Evaluation of a Standardized Internet-based and Telephone-based Patient Monitoring System for Pain Therapy With Transdermal Fentanyl

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Abstract: The aim of the present observational 4-week study was to document the feasibility and utility of telephone-based or Internet-based pain monitoring in patients with chronic cancer or noncancer pain, such as nociceptive or neuropathic pain, using transdermal fentanyl. Pain intensity, treatment tolerability, activities of daily living, quality of life, and patient and physician satisfaction were evaluated in 60 (60% women, 42% opioid-naive) chronic pain patients who were switched from oral pain therapy to transdermal fentanyl therapy because of persisting severe pain. When the total dataset of all patient entries was analyzed, treatment with transdermal fentanyl led to decreases in maximal and mean pain scores as reported by the patients (-14% and -19%, respectively, last observation carried forward vs. baseline). Pain reduction was more pronounced in opioid-naive than in opioid-experienced patients (-35% and -25% vs. baseline, respectively; P = 0.03). Overall, impairment of daily activities was reduced by 23% with transdermal fentanyl. No effect was observed with regard to quality of life and use of rescue pain medication. Transdermal fentanyl was generally well tolerated. Most patients (60%) preferred the telephone-based to the Internet-based or Internet combined with telephone questionnaires. Patient preference was driven by age, whereby younger patients tended to prefer the Internet and older patients the telephone (mean age, 45 and 54 y, respectively; difference n.s.). Internet-based and telephone-based monitoring of the efficacy and tolerability of opioid treatment for chronic pain was feasible in daily practice and generally well

accepted by patients and physicians. Future research will determine the relative contribution of these 2 new options for patient-physician interaction and delineate their role in improving chronic pain control.

Key Words: electronic pain diary, disability monitoring, Internet-based and telephone-based pain monitoring

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The perception of pain and its effects on activities of daily living are subject to large interindividual and intraindividual fluctuations. Recording pain and its changes over time provides important evidence that can be used to improve treatment and adapt it to individual sensitivity. This applies particularly to patients with chronic pain after a switch in therapy. The individual pain reported by the patient must provide the basis for clinical decisions and the improvement of pain therapy.

Pain—especially chronic pain—and changes in pain intensity over time are a multidimensional experience. Numerous parameters need to be integrated, such as type and intensity of pain, and degree of impairment of activities of daily living. These parameters are based on the International Classification of Functioning (ICF), ^{1,2} even though the latter only detects effects in patients with acute, but not chronic, lumbar pain. ³ Moreover, pain characteristics may be influenced by the manner in which they are recorded, for example, the intervals between times of recording and qualitative aspects of the questionnaire. ⁴

Changes in pain perception and impairment of activities of daily living are generally recorded in paper diaries, if at all; studies with electronic diaries are still at an early stage. 5-8 However, the acceptance of electronic diaries by elderly patients and other subgroups has not yet been adequately validated. Electronic data recording is already frequently used in clinical studies. 9,10 The first electronic questionnaires for standardized patient interviews have just recently been validated. A computerbased touch-screen (QUALITOUCH) version of the WOMAC and NASS questionnaire was developed and validated for patients with hip or knee osteoarthritis or back pain, with the aim of simplifying the administration

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required for recording, analyzing, storing, and retrieving the data. ^{11,12} The QUALITOUCH method combines the electronic questionnaire with cartoons and sound. The QUALITOUCH method also provides Internet questionnaires.

In recent years, there has been great emphasis in rheumatology on outcome measurement using validated, disease-specific, and standardized questionnaires. ^{13,14} The Internet and communication by telephone/mobile phone makes it possible to perform standardized patient interviews, while remaining flexible with respect to both time and place. This permits close monitoring of outpatients. This option means that drug therapy can be continually adapted to the intensity of pain. In addition, side effects can be recorded rapidly and corrective measures implemented more quickly than with a paper diary.

