

ORIGINAL ARTICLE

Recruiting newly referred lung cancer patients to a patient navigator intervention (PACO): lessons learnt from a pilot study

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ABSTRACT

Objectives: The incidence of and survival from lung cancer are associated with socioeconomic position, and disparities have been observed in both curative and palliative treatment for lung cancer. 'Patient navigation' is valuable in addressing health disparity, with timely treatment and transition to care. We conducted a pilot study to test the feasibility of a patient navigator program (PATient COach) for newly diagnosed lung cancer. We present the trial, the findings from the pilot study and discuss factors that might have affected recruitment rates.

Material and methods: We invited 24 lung cancer patients referred for chemotherapy to the Oncology Department at Herlev University Hospital, Denmark, to participate in the pilot study. To be eligible, patients had to live alone, have no formal education beyond secondary school, have one or more comorbid conditions, have a performance status of 1 or 2 or be over 65 years of age. The patient navigators targeted four phases of treatment: planning, initiation, compliance and end of treatment.

Results: Six months after the start of the study, we had recruited only six patients, due mainly to inherent patient resistance and because only 50% of eligible patients were invited. Of the 18 patients who did not wish to participate, 13 agreed to fill in a baseline questionnaire. The most frequent reason given for not wanting to participate was a belief that a patient navigator would be of no benefit.

Conclusions: The pilot study met a number of internal and external obstacles to patients' recruitment. The study provides insight into the barriers to recruitment of socially disadvantaged cancer patients to clinical trials and will inform future trial designs.

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Social and demographic characteristics like length of education, cohabitation status and age of lung cancer patients are associated not only with incidence and survival [1,2] but also with their treatment. In a nationwide cohort of Danish lung cancer patients, disparities were observed in both curative and palliative lung cancer treatment, even after adjustment for performance status and comorbid conditions [3]; with an inclusive definition of first-line treatment, 46% of patients did not receive the treatment recommended for their stage of disease or performance status, and patients with higher education and income and who lived with a partner were more likely to receive treatment. Other studies show that older lung cancer patients do not receive optimal treatment, although age itself does not worsen the efficacy of or tolerance to combined induction and definitive treatment [4], radiotherapy [5], or concurrent chemotherapy and radiation [6].

Patient navigation might be a useful intervention for addressing social disparities in cancer treatment [7]. Use of lay or professional patient navigators has been tested in a

number of studies, with promising results, especially for vulnerable patient populations [8–11], although the findings are mixed [12–14]. The main functions of patient navigators in many of the previous studies were to identify and address barriers to timely diagnosis, treatment, and other health care, and to help under-served patients to attain better transition to another treatment phase or sector and improve the timeliness of starting treatment.

Few studies have tested patient navigation in lung cancer patients, and, so far, none has addressed the issues of treatment initiation or adherence in these patients. In view of the observed social inequality in survival from lung cancer, means are required to ensure optimal treatment of disadvantaged patients. The survival rate in the most advantaged group of lung cancer patients should be the target for all lung cancer patients in Denmark, regardless of their socioeconomic position or age.

We therefore developed the PATient COach (PACO) program, in which socially disadvantaged patients with newly diagnosed lung cancer are assigned to a health-educated

volunteer patient navigator who addresses barriers to treatment adherence at the levels of the patient, the provider, and the organization, by providing social support, practical assistance, and links with health personnel. As per the protocol, we tested the feasibility of the PACO program in a pilot study before conducting a randomized controlled trial to test the program.

We present here the PACO intervention, evaluate the acceptability of the pilot study and discuss factors that may have affected recruitment to the study.

Material and methods

Setting and patients

We designed a randomized trial involving patients with newly diagnosed lung cancer referred for chemotherapy in the Oncology Department at Herlev University Hospital, University of Copenhagen, Denmark. To be eligible, patients had to fulfill one or more of the following criteria at the time of inclusion: live alone, have no formal education beyond secondary school, have one or more comorbid conditions, have a performance status of 1 or 2 or be over 65 years old. The exclusion criteria included psychosis, dementia, being institutionalized, performance status >3 and lack of proficiency in Danish.

