | Nurse-Led Follow-Up <i>n</i> = 35 | Outpatient Clinic Follow-Up <i>n</i> = 22 | <i>P</i> -value ^a | Nurse-Led Follow-Up <i>n</i> = 30 | Outpatient Clinic Follow-Up <i>n</i> = 19 | <i>P</i> -value ^a |
| Agreement with statement (1–3, 1 = most agreed) | | | | | | |
| Visit proceeded as expected | 1.0 (0.00) | 1.2 (0.59) | 0.07 | 1.1 (0.37) | 1.3 (0.65) | 0.18 |
| I had chosen the same follow-up for myself | 1.0 (0.00) | 2.3 (0.90) | <0.001 | 1.0 (0.00) | 2.2 (0.98) | <0.001 |
| They take enough time for me | 1.0 (0.00) | 1.1 (0.43) | 0.21 | 1.1 (0.31) | 1.2 (0.63) | 0.42 |
| Rating of item (1–10, 10 = best) | | | | | | |
| Overall satisfaction | 8.4 (0.95) | 7.5 (2.02) | 0.02 | 8.0 (1.13) | 6.8 (2.32) | 0.02 |
| Extent of burden follow-up visit | 8.4 (1.90) | 6.0 (2.65) | <0.001 | 8.4 (1.56) | 4.9 (2.44) | <0.001 |
| Satisfaction on item (1–5, 1 = most satisfied) | | | | | | |
| All items listed below together | 1.6 (0.42) | 1.8 (0.54) | 0.14 | 1.8 (0.39) | 2.1 (0.77) | 0.08 |
| Care is readily available | 1.5 (0.70) | 2.1 (1.04) | 0.01 | 1.7 (0.76) | 2.4 (1.26) | 0.01 |
| Knowledge of the physician/nurse | 1.6 (0.50) | 1.7 (0.72) | 0.35 | 1.8 (0.50) | 1.8 (0.75) | 0.91 |
| Confidence given by physician/nurse | 1.5 (0.51) | 1.6 (0.73) | 0.36 | 1.7 (0.54) | 2.0 (1.03) | 0.18 |
| Management of physical complaints | 1.8 (0.54) | 1.7 (0.70) | 0.69 | 1.8 (0.50) | 1.9 (0.91) | 0.44 |
| Information given by physician/nurse | 1.7 (0.48) | 1.7 (0.47) | 0.75 | 1.8 (0.64) | 1.9 (0.87) | 0.40 |
| Advices given by physician/nurse | 1.6 (0.49) | 1.8 (0.70) | 0.37 | 1.8 (0.38) | 2.1 (0.97) | 0.27 |
| Answers you get from physician/nurse | 1.6 (0.50) | 1.8 (0.69) | 0.21 | 1.8 (0.41) | 2.0 (0.82) | 0.25 |
| How the physician/nurse involve you in care planning | 1.7 (0.54) | 1.8 (0.66) | 0.32 | 1.9 (0.45) | 2.2 (1.03) | 0.12 |
| Support you receive from physician/nurse | 1.5 (0.51) | 1.8 (0.66) | 0.08 | 1.8 (0.50) | 2.3 (1.15) | 0.06 |

The values highlighted in bold are statistically significant ($P < 0.01$).
^aStudent's *t*-test.

functioning (median 91.7, IQR 66.7–100 vs. median 83.3, IQR 50.0–100; $P = 0.09$), respectively. These differences were no longer present during follow-up. Patients in the conventional medical follow-up group were more often depressed (median 8.5, IQR 5.0–11.0 vs. median 5.0, IQR 2.0–11.0; $P = 0.15$) after one and a half months of follow-up, and in these patients, loss of appetite was less common (median 0.0, IQR 0.0–66.7 vs. median 66.7, IQR 8.3–100, $P = 0.05$) after four months of follow-up.

Patient and Relative Satisfaction

Both patients and their relatives in the nurse-led group were more satisfied with their follow-up than those receiving conventional medical follow-up (Tables 2 and 3). Mean overall patient satisfaction at one and a half and four months was 8.4 ± 0.95 and 8.5 ± 1.03 , respectively, for the nurse-led follow-up group compared with 7.5 ± 2.02 and 7.1 ± 1.18 , respectively, for the conventional medical follow-up group ($P = 0.02$ and <0.001 , respectively). Mean overall relative satisfaction at one and a half and four months was 8.0 ± 1.13 and 8.5 ± 0.98 , respectively, for the nurse-led

follow-up group compared with 6.8 ± 2.32 and 6.9 ± 2.38 , respectively, for the conventional medical follow-up group ($P = 0.02$ and 0.01 , respectively).