The present study was performed in collaboration with pain specialists from hospitals and office-based physicians. The aim was to investigate the feasibility and utility of intensive, simple pain monitoring with modern methods of communication (telephone and Internet). The Software for the Internet platform (e-diary) and the automated telephone system (interactive voice response system) was developed, provided, and hosted by MEDCONTROL AG (www.medcontrol.ch) in Switzerland.

In particular, the usefulness of an electronic diary, with close standardized patient feedback by telephone/mobile phone or the Internet, was investigated for improved pain management. Moreover, the impact of pain was determined on activities of daily living and quality of life after switching pain treatment to a transdermal opioid, in patients with intensive cancer-related, nociceptive, or neuropathic pain.

METHODS

Design and Aim of Study

This was an open, 1-arm 4-week phase IV pain monitoring study in patients under treatment with transdermal fentanyl, for the indications approved in Switzerland. The study included patients with no prior opiate treatment (opiate-naive patients) who were prescribed transdermal fentanyl, and patients who had already been treated with weak or strong opiates, with an indication for a switch from oral therapy to transdermal fentanyl. Patients could be included with the following chronic pain syndromes, for which treatment with potent opiates was indicated: tumor/cancer pain, neuropathic pain (eg, from herpes neuralgia, phantom pain, polyneuropathy, radiculopathy with disc hernia with nerve root compression), and nociceptive pain (eg, from chronic pancreatitis, vertebral fractures linked to osteoporosis, or severe degenerative changes in the spine). The exclusion criterion was the presence of any contraindication to fentanyl (eg, hypersensitivity, comedication with a CYP 3A4 inhibitor, opioid-dependency without manifest cause of pain, bradyarrhythmia), in accordance with the summary of product characteristics published in the Swiss Drug Compendium for DUROGESIC. Children and adolescents below 18 years of age, old people aged above 80, and pregnant and breastfeeding women were also excluded.

Ethics and Approvals

Patients were not compensated for the participation, the study drug was provided by the company. No costs occurred to the patients (the telephone number to answer the questionnaire was toll-free).

The study was approved by Swissmedic, the Swiss Agency for Therapeutic Products, and by the corresponding cantonal/local ethics committees. All patients signed a consent form before enrollment and were informed in accordance with the Declaration of Helsinki.

Patients

Sixty-four female and male patients from 21 paintreating physicians in the German-speaking and French-speaking areas of Switzerland were screened and documented. Sixty patients (60% female) were included in the study. The average age of the patients was 52.1 years (range, 23 to 79 y; median, 52.0 y; interquartile range, 27 y). The main reason for inclusion was nociceptive pain (53%), followed by neuropathic pain (33%) and cancer-related pain (3 patients).

Visit 1 was completed by 60 patients, visit 2 by 58, and visit 3 by 56 patients. Fifty patients used the option to report pain and symptoms by answering more than once the 7 items questionnaire over Internet and telephone. The number of patients and datasets included in the different types of evaluation are summarized in Table 1.

Patients were recruited by pain specialists in hospitals, ambulatory pain centers, and by general practitioners. Patients received pain therapy and were either not satisfied or did not tolerate the current therapy. An informed consent had to be signed by every patient.

Of the 60 patients at visit 1, 35 (58%) had a prior opioid therapy. Twenty-five patients (42%) were opioidnaive. Most of the patients (62%) suffered from severe low back pain of different origin, 12% from severe neck pain, 8% from arthritis, degenerative joint disease or tumors, and 10% from other pain syndromes (Fig. 1).

Forty-eight patients (86%) used transdermal fentanyl over 4 weeks. Eight (14%) patients did not complete the pain therapy during the complete study period. Of these, 4 patients stopped the therapy due to unacceptable side effects (dizziness, constipation, and heat flush), 2 for incomplete pain control, 1 patient did not show up at the follow-up visit, and 1 patient withdrew informed consent.

