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Impact of Patient Information Leaflets on Doctor-Patient Communication in the context of acute conditions: a prospective controlled before- after study in in two emergency departments.

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Keywords: Doctor-Patient Communication, Patient Information Leaflet, acute condition, emergency department, satisfaction, patient behavior, doctor behavior, adherence.

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Contributorship statement

ABSTRACT

Objectives: In the context of acute conditions, where communication is difficult, Patient Information Leaflets (PILs) could improve Doctor-Patient Communication (DPC) and have an impact on other well-known consultation outcomes. Our objective was to assess the impact of PILs on DPC, satisfaction, adherence, and patient and doctor behaviors.

Design: Prospective controlled before-after trial between November 2013 and June 2015.

Settings: Two emergency departments.

Participants: Adults and adolescents > 15 years diagnosed with ankle sprain, 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. Seven to 10 days later, patients were contacted by phone to answer questionnaires.

Main outcome mesures: The scores were calculated from the replies to the validated questionnaires.

Main findings: Analysis of the 324 patients showed that PILs improved the DPC score (range from 13 to 52): with 46 [42-49] for 168 patients with PILs versus 44 [38-48] for 156 patients without (p-value< 0.01). The adjusted Odds Ratio for good communication (a score >35) was 2.54 [1.27-5.06]. The overall satisfaction and adherence scores did not show significant differences. In contrast, satisfaction with healthcare professionnals and timing of medication intake were improved. The overall satisfaction score improved significantly on per-protocol analysis. With PILs, the doctors prescribed fewer drugs and more examinations (radiology, biology,

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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 [0.27-0.77]) particularly readmissions to the ED.

Conclusions: In emergency departments, PILs given by the doctor improve DPC, increase satisfaction with healthcare professionnals, reduce the number of emergency consultations for the same pathology and change the doctor's behavior.

STRENGTHS AND LIMITATIONS

- A simple way to improve Doctor-Patient Communication and physician behavior in EDs.

- All scores used in the methodology were generic and based on the same solid theoretical model describing acute consultation.

- The only study design possible was a before-after study to avoid a biais of contamination between physicians in the particular context of EDs.

- No non-inclusion form was registred by physicians, which may be a bias of patient selection.

INTRODUCTION

Acute conditions (AC) are a very common reason for consultation in primary care, both in general medicine and in emergency departments (ED). An AC can be defined as being 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 ED, 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.[3] Besides the condition itself, EDs are frequently places where lack of comfort and high influx may be upsetting for the patient. Discharge from the ED can be a period of vulnerablity for patients.[3,4] They run the risk of further clinical deterioration, may experience side effects from a newly prescribed drug, or even suffer from a wrong diagnosis.[3,5]

In the ED, the information delivered by the physician to the patient is crucial[6,7] and if it is insufficient, neglected or misunderstood, the patient could suffer complications.[8] Patients Information Leaflets (PILs) appear to be a highly suitable tool in this context. They have a role in the continuity of care by enabling the hospital to outpatient transition and can be considered as a resource both for the patient and the doctor.[9] Indeed, PILs given

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during a consultation play a important role in assisting patients in making informed choices, taking treatments appropriately, or following advice on lifestyle changes.[10,11] They have become an integral part of everyday medical practice.[9]

Over the last few decades, many authors have attempted to evalute PILs.[9, 12-14] However, heterogeneity of research protocols, in particular in 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.[9,15]

Primary outcomes have mainly concerned adherence to treatment, knowledge or patients' satisfaction,[9,15-17] but seldom communication effectiveness,[10,9] which has been identified as one of the six general competencies essential for physicians[18] and as the ultimate criterion of PILs' assessement.[11] Whatever the outcome selected, it is seldom defined with clarity and when it is, its definition never takes into account those other outcomes of interest, which would make it possible to avoid redundancies.[9]

Although the literature on PILs is large, few studies have focused on acute conditions and/or been conducted in ED.[8] Most of the studies dealing with PILs for AC were focused on a specific condition[12-14,19-23] using research protocols which combined several tools since no single tool was completely satisfactory.[24] Most of these tools were not generic and didn't allow comparisons between studies.[9,24]

To overcome all those obstacles, we started from a theoretical multidisciplinary model describing the main outcomes of a consultation found in the literature.[9] We then used generic scales usable in the context of acute conditions and measuring Doctor-Patient Communication (DPC),[26] adherence, patient and doctor behaviors, and satisfaction.

In the present study, based on this commun model, we assess the impact of 6 Patients Information Lealfets on Doctor-Patient Communication in two EDs. The secondary objectives were to assess the impact of the PILs on satisfaction, adherence, patient and doctor behaviors.

MATERIALS AND METHODS

Study design and settings

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A prospective comparative interventional non-randomized study was conducted in France (region Rhone-Alps) in two ED between September 2013 and June 2014 (control group) and between September 2014 and June 2015 (intervention group) in a controlled before-after design. The study was approved by the regional ethics committee on 31/10/2013 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand).

Cohort description

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

For both groups, all consecutive outpatients (adults and adolescents >15 years) diagnosed with ankle sprain, acute pyelonephritis, acute prostatitis, pneumonia, acute diverticulitis or infectious colitis and who would be contactable by telephone 7 to 10 days after the consultation, were informed of the study by the physician (orally and in a patient information letter). If they agreed to participate, the patients had to sign the 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 to the physicians to record this. Patients who were hospitalised for more than 48 hours were excluded.

The intervention

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 leaflet was A4 size (210 × 297 mm), included an illustration related to the condition and information on the causes of the condition, its symptoms, the risks, the usual course of the disease, the treatments, and any persisting or new symptoms which would require further medical consultation. Each PIL had be elaborated following a rigourous methodology based on a synthesis of the literature.[9,26] Their development had consisted of the 10 following steps: selection of the topic and the objectives, a literature review on the suject, selection of the sections, drafting, expert consensus of the contents, assessment by patients, agrement on the layout, selection of the diffusion strategy, delivery to patients and regular updates. An updated literature search and reading by volunteer patients were conducted and any corrections were made. Each PILs was reviewed by at least two physicians to verify their coherence with evidence based medicine and their readability. In addition a Flesch readability score of 60 was required, corresponding to a junior high school level of reading. The PILs selected for our study concerned 6 conditions that often require prescriptions for

medication, additional examinations, advice on lifestyle changes and instructions on if and when to consult again.