At both time points, patients and relatives in the conventional medical follow-up group less frequently agreed on the statement that they had opted for this follow-up strategy when given a choice ($P < 0.001$), and they evaluated the conventional medical follow-up as more burdensome ($P < 0.001$). According to the visits, patients in the nurse-led follow-up group were more satisfied about the following aspects: advice and information given by the care provider (at four month follow-up, $P < 0.001$) and the involvement of the patient in his or her own care planning (at four month follow-up, $P < 0.001$). For these items, patients in the conventional medical follow-up group became less satisfied over time, whereas the scores remained the same in the nurse-led follow-up group.

Health Care Use

In total, 268 visits were made in the nurse-led group (157 home visits, 95 telephone consultations, and 16 referral visits to the outpatient

Table 3
Satisfaction of Patients and Relatives With Follow-Up Strategy At Four-Month Follow-Up

| Statement/Item from Satisfaction Questionnaire | Mean (SD) Score at Four-Month Follow-Up | | | | | |
|---|---|--|------------------------------|--------------------------------------|--|------------------------------|
| | Patients | | | Relatives | | |
| | Nurse-Led Follow-Up <i>n</i> = 21 | Outpatient Clinic Follow-Up <i>n</i> = 17 | <i>P</i> -value ^a | Nurse-Led Follow-Up <i>n</i> = 21 | Outpatient Clinic Follow-Up <i>n</i> = 12 | <i>P</i> -value ^a |
| Agreement with statement (1–3, 1 = highly agree) | | | | | | |
| Visit is proceeded as expected | 1.0 (0.00) | 1.4 (0.70) | 0.01 | 1.0 (0.00) | 1.5 (0.82) | <0.001 |
| I had chosen the same follow-up for myself | 1.0 (0.20) | 2.1 (1.00) | <0.001 | 1.1 (0.22) | 2.1 (0.99) | <0.001 |
| They take enough time for me | 1.0 (0.00) | 1.3 (0.58) | 0.03 | 1.1 (0.31) | 1.3 (0.65) | 0.32 |
| Rating of item (1–10, 10 = best) | | | | | | |
| Overall satisfaction | 8.5 (1.03) | 7.1 (1.18) | <0.001 | 8.5 (0.98) | 6.9 (2.38) | 0.01 |
| Extent of burden follow-up visit | 8.5 (1.42) | 5.2 (2.69) | <0.001 | 8.8 (0.98) | 4.8 (2.64) | <0.001 |
| Satisfaction on item (1–5, 1 = most satisfied) | | | | | | |
| All items listed below together | 1.6 (0.45) | 2.2 (0.62) | <0.001 | 1.7 (0.49) | 2.1 (0.65) | 0.07 |
| Care is readily available | 1.7 (0.64) | 2.2 (1.03) | 0.04 | 1.7 (0.64) | 2.1 (0.79) | 0.16 |
| Knowledge of the physician/nurse | 1.5 (0.51) | 1.8 (0.53) | 0.03 | 1.6 (0.51) | 1.8 (0.45) | 0.35 |
| Confidence given by physician/nurse | 1.5 (0.51) | 1.8 (0.81) | 0.08 | 1.6 (0.60) | 2.1 (0.79) | 0.06 |
| Management of physical complaints | 1.8 (0.59) | 2.2 (0.78) | 0.14 | 1.7 (0.56) | 2.0 (0.95) | 0.35 |
| Information given by physician/nurse | 1.7 (0.48) | 2.2 (1.03) | 0.03 | 1.8 (0.62) | 2.1 (0.83) | 0.28 |
| Advices given by physician/nurse | 1.6 (0.51) | 2.3 (0.87) | <0.001 | 1.9 (0.58) | 2.2 (0.83) | 0.29 |
| Answers you get from physician/nurse | 1.6 (0.50) | 2.2 (0.83) | <0.001 | 1.8 (0.62) | 2.3 (0.97) | 0.12 |
| How the physician/nurse involve you in careplanning | 1.6 (0.57) | 2.3 (0.85) | 0.01 | 1.9 (0.58) | 2.3 (0.97) | 0.21 |
| Support you receive from physician/nurse | 1.6 (0.58) | 2.3 (0.92) | 0.01 | 1.8 (0.52) | 2.3 (0.89) | 0.04 |