Data Collection

According to the study protocol, patients visited their doctors 3 times during the 4-week observational period, for normal clinical monitoring of changes in pain (visits 1 to 3) (Fig. 2). During these visits, the patients answered 4 questions to their doctors. Questions (i) + (ii) addressed pain-related impairment of activities of normal daily living and at work; question (iii) addressed sleep impairment due to pain; and question (iv) addressed the

TARIF 1	Number of E	Patients and Datasets	From Visits	Head in	the Evaluation
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Stage	n (patients)	No. Patients Subtracted	Description	Evaluation
Evaluation of patient visits				
No. patients at screening visit	64			
Visit 1 (included patients)	60	4	 1 patient did not show up at visits 	• Evaluation of previous therapy
			• 3 patients did not sign	 Demographics
			the informed consent	 Quality of life
				 Activity of daily living
Visit 2	58	2	 Visit not completed by 	 Quality of life
			physician	 Activity of daily living
Visit 3	56	2	• Visit not completed by physician	 Patient and physician satisfaction with the therapy and system
Evaluation of patient sessions			1 3	17
Patients included (at least visit 1)	60			
Patients with a least 1 reported score	56	4	 4 patients never answered to the questionnaire 	• Adherence to study protocol
Patients with more than 1 score	50	6	6 patients only reported one score	Pain scores (LOCF)Internet, sex, and age-related analysis

patient's own assessment of his or her general state of health. The resulting data on functional impairment (questions 1 to 3) and on quality of life (question 4) were recorded by the doctor in an electronic case report form.

During the first visit, patients were instructed on the procedure for the electronic Internet-based or telephonebased recording of pain scores over time and on data access and control. The patients could decide at any time whether to enter data via the Internet or by telephone. All participating patients had given study consent in advance to provide telephone-based or Internet-based feedback every day during the first week after starting or switching pain therapy, followed by every 3-4 days or according to when the patch was changed during weeks 2 to 4 (Fig. 2). This was based on a standardized questionnaire with a total of 7 questions (Table 2). Three questions related to pain control, covering the mean and maximal pain intensity during the past 24 hours on an ordinal scale from 0 to 10, together with a question on rescue pain medication requirements. Four questions related to the tolerability of the pain medication, particularly gastro-

Distribution of diagnosis (n=60 at Visit 1)

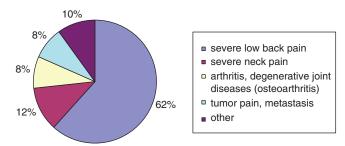
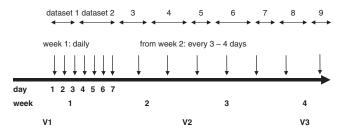


FIGURE 1. Distribution of diagnosis and related pain syndromes.

intestinal side effects (constipation, nausea, sleep disturbances and dizziness, and general side effects).

To answer the questionnaire over the interactive voice response system, a toll-free number was provided. To answer the questions, the appropriate numbers were





V= Visit number (medical consultation)

FIGURE 2. Schedule of telephone and Internet data collection and medical consultations. Overview of study plan. Patients are seen by the doctor at 3 visits (V1-V3). During the first week, patients complete the telephone-based or Internetbased questionnaire once daily. From weeks 2 to 4, patients complete the questionnaire every 3-4 days or according to when the patch was changed. Scores of patients were recorded within 1 month. Fourteen scores per patient were averaged. A basic scheme with 1 answer per day in the first week and 2 answers per week in the weeks 2 to 4 was proposed. However, the scores did not have to be answered at fixed intervals and were therefore recorded at different times and intervals. To display some of the results graphically, all scores were averaged to 9 datasets and averaged as follows: the average of the scores of the first 3 days of the first week represent the first dataset. The next 4 days of the first week represent the second dataset, the first 3 days of the second week represent dataset 3, the next 4 days dataset 4 etc, until dataset 9 after 30 days.