Patient and public involvement statement

The 6 PILs of the intervention were read each by at least two patients.[25] They were written according to a methodology previously developped and taking into account the patients' priorities, experience, and preferences.[9,26] All questionnaires used in this study were patient-centred and self-reported by the patients.[25] They have been elaborated from the conclusions of a review of the literature, so as to take into account the patient's point of view.[25] Patients were not involved in the design of the study, nor in the conduct of the study.

Measurements

Between 7 and 10 days after the consultations patients were telephoned by an investigator who had not participated in the patient recruitment and who was not involved in their care. They were asked to answer several short questionnaires. 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. In case of failure the patient was considered as lost to follow-up.

Outcomes

Data about socio-demographic characteristics of patients (9 questions), about the PIL received (16 questions) and about doctor behavior (4 questions) were collected. For the DPC score, we used a generic questionnaire validated for acute conditions (13 questions).[27] For scores of satisfaction and adherence score, we used the short questionnaires we had previously developed: 5 questions about satisfaction, 6 questions on patient adherence (including 3 items about drug adherence, one item about non-drug prescriptions, one about recommandations and advice, and one about the way to use the health care system after the current consultation), 3 questions on patient behaviors and 4 questions on doctor behaviors. Each of the outcomes had been clearly defined according to the same theoretical model[9] to study the correlation links between them. DPC, satisfaction and adherence scores were calculated from replies to the phone questionnaires.

Sample size calculation

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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 around 40 (ie 75% of the maximum score) and a minimum effect level of 15% i.e. a gain of 6 points (by analogy with the recommended Minimaly Clinically Important Improvement pain or function scales);[28] then for an Standard Derivation (ecart type) of 16 points and a power of 90% (logiciel Stata, estimated sample size for two-sample comparison of means with t-test, commande sampsi) 150-patients per group were needed. With an estimated lost to follow-up rate of 12.5% and erronous inclusions, we planned 200 patients per group i.e. 400 in total.

Analysis

Statistical analysis was performed with the recommended procedures of data management and database freezing using Stata version 13.0 software (Stata Corp, College Station, Texas) OSX. We planned an intention-to-treat analysis (all patients in both Phase 1 and 2) and a strictly per-protocol analysis (patients without PILs in Phase 1 versus those patients who recieved PILs with an oral explanation given by doctor in Phase 2). Statistical tests were carried out with an alpha risk of error equal to 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 two groups. For qualitative variables, the Chi2 test was used if applicable, otherwise the Fisher exact test was used. The DPC score 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. The replacement of missing values for the DPC score, the main outcome, was performed for patients with less than 20% of missing answers, i.e two missing out of 13 at most. Replacement was done using the answers obtained to 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 3 or more responses were missing, the patient was excluded (not necessary).

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 the groups.

Table 1. Comparison of baseline characteristics of patients between groups who received a patient Information Leaflet during the emergency department consultation and those who did not. Values are numbers (percentages) or median (interquartile range).

Variables	Control Group without PILs (N=156)	Intervention Group with PILs (N=168)	p-value
Condition			
Ankle sprain	83 (53.2 %)	100 (59.5 %)	0.25
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			
Junior high school	62 (39.7 %)	62 (36.9 %)	0.55
High school	39 (25 %)	37 (22 %)	
University	55 (35.3 %)	69 (41.1 %)	
Socio-professional category			
Farmers/artisans/tradesmen	7 (4.5 %)	6 (3.6 %)	
Intellectuals/managers	30 (19.2 %)	32 (19 %)	0.90
Employees/workers	43 (27.6 %)	52 (31 %)	
Retirees/students etc.	76 (48.7 %)	78 (46.4 %)	

Marital status			
Single	79 (50.6 %)	67 (39.9 %)	0.05
Living as a couple	77 (49.4 %)	101 (60.1 %)	

Values are numbers (percentages) or median (interquartile range)

Main results

In ED, PILs given by the doctor improve the DPC score, in all comparisons (medians comparedor classes compared). Figure 2 presents the Doctor Patient Communication scores.This result is identical after adjusting for age, sex, family status and pathology. It is reinforced in the strictly per-protocol population. Table 2 shows the DPC scores.

Table 2. Comparison of scores for Doctor-Patient Communication (DPC) between the two groups without and with PILs.

SCORES	Control Group without PILs	Intervention group with PILs	Odds Ratio (OR) with 95% confidence interval	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	**<0.01**

> 35	25/156 (80.1%)	154/168 (91.7%)	[1.39-5.35] Adjusted* OR for good communication (score >35): 2.54 [1.27-5.06]	
		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 [1.98-22.6]	**<0.01**
> 35	125/156 (80.1%)	81/84 (96.4%)	Adjusted* OR for good communication (score >35): 5.60 [1.63-19.2]	

* adjusted for age, sex, family situation and pathology

Secondary objectives

Table 3 shows comparisons of overall scores and of patients' responses about their satisfaction, adherence, and patient and doctor behaviors in the two phases.

Table 3. Secondary objectives: satisfaction, adherence, and patients' and doctors' behaviors (ITT analysis).

