

BMJ Open Impact of patient information leaflets on doctor–patient communication in the context of acute conditions: a prospective, controlled, before–after study in two French emergency departments

Mélanie Sustersic,^{1,2} Marisa Tissot,² Julie Tyrant,² Aurelie Gauchet,³ Alison Foote,² Céline Vermorel,² Jean Luc Bosson²

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MT and JT contributed equally.

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For numbered affiliations see end of article.

Correspondence to

Dr Mélanie Sustersic;
melanie.sustersic@gmail.com

ABSTRACT

Objective In the context of acute conditions seen in an emergency department, where communication may be difficult, patient information leaflets (PILs) could improve doctor–patient communication (DPC) and may have an impact on other outcomes of the consultation. Our objective was to assess the impact of PILs on DPC, patient satisfaction and adherence, and on patient and doctor behaviours.

Design Prospective, controlled, before–after trial between November 2013 and June 2015.

Setting Two French emergency departments.

Participants Adults and adolescents >15 years diagnosed with ankle sprain or an infection (diverticulitis, infectious colitis, pyelonephritis, pneumonia or prostatitis).

Intervention Physicians in the intervention group gave patients a PIL about their condition along with an oral explanation.

Main outcome measures 7–10 days later, patients were contacted by phone to answer questionnaires. Results were derived from questions scored using a 4-point Likert scale.

Main findings Analysis of the 324 patients showed that PILs improved the mean DPC score (range: 13–52), with 46 (42–49) for 168 patients with PILs vs 44 (38–48) for 156 patients without PILs ($p<0.01$). The adjusted OR for good communication (having a score >35/52) was 2.54 (1.27 to 5.06). The overall satisfaction and adherence scores did not show significant differences. In contrast, satisfaction with healthcare professionals and timing of medication intake were improved with PILs. The overall satisfaction score improved significantly on per-protocol analysis. When using PILs, doctors prescribed fewer drugs and more examinations (radiology, biology, appointment with a specialist); the need for a new medical consultation for the same pathology was reduced from 32.1% to 17.9% (OR 0.46 [0.27 to 0.77]), particularly revisiting the emergency department.

Conclusion In emergency departments, PILs given by doctors improve DPC, increase patients' satisfaction with healthcare professionals, reduce the number of emergency consultations for the same pathology and modify the doctor's behaviour.

Trial registration number NCT02246361.

Strengths and limitations of this study

- A patient information leaflet is a simple way to improve doctor–patient communication and physician behaviour in emergency departments (EDs).
- All scores used in the methodology were generic and based on the same solid theoretical model describing a consultation for an acute condition.
- The only study design possible was a before–after study to avoid contamination bias between physicians in the particular context of an ED.
- No non-inclusion form was registered by physicians, which may bias patient selection.

INTRODUCTION

Acute conditions (ACs) are a very common reason for consultation in primary care, both in general practice and in emergency departments (EDs). An AC can be defined as a condition of short duration.¹ Faced with an AC, 'the primary goal of the physician is to improve health and effectiveness largely depends on time-sensitive and, frequently, rapid intervention'.²

In an ED, the combination of frequent interruptions and multiple concurrent doctor tasks may lead to clinical errors.³ The lack of familiarity between patients and physicians, and the complex, high-stress, unpredictable and dynamic work,⁴ present challenges for effective communication.

In this stressful context, giving patients information can be difficult as physicians have restricted time for each patient and the patient's capacity to retain information is often limited.⁵ Besides the condition itself, the ED is a place where frequent lack of comfort, high influx and overcrowding may be upsetting for the patient. Discharge from the ED can be a period of vulnerability for patients.^{5,6} They run

the risk of further clinical deterioration, may experience side effects from a newly prescribed drug or even suffer from the consequences of a wrong diagnosis.^{5,7}

In the ED, the information delivered by the physician to the patient is crucial,^{8–10} and if it is insufficient, neglected or misunderstood the patient could suffer complications.^{8,9} Patient information leaflets (PILs) appear to be highly suited to this context. They play a role in the continuity of care by facilitating hospital to home transition, and can be considered as a resource both for the patient and the doctor.¹¹ Indeed, PILs given during a consultation play an important role in assisting patients in making informed choices, taking treatments appropriately or following advice on lifestyle changes.^{12,13} While PILs have become an integral part of everyday medical practice,¹¹ their use in EDs has been relatively little studied.