Question 1	"On average, how intense was your pain over the past 24 hours?"	Please enter a number between 0 and 10, where 0 indicates no pain and 10 extremely intense pain	
Question 2	"How intense was the most intense pain you suffered from over the past 24 hours?"	Please enter a number between 0 and 10, where 0 indicates no pain and 10 extremely intense pain	
Question 3	"How often over the past 24 hours have you taken	Please enter a number between 0 and 4:	
	additional pain medication to treat breakthrough pain?"	0 indicates never,	
		1 once,	
		2 twice,	
		3 three times,	
		4 more than three times	
Question 4	"Have you felt constipated over the past 24 hours?"	0 indicates never,	
		1 mild,	
		2 intermediate,	
		3 severe,	
		4 extreme	
Question 5	"Did you feel nausea over the past 24 hours?"	0 indicates never,	
		1 mild,	
		2 intermediate,	
		3 severe,	
		4 extreme	
Question 6	"Have you felt light-headed or sleepy over the past 24	0 indicates never,	
	hours?"	1 mild,	
		2 intermediate,	
		3 severe,	
		4 extreme	
Question 7	"Have you suffered new side effects over the past 24 hours that you have not yet told your doctor about?" We would like to thank you very much for your valuable help and wish you all the best!	Please enter 0 for No and 1 for Yes. "Yes" indicates that you are suffering from considerable or new side effects. Please tell your doctor (or the doctor on duty) about this, so that your therapy can be optimized	

entered using the touch-tone-keypad of the telephone. Patients were instructed by their physician to answer the questionnaire either by telephone or Internet or to use both.

It may have been easier for most physicians to explain the use of the telephone than the Internet. The same username and password were valid to log into the telephone and the Internet system. For security reasons to log into the Internet, 2 randomly drawn letters or digits from a second password were asked to be entered at every login in addition to the username and password.

Data could be entered 24 hours per day and 7 days per week. Additional entries to the study protocol were allowed at any time during the study period. However, a minimal interval of 12 hours between 2 entries had to be respected to allow consecutive entries to be considered as valid. Entries within 12 hours were considered as corrections of the previous entry. Therefore, if 2 entries were recorded within 12 hours only the last entry would be considered as valid and the previous entry would be set as invalid (yet kept in the database to assure a complete track record). This option was provided to allow the patients to change their last entry within 12 hours. Patients were given the option to review their entries over the Internet platform in a graph and to check their answers.

Patients were reminded 3 times within a 3-hour interval by e-mail and SMS (this option could be selected by the physician or the patient and depended on the availability of these tools for the patients) to answer to the questionnaire according to the study protocol (ie, every day in the first week, twice a week from

week 2 to 4). If no answer was recorded after the third reminder, the entry was labeled as missing. Patients received short written instructions how to use both data entry systems.

The option to enter additional data was offered to the patients to enable the information of the physicians about peaks of pain and possible side effects at any time. Physicians could define in the system if they wanted to receive alerts by e-mail and SMS when a patient answered the questionnaire, or if they wanted to receive a message only when a predefined threshold level for each answer was met.

Notification was sent to the physician if the mean pain score was 5 or more and if the physician activated this option on the platform. Additionally, an optional alert was sent to the physician if severe or extreme side effects (questions 3 to 6) were reported or if the last question about new and severe side effects was answered with "yes" (question 7).

On the occasion of the last study visit, usually after 4 weeks, general patient satisfaction with the pain therapy, patient preference for either Internet or telephone, and the doctor's overall satisfaction with this novel instrument for documenting changes in chronic pain over time were recorded.

Analysis and Statistics

Scores of patients were recorded within 1 month. The system was setup to ask for 14 scores per patient within 1 month. The scheme included 1 answer per day in the first week and 2 answers per week in the week 2 to 4.

However, the scores did not have to be answered at fixed intervals and were therefore recorded at different times and intervals.