A. Satisfaction	Control group without PIL n = 156	Intervention group with PILs n= 168	OR [95%CI] p-value

	Control group without PILs	Intervention group with PILs	OR [95%CI]	p-value
I. Satisfaction with infrastructure (reception, food, waiting time)	92/156 (59 %)	91/168 (54.2%)	0.82 [0.53-1.28]	0.38
II. Satisfaction with nurses and care assistants	112/156(71.8%)	137/168 (81.6%)	1.74 [1.03-2.93]	**0.04**
III. Satisfaction with the doctor	103/156 (66%)	131/168 (78%%)	1.82 [1.11-2.98]	**0.016**
IV. Satisfaction with the medical consultation	93/156 (59.6%)	129/168 (76.8%)	2.24 [1.39-3.62]	**<.0.01**
V. Would you recommend the ED to friends or family?	119/156 (76.3%)	135/168 (80.4%)	1.27 [0.75-2.16]	0.37
Total satisfaction score:	19 [16-20]	19[17-20]		0.20

B. Adherence* (according to doctor behaviors)	Control group without PILs	Intervention group with PILs	OR [95%CI]	p-value
I- Have you taken the whole course of the prescribed treatment?	108/134 (80.6%)	107/130 (82.3%)	1.12 [0.60-2.09]	0.72
II- Did you respect the prescribed doses?	127/134 (94.8%)	122/124 (98.4%)	3.36 [0.68-16.5]	0.18
III- Did you comply with the regimen and conditions (time at which you should take the medication, if you were fasted or not, during meals etc.)?	113/134 (84.3%)	116/124 (93.5%)	2.69 [1.15-6.33]	**0.02**
IV- Did you have additional examinations or a specialized consultation prescribed by your doctor (imagery, laboratory analyses, an appointment	87/98 (88.8%)	119/141 (84.4%)	0.68 [0.32-1.48]	0.34

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with a specialist)?

	Control group	Intervention group	OR [95%CI]	p-value
V- 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 [0.19-1.17]	0.10
VI- Did you follow health monitoring instructions and advice on if and when to reconsult a healthcare professional given by your doctor?	75/78(96.2%)	81/83 (97.6%)	1.62 [0.26-9.96]	0.67
Total adherence score:	0.93 [0.80-1] (n=154)	0.89 [0.76-0.97] (n=165)		0.21

C- Patient behaviors	Control group without PILs	Intervention group with PILs	OR [95%CI]	p-value
I-Did you need a new medical consultation for the same condition?	50/156 (32.1%)	30/168 (17.9%)	0.46 [0.27-0.77]	**< 0.01**
I.1- Did you consult an ED physician?	42/156 (26.9%)	14/168 (8.3%)	0.25 [0.13-0.47]	**<0.01**
I.2- Did you consult your primary care physician?	11/156 (7.1%)	17/168 (10.1%)	1.48 [0.67-2.28]	0.32
D- Doctor behaviors				
I-Drug prescriptions?	134/156 (85.9%)	130/168 (77.4%)	0.56 [0.32-1.00]	**0.049**
II- Prescriptions of further tests (laboratory analysis, imaging, appointment with specialists)?	98/156 (62.8%)	141/168 (83.9%)	3.09 [1.83-5.22]	**<0.01**
III- Given advice to follow?	89/155 (57.4%)	123/168 (73.2%)	2.03 [1.27-3.23]	**<0.01**
IV- Information on if and when to consult a doctor again ?	79/155 (51.0%)	84/165 (50.9%)	1.00 [0.64-1.55]	0.99

*Two patients in phase 1 (control) and three patients in phase 2 (with PILs) didn't receive any prescription and weren't included in the adherence analysis.

There were no significant differences in overall satisfaction and adherence scores across the entire population (ITT). All three satisfaction' items related to healthcare professionals and, for adherence the item related to timing of medication intake, were improved significantly. The overall satisfaction score improved significantly on per-protocol analysis. Table 4 shows answers to questions concerning the PIL in the intervention group.

Table 4. Answers to questions concerning the Patient Information Leaflet (numbers and percentages).

Questions	Yes	Does not remember
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

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Did you receive 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%)

The comparison of DPC and satisfaction scores, each in 2 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 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 [0.27-0.77] p < 0.01).

DISCUSSION

Our study shows that patient information leaflets handed out during emergency department 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). Regarding patient satisfaction, all three items concerning healthcare professionals improved with PILs. Concerning adherence, PILs also improved the respect of medication intake schedules. PILs reduced the need for consultations for the same pathology, particularly a return to the ED. When doctors used PILs, they prescribed fewer medications and more additional diagnostic tests.

Doctor-Patient Communication

In 2010, Ha and Longnecker 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".[24] 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 a nurse.Nonetheless, whoever gave the PIL, DPC and satisfaction increased when the leaflets were explained to the patients. This is consistent with other studies.[29,30] 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 personnaly delivered during the consultation by the doctor who adapts his behavior according to the content of the PIL.

Satisfaction

Patient satisfaction was partially improved by PILs. Among the 5 items included in the satisfaction score, all three items about healthcare professionnals underwent a statistically significant improvement. One item, concerning whether the patient would recommend the ED to a friend or family, tended to be improved. Another item, related to the infrastructure and organization of the ED (reception, waiting time), could not be influenced by the use of the 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.[31]

We note that in the literature, results concerning satisfaction linked to PILs are not unanimous. One explanation is the heterogeneity of the questions between different satisfaction scales. For example, the scale developed by Arnold et al. explores accessibility of care, the attitude of medical and paramedical staff, quality of care, waiting times, practical information delivered (costs of care etc.) and in a study of groups receiving PILs or not, 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.[32] In their satisfaction scale, Little et al. assessed what 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 he concluded that a leaflet increased patient satisfaction.[19] Different satisfaction scales explore different dimensions and a detailed comparaison with the content of various scales, showed that our results are consistent with the literature.

Adherence and patient behaviors

We observed a ceiling effect with a high global adherence score in both groups (with and without PILs). As seen in our results, it was very difficult to improve adherence. Good adherence to treatment and recommandations 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.[19] Nevertheless, the patients'

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responses show that PILs given out in the context of an AC help patients to 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 rather than the ED.