Over the last few decades, many authors have attempted to evaluate PILs.^{11,14–16} However, the heterogeneity of research protocols, in particular the choice of outcomes and the way they are measured, has made it impossible to pool relevant data and to draw general conclusions about their effectiveness.^{11,17}

Primary outcomes have mainly concerned adherence to treatment, knowledge or patient satisfaction,^{11,17–19} but seldom communication effectiveness,^{11,12} which has been identified as one of the six general competencies essential for a physician²⁰ and as the ultimate criterion of PIL assessment.¹³ Whatever the outcome selected, it is seldom defined with clarity, and when it is, its definition never takes into account other outcomes of interest which would make it possible to avoid redundancy.⁹

Although the literature on PILs is large, few studies have focused on ACs and/or has been conducted in the ED.¹⁰ Most of the studies dealing with PILs for AC have been focused on a specific condition,^{14–16,21–25} using research protocols which combined several tools since no single tool was considered completely satisfactory.²⁶ Most of these tools were not generic and do not allow comparisons between studies.^{11,26}

To overcome all these obstacles, we started from a theoretical multidisciplinary model found in the literature describing the main outcomes of a consultation.¹¹ We then used generic scales usable in the context of ACs and measuring doctor–patient communication (DPC),²⁷ adherence, patient and doctor behaviours, and patient satisfaction.

In the present study, based on this common model, we assess the impact of six PILs on DPC in two French EDs. The secondary objective was to assess the impact of the use of PILs on patient satisfaction, patient adherence, and patient and doctor behaviours.

MATERIALS AND METHODS

Study design and setting

A prospective, comparative, interventional, non-randomised study was conducted in France (Rhône-Alpes region) in the ED of two hospitals between September 2013 and June 2014 (phase 1, control group) and between

September 2014 and June 2015 (phase 2, intervention group) in a controlled before–after design. The study was approved by the regional ethics committee on 31 Oct 2013 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand).

Cohort description

The study had two arms: a control group with standard consultations (phase 1: no PILs) and an intervention group with standard consultations plus PILs given by the physician (phase 2: with PILs).

For both groups, all consecutive outpatients (adults and adolescents >15 years) diagnosed with one of the following conditions—ankle sprain, acute pyelonephritis, acute prostatitis, pneumonia, acute diverticulitis or infectious colitis—and who would be contactable by telephone 7–10 days after the consultation were informed of the study by the physician (orally and through a patient information letter). The six diagnoses selected (covered by six different PILs) concerned two different types of condition frequently encountered in an outpatient ED: non-life-threatening traumas and infections.

If they agreed to participate, patients were asked to sign an informed consent form and the physician had to complete a short inclusion case report form describing the patient's profile. If the patient declined to participate, we asked the physician to record this by completing a form. Patients who were hospitalised for more than 48 hours following the consultation were excluded.

The consent letter was identical for both groups. It explained the purpose of the study, which was to assess DPC and patient satisfaction, and that this study might help improve these in the future.

The intervention

After establishing a diagnosis and including patients in the study, the physician gave patients in the intervention group a PIL corresponding to their condition. Physicians were instructed to refer to the PIL during the consultation.

The six PILs used had been selected from among 100 PILs that had been written during the last 3 years and are available in French on a medical website (<https://www.ssmg.be/fiches-dinformation-des-patients>). An example of the PILs used is shown in the online supplementary file (colitis). The leaflet was of A4 size (210×297mm), and featured an illustration related to the condition and information on the causes of the condition, its symptoms, risks, usual course of the disease, treatments, and any persisting or new symptoms which would require further medical consultation. Each PIL had been elaborated following a rigorous methodology based on a synthesis of the literature.^{11,28} Their development had consisted of the 10 following steps: selection of the topic and the objectives of the PIL, a literature review on the subject, definition of the sections, drafting, expert consensus on the content, assessment by patients, agreement on the layout, choice of the diffusion strategy, delivery to patients, and regular updates. Each PIL had been reviewed by at least two physicians to verify its coherence with evidence-based medicine

and readability. In addition a Flesch readability score of 60 was required, corresponding to a junior high school level of reading. The PILs for our study concerned six conditions that often require prescriptions for medication, additional examinations, advice on lifestyle changes and instructions as to if and when to consult again.

For the purposes of the study, we checked that the information was completely up-to-date and any corrections were made. This took about 2 days for one of our research team members.