To display graphically some of the results, all scores were averaged to 9 datasets (Fig. 2). The average of the scores of the first 3 days of the first week represent the first dataset. The next 4 days of the first week represent the second dataset, the first 3 days of the second week represent dataset 3, the next 4 days dataset 4 etc, until dataset 9 after 30 days.

The following analysis and statistical tests were performed to describe the changes in the different parameters collected from patients (overall and in specified subgroups). The baseline was defined as the mean score from the first pain score and the end point is defined by the last observation carried forward (LOCF) method. The average number of scores recorded in this group, which included only patients with at least 2 selfreported pain scores were included. To analyze the statistical significance of changes in pain (overall and in the specified subgroups), the baseline (defined as the first score per patient) was compared with the last dataset as defined by the LOCF method. Wilcoxon signed-rank test was used to compare the scores at baseline and LOCF with the same group. Mann-Whitney test was performed to compare scorers between different subgroups.

Mann-Whitney test was also performed to compare parameters collected at the physicians' visits 1 to 3 (mean and maximum pain score, limitation in daily activities of living, quality of life). P < 0.05 were considered significant.

RESULTS

Method-related Results and Overall Patient and Doctor Satisfaction With Therapy and Pain Monitoring

A completely documented series of doctor visits (V1 to V3) was recorded and analyzed for 56 (93%) of the 60 included patients. Of the 60 patients included into the study who were expected to answer 14 times (total of 840 expected scores), 56 have answered at least once and collected together a total of 712 scores within 30 days. This corresponds to 84.6% of the datasets asked (Fig. 3). The average number of scores per patients was 12.7 (mean number of scores in LOCF) (Fig. 4).

Patients who used the telephone alone were compared with the patients who used the Internet (either with or without additional use of the telephone). Only patients who answered at least twice were considered (n = 50 patients). As expected patients who used the Internet alone or in addition to the telephone tended to be younger, however, this difference was not significant (mean, 46 vs. 54 y; P = 0.054). After completion of the 4-week monitoring phase, a total of 52% of patients switched to transdermal fentanyl were satisfied with the therapy. Thirty percent perceived no difference and 18% evaluated their condition as worse than before switching therapy (Fig. 5).

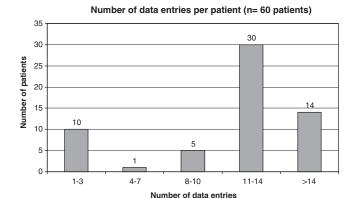


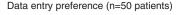
FIGURE 3. Number of data entries per patient.

Seventy percent of the patients would prefer an electronic pain diary to a paper pain diary (Fig. 6). Moreover, 62% of the participating doctors rated this new flexible manner of monitoring pain changes as good or very good (Fig. 7).

Results Related to the Internet-based or Telephone-based Pain Monitoring

In the total period of 4 weeks after starting or switching to treatment with transdermal fentanyl, the mean pain intensity as reported by the patients decreased by 19% [from 6.8 to 5.5 (mean of LOCF) of the Numeric Rating System score 0 to 10; P < 0.0001]. The changes in maximal pain intensity exhibited a similar profile [from 7.8 to 6.7 (LOCF), -14%, P = 0.0001]. Significant improvement of pain score from baseline to LOCF was found for both opioid-naive patients [6.6 vs. 5.3 (LOCF); -19.7%, P = 0.04] and for patients with prior opioid use [6.9 vs. 5.6 (LOCF); -18.8%, P = 0.03].

At the time of inclusion in the study, the average pain reported by opiate-naive patients was somewhat less (but not significantly) than that suffered by previously treated patients (6.6 vs. 6.9, P = 0.4). Moreover, the opiate-naive patients responded slightly but not significantly better to therapy after 4 weeks of treatment [5.3 vs. 5.6 (LOCF) of 10 points, P = 0.54] (Fig. 8).