The values highlighted in bold are statistically significant ($P < 0.01$).
^aStudent's *t*-test.

clinic) and 80 in the conventional medical follow-up group (35 outpatient clinic visits and 45 telephone consults) (Fig. 2). Of these visits, 157 (59%) and 47 (59%), respectively, were regular visits and 111 (41%) vs. 33 (41%) were extra visits initiated by the patient, the relative, or the nurse/physician. In the conventional medical follow-up group, more

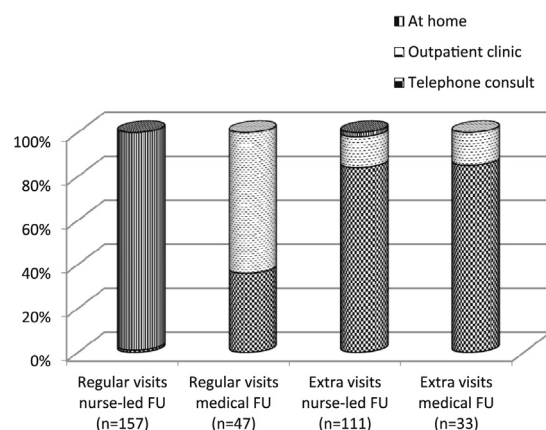


Fig. 2. Characteristics of 348 home care visits, outpatient clinic visits, or telephone consults for 66 patients (first four months of follow-up).

regular visits were replaced by telephone contacts (17 visits [36%] vs. two visits [1%] in nurse-led follow-up group). Ten patients (28%) from the nurse-led follow-up group were referred to the outpatient clinic for a visit with the physician.

Costs of a nurse-led follow-up visit per patient were 38% lower than those of a conventional follow-up visit (€89.97 nurse-led visit vs. €144.48 conventional medical follow-up visit) (Table 4). Overall, within the four first months, costs for the nurse-led follow-up strategy were €336.91 vs. €144.48 per patient for conventional medical follow-up visits because of the higher volume of visits in the nurse-led group.

On average, patients in the nurse-led follow-up group had a slightly higher number of contacts with GP compared with patients in the conventional medical follow-up group (nurse-led follow-up, median 6.0 contacts [IQR 2.75–11.0] vs. conventional medical follow-up, median 4.0 contacts [IQR 1.50–7.50]; $P = 0.11$) and a similar number of hospital admissions (nurse-led follow-up, median 1.0 admission [IQR 0.00–1.25] vs. conventional

Table 4
Costs of Both Follow-Up Strategies per Person

| Types of Costs | Nurse-Led Follow-Up | | Physician-Led Follow-Up | |
|---|--|--|-------------------------|--------------------------------|
| | Cost for One Visit per Patient | Volume: Median per Patient in This Study | Costs (€) | Cost for One Visit per Patient |
| Travel costs home visit ^a | €7.88 = €0.20 × 37.5 km ^b (×2 for return) | 4 | 63.04 | NA |
| Time costs traveling home visit | €18.87 = €0.51 × 37 min ^b (×2 for return) | 4 | 150.96 | NA |
| Time costs home visit ^{c,d} | €28.82 = €0.51 × 56.5 min ^b | 4 | 115.26 | NA |
| Time costs outpatient clinic visit ^{e,f} | €8.93 = €0.51 × 17.5 min ^b | 0 | 0.00 | €129.00 per visit |
| Time costs telephone consult | €7.65 = €0.51 × 15 min ^b | 1 | 7.65 | €1.72 × 9 min ^b |
| Total per person | €89.97 | | 336.91 | €144.48 |

NA = not applicable.

^aParking costs not included.

^bMedian per patient in this group.

^cInclusive time for direct patient contact, administration, and consultation with other professionals.

^dCost per minute (reference value 2009 cost per nurse per hour €30.50 inclusive of holiday pay and social security).

^eCost per minute (reference value 2009 cost per medical physician per hour €103.00 inclusive of holiday pay and social security or cost for outpatient clinic visit €129.00 for 20 minutes inclusive of nurse assistant, overhead, accommodation, and material).

medical follow-up, median 1.0 admission [IQR 0.00–1.00]; $P = 0.91$), within the first four months (Fig. 3).