Doctor behaviors

Like Little et al., we found that physicians tended to increase the number of explorations[33] and reduce the

number of drug prescriptions when they used PILs.[23, 34-36] It may be that PILs act as reminders for over-worked

physicians and also help structure the dialogue resulting in less drug prescriptions and more tests (laboratory

analyses, imaging, examinations etc).

Strengths and Limitations

In this multicenter prospective interventional study, we used several different PILs for different acute conditions

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.[37] In the ED context, PILs can be a valuable tool both for the patient, helping them to

respect the instructions given when they return home, and for doctors, to better inform their patient in the short

timespan of an emergency consultation.[3] In our study, all 6 PILs were developed according to the same rigorous

methodology and generic questionnaires were used, as recommended.[26]

The AC included in the study were all non-severe, thus we cannot generalize 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 ED.[3] It

is impossible to tell whether patients lost to follow-up (who could not be contacted by telephone after 3

attempts) were the least satisfied, and/or least adherent. These biases might have led to an over-estimation of the

results.

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Although the strongest interventional study design is a randomized controlled trial,[39] individual patient randomization 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). The investigators were independent of the ED physicians. In ED, interventional studies are relatively scarce, probably due to difficulties in implementing them. In a systematic review[31] about the effectiveness of interventions to decrease ED visits by frequent adult users (which is one of our outcomes), 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 randomized controlled trials. In our study, the two groups were comparable at baseline, confirmed statistically after adjustment on the main characteristics of the patients. To minimize 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 randomized trial involving many EDs.

Practice implications

In ED, PILs are an easy-to-use tool for improving DPC, benefiting both the doctor and the patient.

Data sharing

Extra data is available by emailing Dr Mélanie Sustersic: melanie.sustersic@gmail.com.

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21

Figure 1. Patient flow chart.

Figure 2. Doctor-patient communication scores.

22

| 189 recruited patients | 0 withdrew participation | 211 recruited patients |

| | 12 recruited in error | | 15 recruited in error (11 hospitalised> 48h, 2 did not speak XXX, 2<15 years old) |

| 177 eligible patients | | 196 eligible patients |

| | 21 lost to follow-up -19 unreachable -2 withdrew participation | | 28 lost to follow-up -25 unreachable -3 withdrew participation |

| 156 analysed patients | | 168 analysed patients |

Patient flow chart

161x95mm (300 x 300 DPI)

Doctor-patient communication scores.

146x106mm (300 x 300 DPI)

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.
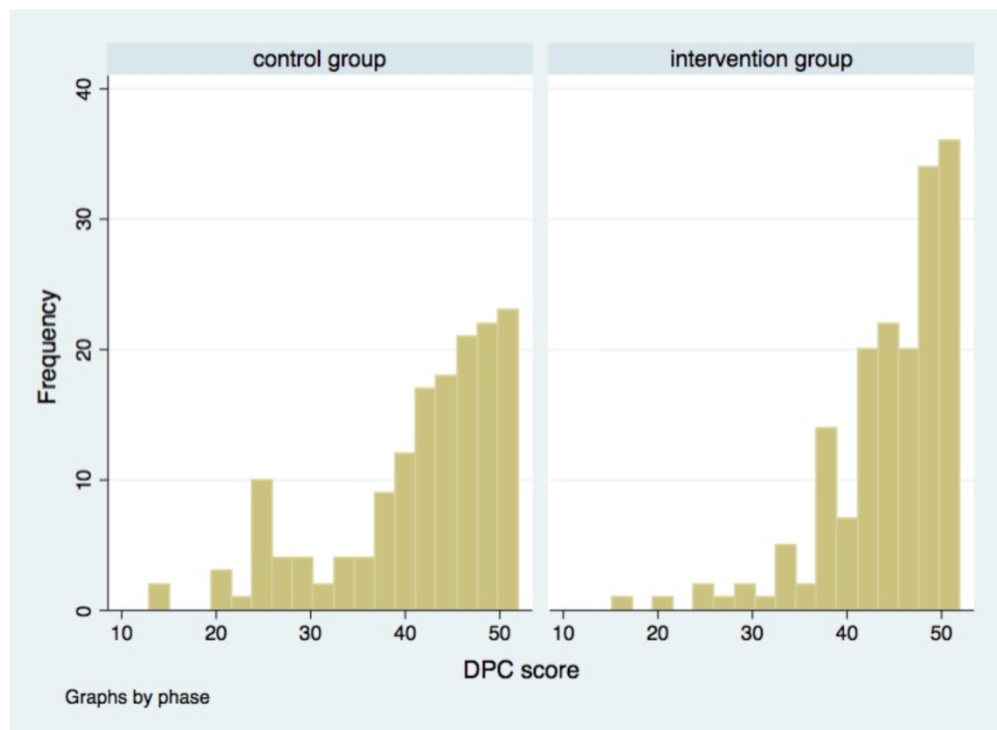
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2 **Impact of Patient Information Leaflets on Doctor-Patient Communication in the context of**

3 **acute conditions: a prospective controlled before-after study in two French emergency**

4 **departments.**

5

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37

30   **Contributorship statement**

2

39   MS, AG and JLB conceived the project.

40   MS, JT and MT conducted the study.

41   CV and JLB performed the statistical analyses, interpreted the results and prepared the figures.

42   MS, JLB, JT, MT, AG and AF wrote the article.

43

44   **ABSTRACT**

45   **Objectives**: In the context of acute conditions seen in an emergency department, where

46   communication may be difficult, Patient Information Leaflets (PILs) could improve Doctor-Patient

47   Communication (DPC) and may have an impact on other outcomes of the consultation. Our

48   objective was to assess the impact of PILs on DPC, patient satisfaction and adherence, and on

49   patient and doctor behaviours.

50   **Design:** Prospective controlled before-after trial between November 2013 and June 2015.

51   **Settings:** Two French emergency departments.