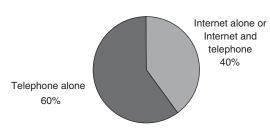


FIGURE 4. Data entry preference: 24 (40%) used the Internet alone or the Internet and telephone to answer to the questions.

"He/she is satisfied with the Durogesic -pain therapy compared to the time before" (n=56 patients)

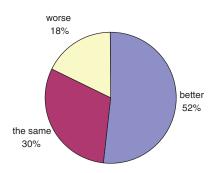


FIGURE 5. Satisfaction of patients with the pain therapy.

The improvement in mean pain score from baseline to LOCF was smaller for men (-11.9%, P=0.06) compared with women (-23.2%, P=0.03). The difference between men and woman at the study end was not significant (5.9 vs. 5.3, P=0.42). Intake of rescue pain medication (baseline vs. LOCF) did not change significantly during the observation period (once to twice daily; P=0.12).

The overall tolerability of transdermal fentanyl in pain treatment was good. No significant increase was observed in constipation, nausea, or dizziness from baseline to LOCF of these parameters (P = 0.62 for constipation, P = 0.61 for nausea, and P = 0.3 for dizziness.

In accordance with the protocol, thresholds were predefined for alerting the physician by e-mail if new side effects appeared or did exacerbate. This option was optional and had to be activated by the physician. Overall, this threshold (severe, extremely severe) was reached for side effects (question 4 to 6) in average 1.0 times per patient [total of 51 (7%) of all 712 recorded scores for constipation]; 1.3 times [total of 64 (9%) of all scores for nausea], and 1.5 times [total of 77 (11%) scores for dizziness]. New side effects (question 7) were reported 81 times (11%) out of 712 recorded answers (11%) of the patients' scores. The relatively high number of reported

"He/she prefers an electronic pain-diary to a paper-diary" (n=56)

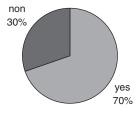


FIGURE 6. Preference of patients of an electronic pain-diary versus paper diary.

My degree of satisfaction with the e-diary is as follows (n = 21 doctors)

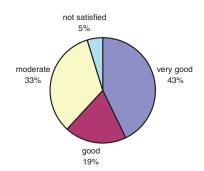


FIGURE 7. Satisfaction of physicians with the e-diary.

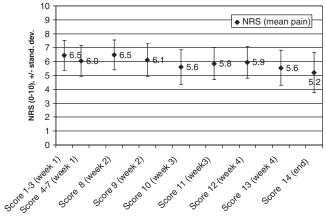
new side effects were all reported by 20 patients (40%) alone.

Although physicians were advised to use laxatives and antiemetics, 9 (18%) patients reported 65 (80%) of all strong side effects, and 1 patient reported 17 times that he had experienced severe new side effects (Fig. 9).

Evaluation of Physician's Visits: Pain and Pain-related Limitation of Activities of Daily Living and Quality of Life

The data recorded by the investigator during the 3 visits were compatible with those from the electronic patient questionnaire. The mean pain intensity decreased from 5.8 to 4.4 (-24%, P=0.005) and the maximal pain intensity from 7.1 to 5.8 (-18%, P=0.003) within 4 weeks (Fig. 10). Pain-related limitation of activities of daily living was reduced by 23% (from 2.6 to 2.0, P=0.0008) on a 5-point scale (from 0, none, to 4, extreme limitation). Pain treatment showed no effect on quality of life (from 2.4 to 2.2, P=0.26 on a 5-point scale from 0, very good, to 4, very poor) (Fig. 11).

Mean Pain Score (n=50 patients)



Mean of score number in week 1-4

FIGURE 8. Mean pain score averaged to scores as 9 datasets.

FIGURE 9. Number of new side effects reported by patients.

DISCUSSION

This open-label 4-week study was performed in collaboration with pain specialists. The aim was to document the feasibility and utility of freely selected Internet-based or telephone-based monitoring of pain changes in patients reporting chronic cancer or noncancer pain. In addition, the effects of transdermal fentanyl were examined on activities of daily living and quality of life.