Patient and public involvement statement

All PILs were written according to the same methodology taking into account patients' usual priorities, experience and preferences.^{11 28} They were each read by at least two volunteer patients.^{11 28} Patients were not involved in the design of the study nor in the conduct of the study. Answers to the questions were provided by the patients themselves over the phone, and they assumed the responsibility of reporting on their behaviour since the consultation and whether to be truthful or not.

Measurements

Between 7 and 10 days after the consultation, patients were telephoned by an investigator who had not participated in the patient recruitment, was not involved in their care, and who did not know a priori the patient's diagnosis or which PIL they had been given. They were asked to answer a series of questions. If they were unreachable the first time, the call was repeated twice. If the investigator was not able to contact them, a contact person designated by the patient on the inclusion sheet was phoned. If this also failed, the patient was then considered lost to follow-up.

Outcomes

Data on patients' sociodemographic characteristics (9 questions) and PIL received (16 questions) and doctors' behaviour (4 questions) were collected. For the DPC score, we used a validated generic questionnaire for ACs (13 questions).²⁷ For satisfaction and adherence scores, we used the short questionnaires we had previously developed: five questions on satisfaction, six questions on patient adherence (including three items on drug adherence, one item on non-drug prescriptions, one on recommendations and advice, and one on the way to use the healthcare system after the current consultation), three questions on patient behaviour and four questions on doctor behaviour. Each of the outcomes had been clearly defined according to the same theoretical model¹¹ to study the correlations between them. DPC, satisfaction and adherence scores were calculated from replies (scored on a 4-point Likert scale) to the phone questionnaires.

Sample size calculation

The main objective was to measure the impact of PILs given during the consultation on the DPC score. In the absence of published data on the subject, we made the following assumptions: taking an average DPC score of

40, that is, 75% of the maximum score, and a minimum effect level of 15%, that is, a gain of 6 points (by analogy with the recommended minimally clinically important improvement pain or function scales),²⁹ and for an SD of 16 points and a power of 90% (estimated sample size for two-sample comparison of means using a t-test with Stata V.13.0 software), 150 patients per group were needed. With an estimated lost to follow-up rate of 12.5% and erroneous inclusions, we planned 200 patients per group, that is, 400 in total.

Analysis

Statistical analysis was performed with the recommended procedures on data management and database freezing using Stata V.13.0 software (OSX). We planned an intention-to-treat analysis (all patients in both phases 1 and 2) and a strictly per-protocol analysis (patients without PILs in phase 1 vs those patients who received PILs with an oral explanation given by the doctor in phase 2). Statistical tests were carried out with an alpha risk of error of 0.05. Variables are described by numbers and percentages, and continuous variables by median and IQR (25th and 75th percentiles). For quantitative variables, the Mann-Whitney test was used to compare the two groups. For qualitative variables, the χ^2 test was used if applicable; otherwise the Fisher's exact test was used. The DPC scores were classified as high (>50), intermediate (36-50) or low (≤ 35) to test the difference between the two groups. Multivariate analysis was performed by logistic regression to give an OR (and 95% CI) for good communication (score >35) adjusted on age, sex, marital status and type of condition. Replacement of missing values for the DPC score (the main outcome) was performed for patients with less than 20% of missing answers, that is, 2 missing out of 13 at most. Replacement was done using the answers obtained from the other questions (11 patients out of 324 [3.4%], including 9 patients with 1 missing item and 2 patients with 2 missing items out of 13). If three or more responses were missing, the patient was excluded from the analysis.

RESULTS

Characteristics of study subjects

Four hundred patients were included in our study and 324 sets of answers were analysed: 156 patients without PILs and 168 with PILs. More patients presented with ankle sprain (183) than with an infectious disease (141). [Figure 1](#) shows the patient flow chart. No non-inclusion form was registered. [Table 1](#) presents a comparison of baseline characteristics and shows no statistically significant difference between groups.