The study protocol was accepted by the Danish Data Protection Board (file no. 2015-41-4236) and notified to www.clinicaltrials.gov (Protocol no. R73-A4769-13-S17). As no human biological material was included in the project, the study did not require approval from the Committees on Health Research Ethics for the Capital Region of Denmark (Protocol no. H-15008269 FSP).

Preparation for the randomized trial

A previous study in Denmark showed that optimal treatment is initiated on the basis of performance status and cancer stage for 57–63% of patients with higher education and for 50% of patients with short education, and the corresponding numbers for patients who are cohabiting versus single were 57% and 50% [3]. We assumed that the intervention would increase the proportion of patients who initiate treatment to 65% and therefore required 133 patients in each study arm for a power of 80% and a confidence level of 5% (one-sided test). On the assumption of 15% attrition during follow-up (mainly due to death), 306 patients were to be enrolled. We planned to randomize 1:1 to standard treatment plus the PACO intervention or to standard treatment alone.

The primary outcome of the PACO intervention was receipt of optimal, standardized first-line treatment according to stage, histological findings and performance status. Supplementary Table 1 illustrates the matrix for defining optimal first-line treatment. The secondary aims were improved quality of life, lower symptom burden, greater self-efficacy and patient 'activation' (patients' knowledge, skill and confidence for self-management), smoking cessation, more physical activity, dietary changes and longer short-term

survival. More detailed information on the design of the trial and the underlying concepts is available at www.clinical.gov.

To test the acceptability of the program, patients were assigned to a volunteer patient navigator during a pilot study between January and June 2016.

Recruitment

We recruited patients as early as possible after their referral so that the patient navigator could help them during all phases of treatment. A few days before the start of treatment, the medical staff at the clinic approached eligible patients, provided oral and written information and obtained informed consent. To optimize recruitment rates, the patients were allowed to postpone their decision to participate until after the first treatment (chemotherapy) but before the second treatment one week later.

Outcome measures

Information on clinical factors such as disease stage, treatment, performance status and comorbid conditions was obtained from medical files. Questionnaires were distributed to participants before the start of treatment, at the end of treatment and one month after the end of treatment.

Patient-reported outcome measures were derived with three validated questionnaires: EORTC-C30 and LC13 (overall quality of life, functioning and lung cancer-specific symptoms) [15,16]; the General Self-Efficacy Scale, a measure of patients' belief in their ability to deal efficiently with stressors [17]; and the Patient Activation Measure (PAM13) which measures the patients' knowledge, skill and confidence for self-management [18].

Information on sociodemographic status (education, cohabitation, work market affiliation, social relations) and lifestyle factors (smoking, alcohol consumption, height and weight) was obtained from a study-specific questionnaire.

Further, at each session, the patient navigators assessed lung cancer-specific symptoms with EORTC LC13. At Sessions 1, 4 and 6, the navigators also assessed the patients' requirements for supportive care with a study-specific checklist. The needs assessed included help in relation to treatment, arranging transport, personal needs, communicative and cultural needs, economic or administrative needs, and establishing or maintaining a social network.

The PACO intervention

The PACO intervention and outcome measures are illustrated in Figure 1. The tasks of patient navigators are based on three principles: assist, support, and link. They provide practical assistance, such as help in expressing concerns or organizing transport; social support by showing empathy and acceptance; and links with health personnel if symptoms progress or patients do not comply with treatment. Eight navigator-patient sessions were planned, to target the four phases of the treatment trajectory (planning, initiation, adherence, and end of treatment) in four face-to-face sessions of