52   **Participants:** Adults and adolescents > 15 years diagnosed with ankle sprain, or an infection

53   (diverticulitis, infectious colitis, pyelonephritis, pneumonia or prostatitis).

54   **Intervention:** Physicians in the intervention group gave patients a PIL about their condition

55   along with an oral explanation.

56   **Main outcome mesures:** Seven to 10 days later, patients were contacted by phone to answer

57   questionnaires. Results were derived from questions scored using a 4-point Likert scale.

3

58 **Main findings**: Analysis of the 324 patients showed that PILs improved the mean DPC score

59 (range from 13 to 52): with 46 [42-49] for 168 patients with PILs versus 44 [38-48] for 156

60 patients withouta PIL (p-value< 0.01). The adjusted Odds Ratio for good communication (having

61 a score >35/52 was 2.54 [1.27-5.06]. The overall satisfaction and adherence scores did not

62 show significant differences. In contrast, satisfaction with healthcare professionnals and timing of

63 medication intake were improved with PILs. The overall satisfaction score improved significantly

64 on per-protocol analysis. When using PILs, the doctors prescribed fewer drugs and more

65 examinations (radiology, biology, appointment with a specialist); the need for a new medical

66 consultation for the same pathology was reduced from 32.1% to 17.9% (OR 0.46 [0.27-0.77])

67 particularly re-visiting the ED.

68 **Conclusions**: In emergency departments, PILs given by the doctor improve DPC, increase

69 patients' satisfaction with healthcare professionnals, reduce the number of emergency

70 reconsultations for the same pathology and modify the doctor's behaviour.

71

72 **STRENGTHS AND LIMITATIONS**

73 • A simple way to improve Doctor-Patient Communication and physician behaviour in EDs.

74 • All scores used in the methodology were generic and based on the same solid

75 theoretical model describing a consultation for an acute condition.

4

76 • The only study design possible was a before-after study to avoid a biais of

77 contamination between physicians in the particular context of an ED.

78 • No non-inclusion form was registred by physicians, which may be a bias of patient

79 selection.

80
81

82 **INTRODUCTION**

83 Acute conditions (AC) are a very common reason for consultation in primary care, both in

84 general practice and in emergency departments (ED). An AC can be defined as being a

85 condition of short duration.[1] Faced with an AC "the primary goal of the physician is to improve

86 health, and effectiveness largely depends on time-sensitive and, frequently, rapid intervention".[2]

87 In an ED, the combination of frequent interruptions and multiple concurrent doctor tasks may

88 lead to clinical errors.[3] The lack of familiarity between patients and physicians, and the complex,

89 high-stress, unpredictability and dynamic of the work,[4] present challenges for effective

90 communication.

91 In this stressful context, giving patients information can be difficult as physicians have restricted

92 time for each patient and the patient's capacity to retain information is often limited.[5] Besides

93 the condition itself, EDs are frequently places where lack of comfort, high influx and

94 overcrowding may be upsetting for the patient. Discharge from the ED can be a period of

5

95 vulnerablity for patients.[5,6] They run the risk of further clinical deterioration, may experience side-

96 effects from a newly prescribed drug, or even suffer from the consequences of a wrong

97 diagnosis.[5,7]

98 In the ED, the information delivered by the physician to the patient is crucial[8,9,10] and if it is

99 insufficient, neglected or misunderstood, the patient could suffer complications.[8,9] Patients

100 Information Leaflets (PILs) appear to be–highly suited to this context. They have a role in the

101 continuity of care by facilitating the hospital to home transition and can be considered as a

102 resource both for the patient and the doctor.[11] Indeed, PILs given during a consultation play a

103 important role in assisting patients in making informed choices, taking treatments appropriately,

104 or following advice on lifestyle changes.[12,13] While PILs have become an integral part of

105 everyday medical practice, [11] their use in EDs has been relatively little studied.

106

107 Over the last few decades, many authors have attempted to evaluate PILs.[11, 14-16] However, the

108 heterogeneity of research protocols, in particular in the choice of outcomes and the way they

109 are measured, has made it impossible to pool relevant data and to draw general conclusions

110 about their effectiveness.[11, 17]

111

112 Primary outcomes have mainly concerned adherence to treatment, knowledge or patient

113 satisfaction,[11,17-19] but seldom communication effectiveness,[11,12] which has been identified as one

6

114 of the six general competencies essential for a physician[20] and as the ultimate criterion of PILs'

115 assessement.[13] Whatever the outcome selected, it is seldom defined with clarity and when it is,

116 its definition never takes into account the other outcomes of interest, which would make it

117 possible to avoid redundancy.[9]

118

119 Although the literature on PILs is large, few studies have focused on acute conditions and/or

120 been conducted in ED.[10] Most of the studies dealing with PILs for AC have been focused on a

121 specific condition[14-16,21-25] using research protocols which combined several tools since no single

122 tool was considered completely satisfactory.[26] Most of these tools were not generic and don't

123 allow comparisons between studies.[11,26]

124

125 To overcome all those obstacles, we started from a theoretical multidisciplinary model describing

126 the main outcomes of a consultation found in the literature.[11] We then used generic scales

127 usable in the context of acute conditions and measuring Doctor-Patient Communication (DPC),[27]

128 adherence, patient and doctor behaviours, and patient satisfaction.

129

130 In the present study, based on this commun model, we assess the impact of 6 PILs on Doctor-

131 Patient Communication in two French EDs. The secondary objectives were to assess the impact

132 of the use of PILs on patient satisfaction, patient adherence, and patient and doctor behaviours.