Main results

In EDs, PILs given by doctors improve the DPC score, in all comparisons (medians compared or classes compared). [Figure 2](#) presents the DPC scores. The results are identical after adjusting for age, sex, family status

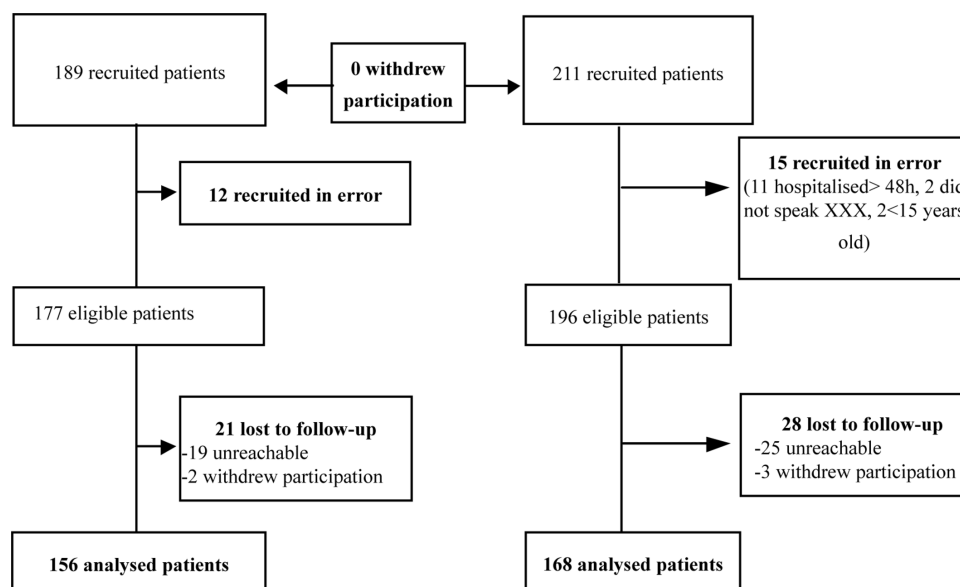


Figure 1 Patient flow chart.

and pathology. It is reinforced in the strictly per-protocol population. [Table 2](#) shows the DPC scores.

Secondary objectives

[Table 3](#) shows comparisons of overall scores and of patients' responses about their satisfaction, adherence, and patient and doctor behaviours in the two phases.

The comparison of DPC and satisfaction scores, each in two classes (DPC ≤ 35 or > 35 ; satisfaction score ≤ 16 or > 16), and whether the PIL was given to the patient by the physician (n=127/159, 79.9%) or by a nurse (28/159, 18.2%) did not show significant differences. DPC and satisfaction scores were higher when patients received

Table 1 Comparison of baseline characteristics of patients between groups who received a PIL during the emergency department consultation and those who did not

| Variables | Control group without PILs (n=156) | Intervention group with PILs (n=168) | P value |
|-----------------------------|------------------------------------|--------------------------------------|---------|
| Condition | | | 0.25 |
| Ankle sprain | 83 (53.2) | 100 (59.5) | |
| Infectious disease | 73 (46.8) | 68 (40.5) | |
| Male | 61 (39.1) | 80 (47.6) | 0.12 |
| Age (years) | 36 (23–57) | 37.5 (24–56) | 0.74 |
| Age ≥ 40 | 71 (45.5) | 76 (45.2) | 0.96 |
| Education level achieved | | | 0.55 |
| Junior high school | 62 (39.7) | 62 (36.9) | |
| High school | 39 (25) | 37 (22) | |
| University | 55 (35.3) | 69 (41.1) | |
| Socioprofessional category | | | 0.90 |
| Farmers/Artisans/Tradesmen | 7 (4.5) | 6 (3.6) | |
| Intellectuals/Managers | 30 (19.2) | 32 (19) | |
| Employees/Workers | 43 (27.6) | 52 (31) | |
| Retirees/Students and so on | 76 (48.7) | 78 (46.4) | |
| Marital status | | | 0.05 |
| Single | 79 (50.6) | 67 (39.9) | |
| Living as a couple | 77 (49.4) | 101 (60.1) | |

Values are numbers (percentages) or median (IQR).
PILs, patient information leaflets.