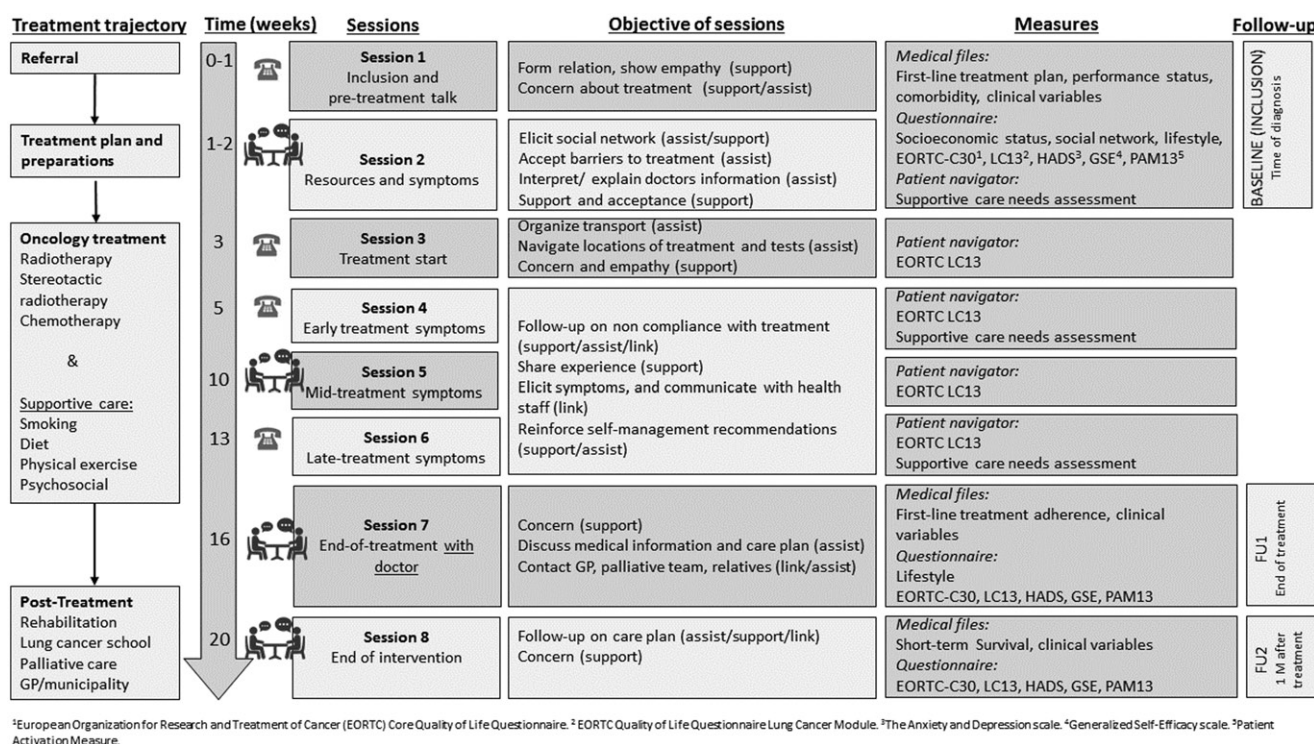


Figure 1. Overview of the PACO intervention.

approximately 1–2 hours and four telephone calls, from inclusion to about one month after the end of treatment over about 20 weeks (Figure 1). Deviations from this schedule depended on the treatment modules and the wishes and needs of the patient. Although the eight sessions were mandatory, more meetings or phone calls could be planned if the patient or navigator considered them necessary.

Training of patient navigators and medical staff

Careful selection and training of patient navigators were critical to the support program. We decided to recruit volunteers with a health education, as knowledge of the health care system is necessary to provide support in treatment decisions, treatment adherence, navigation among wards and adequate feedback to treatment staff. As many lung cancer patients have advanced or rapidly progressing disease, it was important that the volunteer could manage the challenge both personally and professionally. The volunteers were recruited through advertisements in local papers, nursing journals and the professional network of the Danish Cancer Society.

The volunteers attended a three-day workshop, at which they were trained in (1) understanding the project, including privacy and confidentiality; (2) lung cancer, its treatment, organization of care, options for supportive care, municipal rehabilitation programs, palliative care and means of communication with the health care staff in the project; (3) eliciting, exploring and responding to patients' concerns, active listening and providing empathy; and (4) coaching and communication with patients to reinforce self-care strategies recommended by hospital staff. The workshop was run by the study group, with a lung oncologist and a lung oncology nurse.

A manual was prepared, with guidelines for the content of each session and practical information about the organization of lung cancer care on the oncology ward, guidance in the role as a volunteer and patient navigator, step-by-step instructions in how to telephone or otherwise approach patients, a list of useful websites, additional services, available resources, and other possible patient support services.

A training and information session was arranged for the medical staff to introduce the project and the content of the eight coaching sessions, clarify the role of the patient navigators and discuss mutual expectations, formal responsibilities, optimal feedback, and collaboration between coaches and staff. A dedicated nurse employed at the clinic was in charge of daily supervision of the recruitment of patients.