7

133

MATERIALS AND METHODS

Study design and settings

136 A prospective comparative interventional non-randomized study was conducted in France (region

137 Rhone-Alps) in two hospitals' EDs between September 2013 and June 2014 (phase 1, control

138 group) and between September 2014 and June 2015 (phase 2, intervention group) in a

139 controlled before-after design. The study was approved by the regional ethics committee on 31

140 Oct 2013 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand).

141

Cohort description

143 The study had two arms: a control group with standard consultations (phase 1: no PILs) and an

144 intervention group with standard consultations plus PILs given by the physician (phase 2: with

145 PILs).

146 For both groups, all consecutive outpatients (adults and adolescents >15 years) diagnosed with

147 one of the following conditions: ankle sprain, acute pyelonephritis, acute prostatitis, pneumonia,

148 acute diverticulitis or infectious colitis) and who would be contactable by telephone 7 to 10 days

149 after the consultation, were informed of the study by the physician (orally and through a patient

150 information letter). The 6 diagnoses selected (covered by 6 different PILS) concerned two

151 different types of condition frequently encountered in an outpatient emergency department: non

8

152 life-threatening traumas and infections.

153 If they agreed to participate, the patients were asked to sign an informed consent form and the

154 physician had to complete a short inclusion-case report form describing the patient's profile. If

155 the patient declined to participate, we asked to the physicians to record this by completing a

156 form. Patients who were hospitalised for more than 48 hours following the consultation were

157 excluded.

158 The consent letter was identical for both groups. It explained that the purpose of the study was

159 to assess doctor-patient communication and patient satisfaction and that this study might help to

160 improve these in the future.

161

162 **The intervention**

163 After establishing a diagnosis and inclusing the patient in the study, the physician gave patients

164 in the intervention group a PIL corresponding to their condition. Physicians were instructed to

165 refer to the PIL during the consultation.

166 The 6 PILs used had been selected from among one hundred PILs that had been written over

167 the 3 years and which are available in French on a medical website

168 (https://www.ssmg.be/fiches-dinformation-des-patients). Un example of the PILs used is shown in

169 the supplementary file (colite). The leaflet was A4 size (210 × 297 mm), featured an illustration

170 related to the condition and information on the causes of the condition, its symptoms, the risks,

9

171 the usual course of the disease, the treatments, and any persisting or new symptoms which

172 would require a further medical consultation. Each PIL had been elaborated following a

173 rigourous methodology based on a synthesis of the literature.[11,28] Their development had

174 consisted of the 10 following steps: selection of the topic and the objectives of the PIL, a

175 literature review on the subject, definition of the sections, drafting, expert consensus on the

176 contents, assessment by patients, agreement on the layout, choice of the diffusion strategy,

177 delivery to patients and regular updates. Each PIL had been reviewed by at least two

178 physicians to verify its coherence with evidence based medicine and readability. In addition a

179 Flesch readability score of 60 was required, corresponding to a junior high school level of

180 reading. The PILs for our study concerned 6 conditions that often require prescriptions for

181 medication, additional examinations, advice on lifestyle changes and instructions as to if and

182 when to consult again.

183 For the purposes of the study, we checked that the information was completely up-to-date and

184 any corrections were made. This took about 2 days for one of our research team members.

185

Patient and public involvement statement

187 All PILs were written according to the same methodology taking into account the patients' usual

188 priorities, experience, and preferences.[11,28]   They were each read by at least two volonteer

189 patients.[11,28] Patients were not involved in the design of the study, nor in the conduct of the

10

190   study.   Answers to the questions were provided by the patients themselves over the phone,

191   they assumed the responsibility of reporting on their behaviour since the consultation and

192   whether to be truthful or not.

193

194   **Measurements**

195   Between 7 and 10 days after the consultation the patient was telephoned by an investigator

196   who had not participated in the patient recruitment, was not involved in their care, and who did

197   not know *a priori* the patient's diagnosis or which PIL they had been given. They were asked to

198   answer several series of questions. If they were unreachable the first time, the call was

199   repeated, twice. If the investigator was not able to contact them, a contact person designated

200   by the patient on the inclusion sheet was phoned. If this also failed, then the patient was

201   considered as lost to follow-up.

202

203   **Outcomes**

204   Data about the socio-demographic characteristics of the patients (9 questions), about the PIL

205   received (16 questions) and about the doctor's behaviour (4 questions) were collected. For the

206   DPC score, we used a validated generic questionnaire for acute conditions (13 questions).[27] For

207   satisfaction and adherence scores, we used the short questionnaires we had previously

208   developed: 5 questions about satisfaction, 6 questions on patient adherence (including 3 items

11

209 about drug adherence, one item about non-drug prescriptions, one about recommendations and

210 advice, and one about the way to use the health care system after the current consultation), 3

211 questions on the patient's behaviour and 4 questions on the doctor's behaviour. Each of the

212 outcomes had been clearly defined according to the same theoretical model[11] to study the

213 correlations between them. DPC, satisfaction and adherence scores were calculated from replies

214 (scored on a 4-point Likert scale) to the phone questionnaires.

215

216 **Sample size calculation**

217 The main objective was to measure the impact of PILs given during the consultation on the

218 DPC score. In the absence of published data on the subject, we made the following

219 assumptions: taking an average DPC score of 40 (ie 75% of the maximum score) and a

220 minimum effect level of 15% i.e. a gain of 6 points (by analogy with the recommended

221 Minimally Clinically Important Improvement pain or function scales);[29] then for an standard

222 deviation (SD) of 16 points and a power of 90% (Program: Stata, estimated sample size for

223 two-sample comparison of means using a t-test) 150-patients per group were needed. With an

224 estimated lost to follow-up rate of 12.5% and erronous inclusions, we planned 200 patients per

225 group i.e. 400 in total.

226

227 **Analysis**

12

228 Statistical analysis was performed with the recommended procedures of data management and

229 database freezing using Stata version 13.0 software (Stata Corp, College Station, Texas) OSX.