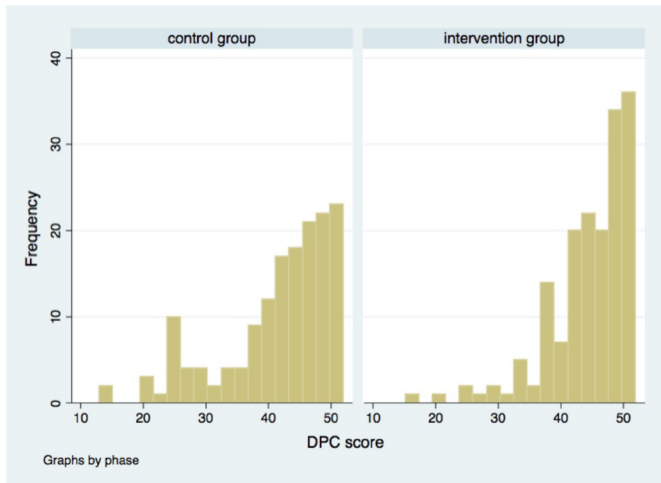


Figure 2 Doctor–patient communication (DPC) scores.

the PIL with an explanation ($p=0.02$). The need for a new medical consultation for the same pathology was reduced with PILs from 32.1% to 17.9% (OR 0.46 [0.27 to 0.77], $p<0.01$).

DISCUSSION

Emergency medicine is largely a communication activity, and medical incidents occurring in this context are too often the result of poor communication processes.^{4 30} Developing tools that improve communication in EDs is a real public health need.

Main results

Our study shows that PILs handed out during ED consultations improve DPC (the number of patients who considered DPC to be very good doubled, and the number of patients who thought that DPC was insufficient halved). On patient satisfaction, all three items concerning health-care professionals improved with PILs. On adherence, PILs also improved with respect to medication intake schedules. PILs reduced the need for consultations for the same pathology, particularly return to the ED. When doctors used PILs, they prescribed fewer medications and more additional diagnostic tests.

Doctor–patient communication

In 2010, Ha and Longnecker²⁶ wrote that ‘most complaints about doctors are related to issues of communication, not clinical competency’ and that ‘effective DPC is a central clinical function in building a therapeutic doctor-patient relationship’. Although in our study the physician was instructed to personally give the PIL to the patient during the consultation along with oral information, some delegated the task to a nurse. Nonetheless, irrespective of who handed over the PIL, DPC and satisfaction increased when the leaflet was explained to the patient. This is consistent with other studies.^{31 32} While this suggests that explaining the PIL to the patient could be a task done by other medical or paramedical staff, we believe it is preferable that the PIL is personally delivered during

Table 2 Comparison of DPC scores between the two groups without and with PILs

| Scores | Control group without PILs | Intervention group with PILs | OR with 95% CI | P value |
|------------------------------------|----------------------------|------------------------------|---|---------|
| Intention-to-treat analysis | | | | |
| DPC score (out of 52) | 44 (38–48) (n=156) | 46 (42–49) (n=168) | | <0.01 |
| ≤35 | 31/156 (19.9%) | 14/168 (8.3%) | | <0.01 |
| 36–50 | 109/156 (69.9%) | 123/168 (73.2%) | | |
| >50 | 16/156 (10.3%) | 31/168 (18.5%) | | |
| ≤35 | 31/156 (19.9%) | 14/168 (8.3%) | Univariate OR for good communication (score >35): 2.73 (1.39 to 5.35) | <0.01 |
| >35 | 25/156 (80.1%) | 154/168 (91.7%) | Adjusted* OR for good communication (score >35): 2.54 (1.27 to 5.06) | |
| Per-protocol analysis | | | | |
| DPC score (out of 52) | 44 (38–48) (n=156) | 48 (44–50.5) (n=84) | | <0.01 |
| ≤35 | 31/156 (19.9%) | 3/84 (3.6%) | Univariate OR for good communication (score >35): 6.70 (1.98 to 22.6) | <0.01 |
| >35 | 125/156 (80.1%) | 81/84 (96.4%) | Adjusted* OR for good communication (score >35): 5.60 (1.63 to 19.2) | |

*Adjusted for age, sex, family situation and pathology.
DPC, doctor–patient communication; PILs, patient information leaflets.