Investigating the acceptability of the study – the pilot study

In order to optimize the analysis of non-responders, patients who refused to participate were asked to sign a consent form, fill in a baseline questionnaire and clarify their reasons for refusing. At their last treatment session in the hospital, the patients were again approached by the study nurse, interviewed about their thoughts about and reasons for not wishing to participate in the study at the time they were asked and whether they would have considered participating if they had been invited at another time or under other circumstances. The interview was based on a standardized guide, with additional open-ended questions. Patients who participated were also interviewed about their experience of the study.

We compared the list of all patients who had attended the clinic during the first three months of the study period with the list of patients who had been invited.

Statistical analysis

Data on feasibility were evaluated with descriptive statistics. Differences in the characteristics of participants and those who refused to participate at baseline were assessed by logistic regression with group as the dependent variable and with adjustment for age at diagnosis. As all participants were assigned a patient navigator, we did not evaluate preliminary outcomes.

Results

During the six-month pilot study, 24 eligible patients were invited to participate. Of these, six (25%) agreed to participate. One died shortly after inclusion and did not receive the intervention, and another died halfway through the intervention and attended only four of the eight sessions. The four remaining participants attended all eight sessions and had 3–16 additional meetings with a navigator by telephone or in person. The length of meeting varied from 10 minutes to four hours.

At the end of the intervention, the four participants reported that the patient navigator had helped them to relieve stress, disentangle worrying thoughts and have a better overview of the treatment and their symptoms.

Owing to the difficulty in recruitment, we did not evaluate the remaining feasibility issues.

Of the 18 patients who refused to participate, 13 agreed to fill in a baseline questionnaire, while five actively refused to do so. Several reasons were given for refusal to participate (Table 1). The most frequent were that they did not consider that they would benefit from the intervention and that they already had a well functioning, supportive social network. Several gave more than one reason for not wishing to participate. At the end of treatment, all those who refused were asked whether they would have considered participating if they had been asked at another time; none said they would.

Although the numbers are very small, no difference was found in baseline variables between participants and those who refused, except the gender distribution, which was reversed in the two groups, and more diagnoses of adenocarcinoma in the group that refused (61% vs. 33%,

$p = 0.0001$) (Table 2). Participants also tended to have higher education than those who refused, although the difference was not significant.

Except for global quality of life, role functioning, pain, insomnia and constipation, the 13 patients who refused but who filled in the questionnaire reported higher mean values in functioning and overall and lung cancer-specific symptoms than participants indicating that those who refused had

Table 2. Baseline clinical factors, sociodemographic and lifestyle information on six participants and 13 who refused to participate in the PACO pilot study.

	Participants (n = 6)	Refusers (n = 13)
Mean age at inclusion (years)	67	71
Gender		
Male	2	8
Female	4	5
Histological type		
Squamous-cell carcinoma	3	4
Adenocarcinoma	2	8 ^a
Large-cell neuroendocrine carcinoma	0	1
Carcinoma not otherwise specified	1	0
Disease stage		
Surgically treated (T1-3, N0-1, M0)	1	2
Locally advanced (T1-4m, N0-3, M0)	2	5
Metastatic (any T, any N, M1)	3	6
Performance score		
0	4	7
1	1	2
2	1	4
Treatment		
Chemotherapy	6	13
Radiation	2	2
Comorbidity		
Chronic obstructive lung disease	3	8
Other	5	12
Smoking		
Never	0	2
Ever	6	11
Alcohol consumption (units) ^b		
≥7/14	1	4
<7/14	2	5
None	2	3
Unknown	1	1
Body mass index (kg/m ²)		
Underweight (<18.5)	1	0
Normal weight (18.5–24.9)	2	5
Overweight (25–29.9)	1	7
Obese (≥30)	1	1
Unknown	1	–
Length of education ^c		
Short	1	4
Medium	1	5
Long	4	4
Civil status		
Married or cohabitating	3	10
Single, divorced or widowed	3	3
Work market affiliation		
Working	3	2
Early retirement	1	1
Age pension	2	10
Social network		
Family nearby	6	11
Family at distance	4	6
Friends nearby	4	9
Friends at distance	0	3

^a $p = 0.0001$;

^bNational alcohol recommendations: maximum 7 units for women and 14 units for men per week;

^cShort education: mandatory education up to 7 and 9 years for patients born before and after 1 January 1958, respectively; medium education: highest grade of primary school, secondary school or vocational education (8–12 years for patients born before 1 January 1958 and 10–12 years for patients born after 1 January 1958); higher education: >12 years of education.