Discussion

This study shows that palliative care for patients with upper GI cancer can be provided at home by specialized oncology nurses with high patient satisfaction. Patients as well as their relatives were highly satisfied with this type of nurse-led follow-up. Our findings also document that this strategy is less costly per visit than the conventional medical follow-up strategy, and patients' QoL and contacts with GP and hospital care are similar to conventional medical follow-up (Fig. 3).

The higher level of satisfaction is largely determined by the fact that the home visits were perceived as less burdensome compared with the visits to the outpatient clinic. This is probably related to the burden of travel to the hospital, delays in physicians' schedules, and the fact that most patients prefer to receive palliative care at home and prefer to die at home.²¹ This could also explain why more patients in the conventional medical follow-up group ended the study before death (30%) than patients in the nurse-led group (8%). Furthermore, we found a difference in travel time between included patients from both groups. This was not the case when we analyzed the difference in travel time between the two groups of all 138 randomized patients. Therefore, patients with conventional medical follow-up with a further distance between home and hospital had ended participation in the study earlier after study entry.

The higher level of satisfaction in the nurse-led follow-up group can further be explained by the fact that patients and relatives appreciated the nurses' care more than physicians' care.²² It has been suggested that quality of care by nurses is better at this disease stage because nurses may deal with broader aspects of the health care experience, rather than concentrating solely on treatment of the disease.^{11,22} A high level of satisfaction with nurses' care was found in two reviews on substitution of doctors by nurses in cancer care and in primary care.^{23,24} Chapple et al.²⁵ found that patients highly valued palliative care by

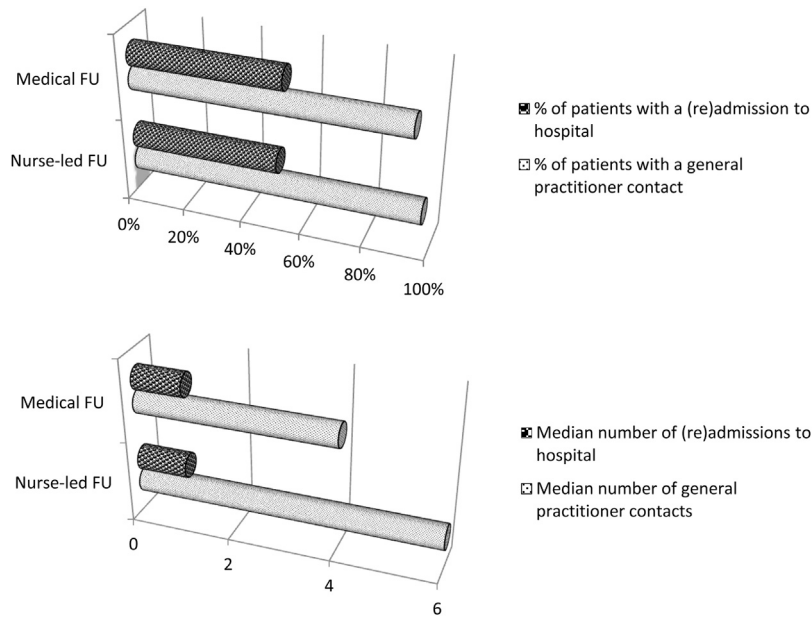


Fig. 3. Health care consumption during four months of follow-up.

nurses, particularly their advice on practical matters, information on their disease, emotional support, advice on symptoms, help with communication, and that nurses' help was readily available. In addition, continuity of care in this study was probably better maintained by the nurse. In the outpatient clinic, there was a high rotation of junior medical staff, although some doctors made sure that they always saw the patient themselves. Nevertheless, there are patients who may feel more confident with follow-up given by a doctor.²⁶ In our study, this involved 14% ($n = 9$) of the patients refusing participation and 3% ($n = 2$) of the patients who at baseline preferred conventional medical follow-up over nurse-led follow-up.