Table 3 Secondary objectives: satisfaction, adherence, and patient and doctor behaviours (ITT analysis)

| (A) Satisfaction | Control group without PILs (n=156) | Intervention group with PILs (n=168) | OR (95% CI) | P value |
|---|---|---|---------------------|-----------------|
| 1. Satisfaction with infrastructure (reception, food, waiting time) | 92/156 (59%) | 91/168 (54.2%) | 0.82 (0.53 to 1.28) | 0.38 |
| 2. Satisfaction with nurses and care assistants | 112/156 (71.8%) | 137/168 (81.6%) | 1.74 (1.03 to 2.93) | 0.04 |
| 3. Satisfaction with the doctor | 103/156 (66%) | 131/168 (78%) | 1.82 (1.11 to 2.98) | 0.016 |
| 4. Satisfaction with the medical consultation | 93/156 (59.6%) | 129/168 (76.8%) | 2.24 (1.39 to 3.62) | <0.0.01 |
| 5. Would you recommend the ED to friends or family? | 119/156 (76.3%) | 135/168 (80.4%) | 1.27 (0.75 to 2.16) | 0.37 |
| <i>Total satisfaction score</i> | 19 (16–20) | 19 (17–20) | | 0.20 |
| (B) Adherence* (according to doctors' behaviours) | Control group without PILs | Intervention group with PILs | OR (95% CI) | P value |
| 1. Have you taken the whole course of the prescribed treatment? | 108/134 (80.6%) | 107/130 (82%) | 1.12 (0.60 to 2.09) | 0.72 |
| 2. Did you respect the prescribed doses? | 127/134 (94.8%) | 122/124 (98.4%) | 3.36 (0.68 to 16.5) | 0.18 |
| 3. Did you comply with the regimen and conditions (time at which you should take the medication, if you were fasted or not, during meals and so on)? | 113/134 (84.3%) | 116/124 (93.5%) | 2.69 (1.15 to 6.33) | 0.02 |
| 4. Did you have additional examinations or a specialised consultation prescribed by your doctor (imagery, laboratory analyses, an appointment with a specialist)? | 87/98 (88.8%) | 119/141 (84.4%) | 0.68 (0.32 to 1.48) | 0.34 |
| 5. Did you follow the recommendations and the advice given (have you changed any habits as a result of the consultation)? | 82/89 (92.1%) | 104/123 (84.6%) | 0.47 (0.19 to 1.17) | 0.10 |
| 6. Did you follow health monitoring instructions and advice given by your doctor on if and when to consult a healthcare professional? | 75/78 (96.2%) | 81/83 (97.6%) | 1.62 (0.26 to 9.96) | 0.67 |
| <i>Total adherence score</i> | 0.93 (0.80–1) (n=154) | 0.89 (0.76–0.97) (n=165) | | 0.21 |
| (C) Patient behaviours | Control group without PILs | Intervention group with PILs | OR (95% CI) | P value |
| 1. Did you need a new medical consultation for the same condition? | 50/156 (32.1%) | 30/168 (17.9%) | 0.46 (0.27 to 0.77) | <0.01 |
| 2.1. Did you consult an ED physician? | 42/156 (26.9%) | 14/168 (8.3%) | 0.25 (0.13 to 0.47) | <0.01 |
| 2.2. Did you consult your primary care physician? | 11/156 (7.1%) | 17/168 (10.1%) | 1.48 (0.67 to 2.28) | 0.32 |
| (D) Doctor behaviours | Control group without PILs | Intervention group with PILs | OR (95% CI) | P value |
| 1. Drug prescriptions? | 134/156 (85.9%) | 130/168 (77.4%) | 0.56 (0.32 to 1.00) | 0.049 |
| 2. Prescriptions of further tests (laboratory analysis, imaging, appointment with specialists)? | 98/156 (62.8%) | 141/168 (83.9%) | 3.09 (1.83 to 5.22) | <0.01 |
| 3. Given advice to follow? | 89/155 (57.4%) | 123/168 (73.2%) | 2.03 (1.27 to 3.23) | <0.01 |
| 4. Information on if and when to consult a doctor again? | 79/155 (51.0%) | 84/165 (50.9%) | 1.00 (0.64 to 1.55) | 0.99 |

Continued

Table 3 Continued

(D) Doctor behaviours

*Two patients in phase 1 (control) and three patients in phase 2 (with PILs) did not receive any prescription and were not included in the adherence analysis.

P values in bold were considered statistically significant ($p < 0.05$).

There were no significant differences in overall satisfaction and adherence scores across the entire population (intention-to-treat). All three satisfaction items related to healthcare professionals and for adherence, the item related to timing of medication intake, were significantly improved. The overall satisfaction score significantly improved on per-protocol analysis.

Table 4 shows the answers to questions concerning the PIL in the intervention group.

ED, emergency department; ITT, intention-to-treat; PILs, patient information leaflets.

the consultation by a doctor, who adapts his behaviour according to the content of the PIL.