230 We planned an intention-to-treat analysis (all patients in both Phase 1 and 2) and a strictly per-

231 protocol analysis (patients without PILs in Phase 1 versus those patients who recieved PILs

232 with an oral explanation given by doctor in Phase 2). Statistical tests were carried out with an

233 alpha risk of error of 0.05. Variables are described by numbers and percentages, and

234 continuous variables by median and IQR [25th and 75th percentiles]. For quantitative variables,

235 the Mann-Whitney test was used to compare two groups. For qualitative variables, the Chi2 test

236 was used if applicable; otherwise the Fisher exact test was used. The DPC scores were

237 classified as high (>50), intermediate (36-50) or low (≤35) to test the difference between the two

238 groups. Multivariate analysis was performed by logistic regression to give an OR (and 95% CI)

239 for good communication (score > 35) adjusted on age, sex, marital status and type of condition.

240 The replacement of missing values for the DPC score (the main outcome) was performed for

241 patients with less than 20% of missing answers, i.e two missing out of 13 at most.

242 Replacement was done using the answers obtained to the other questions (11 patients out of

243 324 (3.4%) including 9 patients with 1 missing item and 2 patients with 2 missing items out of

244 13). If 3 or more responses were missing, the patient was excluded from the analysis.

245

246 **RESULTS**

13

247   **Characteristics of study subjects**

248   Four hundred patients were included in our study and 324 sets of answers were analysed: 156

249   patients without PILs and 168 with PILs. More patients presented with ankle sprain (183) than

250   with an infectious disease (141). Figure 1 shows the patient flow chart. No non-inclusion form

251   was registered. Table 1 presents a comparison of baseline characteristics and shows no

252   statistically significant difference between the groups.

253

254   **Table 1**. Comparison of baseline characteristics of patients between groups who received a

255   Patient Information Leaflet during the emergency department consultation and those who did

256   not. Values are numbers (percentages) or medians (interquartile range).

Variables	Control Group without PILs (N=156)	Intervention Group with PILs (N=168)	p-value
Condition			
Ankle sprain	83 (53.2 %)	100 (59.5 %)	0.25
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			
Junior high school	62 (39.7 %)	62 (36.9 %)	
			0.55
High school	39 (25 %)	37 (22 %)	
University	55 (35.3 %)	69 (41.1 %)	
Socio-professional category			
Farmers/artisans/tradesmen	7 (4.5 %)	6 (3.6 %)	
Intellectuals/managers	30 (19.2 %)	32 (19 %)	0.90
Employees/workers	43 (27.6 %)	52 (31 %)	
Retirees/students etc.	76 (48.7 %)	78 (46.4 %)	
Marital status			
Single	79 (50.6 %)	67 (39.9 %)	0.05
Living as a couple	77 (49.4 %)	101 (60.1 %)	

257

258 Values are numbers (percentages) or median (interquartile range)

259

260 **Main results**

261 In ED, PILs given by the doctor improve the DPC score, in all comparisons (medians compared

262 or classes compared). Figure 2 presents the Doctor Patient Communication scores. This result

263 is identical after adjusting for age, sex, family status and pathology. It is reinforced in the

264 strictly per-protocol population. Table 2 shows the DPC scores.

265

266 **Table 2**. Comparison of Doctor-Patient Communication (DPC) scores between the two groups

267 without and with PILs.

SCORES	Control Group without PILs	Intervention group with PILs	Odds Ratio (OR) with 95% confidence interval	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			Univariate OR for good	**<0.01**

			communication (score >35): 2.73 [1.39-5.35]	
> 35	31/156 (19.9%)	14/168 (8.3%)		
	25/156 (80.1%)	154/168 (91.7%)	Adjusted∗ OR for good communication (score >35): 2.54 [1.27-5.06]	
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 [1.98-22.6]	**<0.01**
> 35	125/156 (80.1%)	81/84 (96.4%)	Adjusted∗ OR for good communication (score >35): 5.60 [1.63-19.2]	

268 ∗ adjusted for age, sex, family situation and pathology

269

270 **Secondary objectives**

271 Table 3 shows comparisons of overall scores and of patients' responses about their satisfaction,

272 adherence, and patient and doctor behaviours in the two phases.

273

274 **Table 3.** Secondary objectives: satisfaction, adherence, and patients' and doctors' behaviours

275 (ITT analysis).

A. Satisfaction	Control group without PIL n = 156	Intervention group with PILs n= 168	OR [95%CI]	p-value
I. Satisfaction with infrastructure (reception, food, waiting time)	92/156 (59 %)	91/168 (54.2%)	0.82 [0.53-1.28]	0.38
II. Satisfaction with nurses and care assistants	112/156(71.8%)	137/168 (81.6%)	1.74 [1.03-2.93]	**0.04**
III. Satisfaction with the doctor	103/156 (66%)	131/168 (78%%)	1.82 [1.11-2.98]	**0.016**
IV. Satisfaction with the medical	93/156 (59.6%)	129/168 (76.8%)	2.24 [1.39-	**<.0.01**

	Control group	Intervention group	OR [95%CI]	p-value
consultation			3.62]	
V. Would you recommend the ED to friends or family?	119/156 (76.3%)	135/168 (80.4%)	1.27 [0.75-2.16]	0.37
Total satisfaction score:	19 [16-20]	19[17-20]		0.20

B. Adherence∗ (according to doctor behaviours)	Control group without PILs	Intervention group with PILs	OR [95%CI]	p-value
I- Have you taken the whole course of the prescribed treatment?	108/134 (80.6%)	107/130 (82.3%)	1.12 [0.60-2.09]	0.72
II- Did you respect the prescribed doses?	127/134 (94.8%)	122/124 (98.4%)	3.36 [0.68-16.5]	0.18
III- Did you comply with the regimen and conditions (time at which you should take the medication, if you were fasted or not, during meals etc.)?	113/134 (84.3%)	116/124 (93.5%)	2.69 [1.15-6.33]	**0.02**
IV- Did you have additional examinations or a specialized consultation prescribed	87/98 (88.8%)	119/141 (84.4%)	0.68 [0.32-1.48]	0.34

by your doctor (imagery, laboratory

analyses, an appointment with a

specialist)?