Despite the higher satisfaction in the nurse-led group, there was no difference in QoL between both groups. It may not be realistic to assume that QoL at this stage of the disease would be significantly influenced by a visit from a nurse once a month.²⁷ Previous studies on the impact of palliative home care teams and coordinating nurses on patients' QoL²⁸ and on the effectiveness of nurse-led follow-up for patients with cancer^{23,29,30} revealed similar results. A review by Corner³¹ found that in situations where the goals of nurse-led initiatives were to improve quality of care, this outcome was not always achieved. This may have

been influenced by the short duration of follow-up, given the rapid death of a considerable proportion of patients,³² or by the possibility that the instruments used were not sufficiently sensitive to provide relevant information at this level.³³

The nurse-led follow-up did not interfere with existing standard health care structures. In instances where GP had a key role in the provision of palliative care, this was not changed. All GPs received a letter from the study coordinators with information about the study and the randomization procedure. Shortly after that, if the patient was randomized to nurse-led follow-up, the nurse contacted GP. GPs generally appreciated this and consented to the study, even more so if they had insufficient knowledge about upper GI cancer and/or specialist treatments (such as stent placement), and they noted that the nurse was readily available for professional advice and support. So we assume that the nurse-led follow-up seems to complement the general GP follow-up, just as the conventional medical follow-up has done in the past.³⁴

Per visit, we found a lower cost for the nurses' home visits in comparison with the cost of the outpatient clinic visit. However, the total follow-up cost of the nurse-led strategy was more expensive than standard care during the four first months of follow-up.

This was mainly because patients in the nurse-led group had more regular visits. We assumed that patients in this phase of their disease had a need for close monitoring and support for symptom control; therefore, our nurse-led protocol included at least one visit each month. A higher frequency revealed no significant changes in symptom burden or QoL. It is unclear if the higher level of satisfaction was caused by more visits. Therefore, further research on the frequency and the duration of visits is necessary in a cost utility study. Because the costs are largely determined by travel time and travel expenses, a study also should investigate if the home-based follow-up can be performed by nurses with less travel time and costs (e.g., community nurses) or by innovative interventions such as tele-health.

Limitations

Six methodological issues merit discussion. First, missing data may have biased the results. Palliative care research is known to be hampered by methodological challenges related to attrition and missing data because of progressive illness and death. However, we found no changes in our results after performing a sensitivity analysis. Second, findings also may have been biased by the fact that a quarter of the questionnaires were completed with the help of a relative or friend. However, the likelihood of such bias was limited because the form elicited patient reports regardless of who completed it. Third, the information on health care use could have been biased by the extent to which patients were able to remember events. However, we used a diary to provide an immediate update after every event, thus reducing the influence of memory. Fourth, the generalizability of our results is unknown. Before the one and a half month follow-up, 58 patients were lost to follow-up, mainly as the result of progression of disease with deterioration and death, with related poor QoL scores. Furthermore, 53% of the patients refusing study participation probably had a poorer performance status as they found participating too burdensome. In addition, we did not include non-Dutch speaking patients in the study, given the fact that we needed input by means of questionnaires. Fifth, we took into account the problem of multiple testing and, therefore, used a two-sided *P*-value of 0.01.

This might not have been conservative enough. It is possible that differences with a *P*-value slightly below 0.01 are a result of multiple testing. Finally, the study was probably underpowered. In our center, approximately 200 patients with esophageal, pancreatic, and hepatobiliary cancer undergo palliative treatment annually. It was expected that at least 60% (120 patients) would consent to participation in this study. Taking into consideration an initial phase of three months, within 18 months a total of 150 patients (esophageal/gastric carcinoma [*n* = 50], pancreatic/duodenum carcinoma [*n* = 50], and hepatobiliary carcinoma [*n* = 50]) were expected to be eligible for randomization. In fact, in three years, only 204 patients were found to be eligible for palliative treatment. This is most likely the result of the fact that the treating physicians quite often concluded that patients were still not in the palliative phase of their illness and, therefore, did not invite patients to participate in this study. It was decided to close inclusion of patients for the study after three years as budget was depleted. Therefore, the results of this study cannot be generalized to all incurable GI cancer patients.

Conclusion

Nurse-led follow-up at home resulted in unchanged satisfaction over time in upper GI cancer patients and their relatives receiving palliative care, whereas conventional medical follow-up in an outpatient clinic resulted in a decrease in satisfaction. The intervention had no significant effect on QoL and health care consumption and was less costly. The results suggest that physician-led follow-up is interchangeable with nurse-led follow-up, although it is unclear which frequency for visits is desirable. A cost utility study is necessary to determine the preferred frequency and duration of home visits. This information can be useful in developing hospital-based palliative care follow-up program and improving palliative care for patients and relatives.

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Appendix

Problem-Oriented Nursing Care Plan During Home Visits