Satisfaction

Patient satisfaction was partially improved by PILs. Among the five items included in the satisfaction score, all three items about healthcare professionals had a statistically significant improvement. One item, on whether the patient would recommend the ED to a friend or family, tended to improve. Another item, related to the infrastructure and organisation of the ED (reception, waiting time), could not be influenced by the use of PILs. In a systematic review, the authors found that key interventions to improve patient satisfaction in ED are those that develop the interpersonal and attitudinal skills of staff, increase the information provided, and reduce the perceived waiting time.³³

We note that, in the literature, results concerning satisfaction linked to PILs are not unanimous. One explanation is the heterogeneity of the questions among the different satisfaction scales. For example, the scale

developed by Arnold *et al*³⁴ explores accessibility of care, attitude of medical and paramedical staff, quality of care, waiting times, and practical information delivered (costs of care and so on) in a study of groups receiving PILs or not, and concluded that both groups had high scores for each dimension of patient satisfaction and that there was no evidence that the PIL was associated with any change in satisfaction. In their satisfaction scale, Little *et al*²¹ assessed items similar to those we explored through our DPC scale (relieving distress, intention to comply with care management decisions, communication, amount of information delivered, confidence in the doctor, relationships) and concluded that a leaflet increased patient satisfaction. Different satisfaction scales explore different dimensions, and a detailed comparison of the content of various scales showed that our results are consistent with the literature.

Adherence and patient behaviours

We observed a ceiling effect with a high global adherence score in both groups (with and without PILs). As seen in

Table 4 Answers to questions concerning the PIL

| Questions | Yes, n (%) | Does not remember, n (%) |
|--|-----------------|--------------------------|
| Did you receive a PIL? | 159/168 (94.6) | 1 (0.6) |
| Did the doctor give it to you? | 127/159 (79.9) | 0 |
| Did the nurse give it to you? | 28/159 (18.2) | 0 |
| I don't know who gave me the PIL | 3/159 (1.9) | 0 |
| Was the PIL signed? | 55/159 (34.6) | 62 (39) |
| Did you read the PIL? | 137/159 (86.2) | 0 |
| Read the whole leaflet? | 127/137 (92.7) | 0 |
| Read only part of the leaflet | 10/137 (7.3) | 0 |
| Did you read it immediately after the consultation? | 112/137 (81.75) | 0 |
| If not, did you read it one or more days after the consultation? | 25/137 (18.25) | 0 |
| Did you read it again? | 50/137 (36.5) | 0 |
| Did you receive an oral explanation when you were given the PIL? | 84/159 (52.8) | 2 (1.3) |
| Did you keep the PIL? | 149/159 (93.7) | 1 (0.6) |
| Did other people in your household use the PIL? | 56/159 (35.2) | 2 (1.3) |
| Did you find the PIL easy to understand? | 133/137 (97.1) | 1 (0.7) |
| Did you find the PIL useful? | 110/137 (80.3) | 1 (0.7) |

PIL, patient information leaflet.

our results, it was very difficult to improve adherence. Good adherence to treatment and to the doctor's advice can be explained by the fact that ED patients are highly motivated to take their treatment, as their medical condition is often painful or could deteriorate. Often they have waited several hours for the consultation (some patients leave the ED before seeing a doctor), they are stressed, anxious and want to get better. Moreover, medical treatment for an AC is usually of short duration, contributing to better adherence.²¹ Nevertheless, patients' responses showed that PILs given out in the context of an AC help patients better respect the schedule for taking their medication. Furthermore, with PILs, they reconsult less for the same pathology and are less likely to return to the ED. If they do reconsult, they tend to visit their primary care physician/general practitioner rather than the ED.

We also observed that even though the results were not significant, the group without PILs tended to follow the recommendations and advice of the physician better than the PIL group. One may wonder whether the doctor gave less oral information when he/she gave the patient a PIL or if some information was lost due to information overload in patients who received two sources of information (oral information and written). This result should be confirmed by a study involving a larger number of patients and/or by an analysis of audio recordings of the consultations.