Table 1. Reasons for not wishing to participate in the PACO pilot study.

Reason	No. of patients
Did not consider they would benefit from a navigator	13
Access to help from other sources (e.g. spouses, children, friends, municipality)	3
Did not want a 'professional mourner'	2
Considered participation would be too time consuming and an extra burden	1
Had no energy to participate	1
Was not comfortable in sharing personal information with strangers	1
Did not approve of the study	1

Patients could state more than one reason.

better functioning but more symptoms (Table 3). Participants also reported higher levels of depression and anxiety than those who refused, which approached significance in spite of the small numbers ($p = 0.06$). No differences in self-efficacy at baseline were found between participants and those who refused [mean (SD), 31.5 (3.7) vs. 30.3 (8.1), respectively]; however, the level of patient activation was higher in the group that refused than in participants [mean (SD), 40.8 (9.9) vs. 58.1 (22.1), respectively], although not significantly.

Comparison of the lists of eligible referred patients and of those invited during the first half of the study period showed that 20 patients were invited, while 21 fulfilled the inclusion criteria but were not invited. Thus, only 50% of eligible patients were invited.

Discussion

Recruiting patients continues to be a problem in many clinical trials. In an analysis of clinical trials of adult cancer patients registered at clinicaltrials.gov, poor accrual was the most common reason for early termination of a clinical trial [19]. Patients' social position and other patient factors affect accrual to trials [20]. Although socially disadvantaged cancer patients are underrepresented in clinical trials, these are the patients who tend to have more comorbid conditions and symptoms and a less healthy lifestyle than socially advantaged patients [21,22], and therefore potentially have more to gain from, for example support through medical care and changes in lifestyle. It is therefore critical to identify barriers to patient recruitment and accrual in order to ensure generalizable, robust findings.

Patient reluctance

The majority of the eligible patients approached for the present study chose not to participate, as they did not regard themselves in need of extra support from a patient navigator, suggesting that the intervention per se (or the way in which it was presented) simply did not appeal to the patient population. Although the numbers are small, we found no obvious differences in characteristics between those who participated and those who did not. A similar problem with inclusion of patients in navigator programs has not been described in the literature where refusal rates from less than 1% to 23% have been reported [7]. However, the difficulty of engaging hard-to-reach patients with low socioeconomic position are well known [23–25], and patient factors such as mistrust of research and the medical system [24,26], concern about loss of control in decision making, the experimental aspect of trials [25] and logistical barriers such as inability to take time off work [23] are major obstacles to accrual in many trials.

Some of the inclusion criteria may also have presented challenges to recruitment. As we identified socially disadvantaged patients by formal sociodemographic criteria, we had no information on their personal resources or informal social networks. In hindsight, it is evident that the patients' personal resources and access to informal help from family or friends was unequally distributed. A better approach would be to screen patients for their need for supportive care before assigning them to a patient navigator.

Timing

Another potential obstacle to recruitment was the timing of inclusion. Within two weeks, patients undergo a number of

Table 3. Baseline information on quality of life, symptoms, general self-efficacy and patient activation in six participants and 13 'refusers' in the PACO pilot study.