A complete dataset was available for more than 90% of the patients enrolled in this study. This result is in accordance with previous studies showing that patients have a clear desire that their responsible doctor is closely monitoring pain and that patients are thus prepared to cooperate in this kind of study. 6,12,15,16

NRS in accordance with patient questionnaire during visits to the doctor (V1-V3)

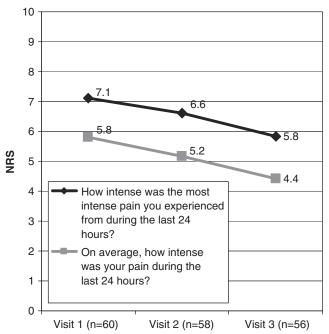


FIGURE 10. Numeric Rating System in accordance with patient questionnaire during visits to the doctor (V1-V3).

How strong have you been limited by pain in your activities of daily living (Visit 1-3)?

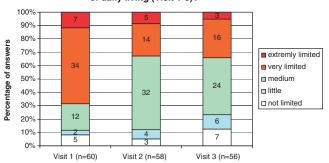


FIGURE 11. Limitation in activities of daily living: this figure depicts the proportion of patients with different degrees of limitations (visits 1 to 3). The proportion of patients who are extremely or very limited decreases significantly over time (P=0.005).

The changes in mean and maximal pain intensity recorded electronically by patients were comparable with the values recorded by doctors during the visits. Although the analgesic effect of transdermal fentanyl tended to be higher in opiate-naive patients compared with opioidexperienced patients, no difference in tolerability was found. This observation is comparable with the results of earlier studies with transdermal fentanyl in opiatenaive^{17,18} and previously opiate-treated pain patients. ^{19–22} Consistent with this observation, limitation of activities of daily living after switching to transdermal fentanyl improved over 4 weeks in comparison with the initial values. This is also compatible with results from earlier controlled studies.^{22,23} No significant improvement in quality of life could be demonstrated, probably reflecting the fact that the evaluation of quality of life was based on a single question that may be insufficiently sensitive to detect the changes described in earlier studies.^{22,23}

It was a characteristic of this study that patients could freely decide whether they wanted to answer the questions via the Internet or by telephone. Younger patients tended to use the Internet, whereas older patients preferred the phone. In an earlier study,²⁴ a technologybased symptom screening process using touch-tone telephones and the Internet was documented for adult cancer patients in the United States. In addition to current employment, and higher education and income, higher rates of Internet access were related to younger patient age, a finding that is consistent with our observations. In addition, the preferred means of symptom reporting in patients with Internet access was the touch-tone telephone (70%), compared with reporting via the Internet (28%), a result that is similar to our observations.²⁴

Although there was no control group, this study revealed that an electronic pain diary was preferred overall by most doctors and patients to keep a paper diary. When asked if they used the Internet at home or at workplace, 54% of the patients stated that they used the Internet. The relatively high number of patients generally

not using the Internet (46%) is likely to have contributed to the low usage of the Internet in our study.

The Internet-login procedure might have discouraged some patients to use the Internet because they were less familiar with the security login procedure. It must be emphasized, however, that the Internet offered more options to the patients than just answering to the questionnaire by touch phone: reviewing the entries and change the way to receive reminders.

A limitation of this study was that it was not designed to show the specific opioid effects in treated patients. Therefore, the efficacy and safety results must be interpreted with caution.

CONCLUSIONS

There is broad consensus on the need for pain monitoring during treatment, especially in patients whose opioid therapy has been initiated or switched. For this reason, patients seem to be ready to participate in Internet-based or telephone-based pain monitoring. The combination of an Internet-based pain diary with a SMS reminder function offers doctors and patients significant advantages for pain monitoring and documentation. The acceptance of electronic pain monitoring by patients and doctors is expected to increase.

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