Doctor behaviours

Like Little *et al.*,³⁵ we found that physicians tended to increase the number of laboratory analyses and examinations ordered and reduce the number of drug prescriptions when they used PILs.^{25 36–38} It may be that PILs act as reminders for overworked physicians and also help structure the dialogue, resulting in less drug prescriptions and more tests (laboratory analyses, imaging examinations and so on). In a future study, it would be interesting to check whether these changes in the behaviour of the doctors, as perceived by the patients, (1) are real by analysing audio or video recordings of the consultations; (2) follow the recommendations (sometimes for further tests) contained in the PILs; and (3) are correlated with an improvement in outcomes. This would allow us to know whether better outcomes are directly linked to PILs or only indirectly by the change in behaviour of doctors when using PILs.

Strengths and limitations

With regard to the improvement in the DPC score, we failed to obtain the expected 6-point gain. Nevertheless, the improvement in DPC was significant and associated with better outcomes, such as satisfaction or fewer reconsultations in an ED for the same condition.

In this multicentre, prospective, interventional study, we used several different PILs for different ACs in two hospital EDs with a relatively large series of patients. Our choice of objectives is supported by a recent study, in which qualitative semistructured interviews were

performed a few days following discharge from ED. The four outcomes that were valued by patients were understanding the cause and expected trajectory of their symptoms, reassurance, symptom relief, and having a plan to manage their symptoms, resolve their issues or pursue further medical care.³⁹ In the ED context, PILs can be a valuable tool both for the patient, helping them to respect the instructions given by the doctor when they return home, and for doctors, to better inform their patient in the short timespan of an emergency consultation.⁵ In our study, all six PILs were developed according to the same rigorous methodology, and generic questionnaires were used as recommended.^{11 28}

The ACs included in the study were all non-severe; thus, we cannot generalise our findings to the entire range of pathologies seen in an ED. We note that the level of severity of a disease impacts on satisfaction; in particular, the more severe the pathology, the less importance the patient gives to the infrastructure and the more satisfied he/she is.³⁸

The study coordinator received no non-inclusion forms, which might be explained by the lack of time in the ED.⁵ It is impossible to tell whether patients lost to follow-up (who could not be contacted by phone after three attempts) were the least satisfied and/or least adherent. These biases might have led to an overestimation of the results.

Although the strongest interventional study design is a randomised controlled trial,⁴⁰ individual patient randomisation was not possible due to the major risk of contamination bias between patients, between doctors (as the physicians shared office space) and a learning effect related to the content of the leaflet (doctors unconsciously adapting what they say to 'control' group patients). Our choice of a prospective, controlled, before–after trial allowed us to have the same doctors in both groups. Doctors were not told the precise objectives of the study; however, we cannot completely exclude a Hawthorne effect bias during phase 2 of the study.

The investigators were independent of the ED physicians. In EDs, interventional studies are relatively scarce, probably due to difficulties in implementing them. In a systematic review of the effectiveness of interventions to decrease ED visits by frequent adult users (one of our outcomes),⁴¹ among the 31 articles analysed the majority (21) were non-controlled studies. Among the 10 interventional studies considered as providing a strong level of evidence, 4 were controlled before–after studies and 6 were randomised controlled trials. In our study, the two groups were comparable at baseline, confirmed statistically after adjustment on the main characteristics of the patients. To minimise biases related to the different temporal contexts of the two phases, we chose two identical periods of the year. Although our choice of design seems to be well adapted to our objective, our findings should be confirmed in a large-scale, cluster randomised trial involving many EDs.

Sustainability of the intervention in everyday practice

To facilitate the feasibility of our study, the PILs were printed in advance to allow patients to read them without having an internet connection. In fact all the PILs are available in electronic format on a medical website and are commonly used by French-speaking primary care general practitioners during consultations. Thus, we do not see any obstacle to their use in EDs, especially as it is often the same pathologies that are encountered. On the feasibility of using PILs in EDs, it would have been interesting to check 6 months after the study if doctors and medical students had continued to use them and whether they downloaded and used the other PILs available on the internet site, but this was not the purpose of our study. Nevertheless, a future study should test whether PILs have an impact on the consultation time and whether the emergency physicians who participate in the study continue to use them after the study. To broaden usability we are planning to translate the PILs into English.

Practice implications

In EDs, PILs could be an easy-to-use tool for improving DPC, benefiting both the doctor and the patient.

Author affiliations

¹Emergency Department, Grenoble Mutualist Hospital Group (Groupe Hospitalier Mutualiste de Grenoble), Grenoble, France

²Research Department, Grenoble Alpes University Hospital, Grenoble, France

³Psychology Department, Grenoble Alpes University, Saint-Martin-d'Herès, France

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