Scale	Participants (n = 6) [mean (SD)]	Refusers (n = 13) [mean (SD)]
European Organization for Research and Treatment QOL-C30 core questionnaire ^a		
Global quality of life	58.3 (19)	51.3 (31.7)
Physical functioning	62.2 (24.8)	74.4 (24.5)
Role functioning	58.3 (37.6)	57.7 (44.4)
Emotional functioning	51.4 (26.6)	71.4 (23.4)
Cognitive functioning	77.8 (25.0)	80.8 (21.3)
Social functioning	66.7 (33.3)	69.2 (38.9)
Fatigue	50 (28.8)	52.1 (36.9)
Nausea and vomiting	5.5 (8.6)	14.1 (30.3)
Pain	44.4 (31.0)	33.3 (46.6)
Dyspnea	22.2 (27.2)	38.5 (22.9)
Insomnia	38.9 (32.8)	35.9 (31.8)
Appetite loss	27.8 (44.3)	33.3 (45.1)
Constipation	38.9 (25.1)	20.5 (34.7)
Diarrhea	11.1 (17.2)	20.5 (34.7)
European Organization for Research and Treatment QOL-LC13 lung cancer-specific module ^a		
Dyspnea	18.5 (19.4)	26.0 (22.6)
Coughing	27.8 (25.1)	43.6 (28.5)
Dysphagia	5.5 (13.6)	23.1 (31.6)
Peripheral neuropathy	5.5 (13.6)	7.7 (14.6)
Chest pain	22.2 (40.4)	12.8 (21.7)
Hospital Anxiety and Depression Scale (HADS)		
Depression	8.8 (4.6)	5.1 (5.2)
Anxiety	11 (3.5)	6.5 (4.9)
Level of general self-efficacy	31.5 (3.7)	30.3 (8.1)
Level of patient activation	40.8 (9.9)	48.1 (22.1)

None of the mean values were significantly different between participants and refusers. ^aOn the functional scales, a higher score represents a higher level of functioning; on the symptom scales, higher scores represent more problems.

tests and preparations before they can begin treatment, and receive careful explanations about their disease and its treatment. Some patients struggle to comprehend and absorb all the necessary information during this short period, while at the same time dealing with the prospect of a possibly deadly disease; this may also have affected patients' willingness to participate in our study. In a study of patients undergoing hematopoietic stem cell transplantation who participated in focus groups, they commented that the informed consent process had included too much verbal and written information, and they were intimidated by the medical and legal language [27].

To allow patients more time to decide on participation, we postponed their inclusion to a few days before the start of treatment and not, as originally planned, at the time of referral. Later, we allowed patients to postpone their decision to participate in the study until after the first treatment. Nevertheless, the interviews with those who refused showed that, retrospectively, none would have agreed to participate if they had been invited at another time, indicating that their perception of the value of a patient navigator was more important than the timing of recruitment. This may indicate that culturally and socially sensitive recruitment strategies should be used [28]. To assure the acceptability of clinical trials by patients who are recruited when they start active treatment, it may be useful to involve patients actively in the design of the intervention and to adjust the content of the intervention according to their preferences.

Provider reluctance

Provider reluctance is another known obstacle to recruitment of patients into clinical trials, and clinicians' attitude to the suitability of patients for clinical trials and their belief in trials are increasingly recognized as important barriers to patient recruitment [25]. For example, Hamilton et al. found that surgeons and recruiters of patients to trials of head-and-neck cancer did not always adhere to the eligibility criteria and different treatment arms were not equipoised [29]. Other barriers include assumptions about patient eligibility, use of resources for conducting a trial in daily clinical practice, concern about loss of control of patient care, logistic barriers, a perceived extra administrative burden, and lack of time and resources [30].

Only about half the eligible patients referred to treatment in the department were invited to participate in the study. The reasons are unknown, but some may have been excluded on the basis of presumptions about the patients rather than their eligibility. Even if all eligible patients had been approached, however, the inclusion rate would probably still have been low, given the small proportion who agreed to participate.

System resources

The complexities and time required in obtaining informed consent and ensuring that patients read the study material and fill in questionnaires might also have been barriers.

Lack of resources is commonly stated as a major obstacle to accrual in daily clinical practice [25]. During the recruitment period in this pilot study, a new, comprehensive electronic system was introduced throughout the hospital, which was relatively demanding and time consuming for staff. Further, shortly before the start of the pilot study, about half the nurses resigned, putting further stress on the remaining staff. The pilot study was initiated before introduction of the new system but after the staff resignations. We therefore simplified the logistics of the trial and minimized the tasks of the staff in recruiting the patients; all other tasks were performed by the research team. These system-level obstacles may have affected both the invitation and the recruitment rate.

Conclusion

In this pilot study of a patient navigator system for socially disadvantaged patients with newly diagnosed lung cancer, a number of internal and external obstacles challenged recruitment. They included patient reluctance, restrictive eligibility criteria and lack of resources at provider level. Due to the low recruitment rate, we chose to abandon PACO; however, the pilot study provided insights into the barriers to the recruitment of socially vulnerable cancer patients into trials. The experience is essential for planning targeted supportive care interventions at the time of treatment.

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