V- 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 [0.19-1.17]	0.10
VI- Did you follow health monitoring instructions and advice given by your doctor on if and when to reconsult a healthcare professional?	75/78(96.2%)	81/83 (97.6%)	1.62 [0.26-9.96]	0.67
Total adherence score:	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
I-Did you need a new medical consultation for the same condition?	50/156 (32.1%)	30/168 (17.9%)	0.46 [0.27-0.77]	**< 0.01**

I.1- Did you consult an ED physician?	42/156 (26.9%)	14/168 (8.3%)	0.25 [0.13-0.47]	**<0.01**
I.2- Did you consult your primary care physician?	11/156 (7.1%)	17/168 (10.1%)	1.48 [0.67-2.28]	0.32
D- Doctor behaviours				
I-Drug prescriptions?	134/156 (85.9%)	130/168 (77.4%)	0.56 [0.32-1.00]	**0.049**
II- Prescriptions of further tests (laboratory analysis, imaging, appointment with specialists)?	98/156 (62.8%)	141/168 (83.9%)	3.09 [1.83-5.22]	**<0.01**
III- Given advice to follow?	89/155 (57.4%)	123/168 (73.2%)	2.03 [1.27-3.23]	**<0.01**
IV- Information on if and when to consult a doctor again?	79/155 (51.0%)	84/165 (50.9%)	1.00 [0.64-1.55]	0.99

276

277 ∗Two patients in phase 1 (control) and three patients in phase 2 (with PILs) didn't receive any

278 prescription and weren't included in the adherence analysis.

279

21

280   There were no significant differences in overall satisfaction and adherence scores across the

281   entire population (ITT). All three satisfaction' items related to healthcare professionals and, for

282   adherence, the item related to timing of medication intake, were significantly improved. The

283   overall satisfaction score significantly improved on per-protocol analysis. Table 4 shows answers

284   to questions concerning the PIL in the intervention group.

285

286   **Table 4.** Answers to questions concerning the Patient Information Leaflet (numbers and

287   percentages).

Questions	Yes	Does not remember
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

22

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%)

288

289   The comparison of DPC and satisfaction scores, each in 2 classes (DPC ≤ 35 or > 35;

290   satisfaction score ≤16 or >16) and whether the PIL was given to the patient by the physician

291   (n=127/159, 79.9%) or by a nurse (28/159, 18.2%), did not show significant differences. DPC

292 and satisfaction scores were higher when patients received the PIL with an explanation

293 (p=0.02). The need for a new medical consultation for the same pathology was reduced with

294 PILs from 32.1% to 17.9% (OR 0.46 [0.27-0.77] p < 0.01).

295

296 **DISCUSSION**

297 Emergency medicine is largely a communication activity and medical incidents occurring in this

298 context are too often the result of poor communication processes.[4,30] Developing tools that

299 improve communication in EDs is a real public health need.

300

301 **Main resultats**

302 Our study shows that patient information leaflets handed out during emergency department

303 consultations improve DPC (the number of patients who considered DPC to be very good

304 doubled and the number of patients who thought that DPC was insufficient halved). Regarding

305 patient satisfaction, all three items concerning healthcare professionals improved with PILs.

306 Concerning adherence, PILs also improved the respect of medication intake schedules. PILs

307 reduced the need for consultations for the same pathology, particularly a return to the ED.

308 When doctors used PILs, they prescribed fewer medications and more additional diagnostic

309 tests.

310

24

Doctor-Patient Communication

312 In 2010, Ha and Longnecker wrote that ¨most complaints about doctors are related to issues of

313 communication, not clinical competency'' and that "effective DPC is a central clinical function in

314 building a therapeutic doctor-patient relationship".[26] Although in our study the physician was

315 instructed to personally give the PIL to the patient during the consultation along with oral

316 information, some delegated the task a nurse. Nonetheless, irrespective of who handed over the

317 PIL, DPC and satisfaction increased when the leaflet was explained to the patient. This is

318 consistent with other studies.[31,32] While this suggests that explaining the PIL to the patient could

319 be a task done by other medical or paramedical staff, we believe it is preferable that the PIL is

320 personnaly delivered during the consultation by the doctor who adapts his behaviour according

321 to the content of the PIL.

322

Satisfaction

324 Patient satisfaction was partially improved by PILs. Among the 5 items included in the

325 satisfaction score, all three items about healthcare professionnals underwent a statistically

326 significant improvement. One item, concerning whether the patient would recommend the ED to

327 a friend or family, tended to be improved. Another item, related to the infrastructure and

328 organization of the ED (reception, waiting time), could not be influenced by the use of PILs. In

329 a systematic review, the authors found that key interventions to improve patient satisfaction in

25

330 ED are those that develop the interpersonal and attitudinal skills of staff, increase the

331 information provided, and reduce the perceived waiting time.[33]

332 We note that in the literature, results concerning satisfaction linked to PILs are not unanimous.

333 One explanation is the heterogeneity of the questions among different satisfaction scales. For

334 example, the scale developed by Arnold et al. explores accessibility of care, the attitude of

335 medical and paramedical staff, quality of care, waiting times, practical information delivered

336 (costs of care etc.); and in a study of groups receiving PILs or not, concluded that both groups

337 had high scores for each dimension of patient satisfaction and that there was no evidence that

338 the PIL was associated with any change in satisfaction.[34] In their satisfaction scale, Little et al.

339 assessed items similar to those we explored through our DPC scale (relieving distress, intention

340 to comply with care management decisions, communication, amount of information delivered,

341 confidence in the doctor, relationships) and he concluded that a leaflet increased patient

342 satisfaction.[21] Different satisfaction scales explore different dimensions and a detailed

343 comparaison with the contents of various scale, showed that our results are consistent with the

344 literature.

345

346 **Adherence and patient behaviours**

347 We observed a ceiling effect with a high global adherence score in both groups (with and

348 without PILs). As seen in our results, it was very difficult to improve adherence. Good

26

349 adherence to treatment and to the doctor's advice can be explained by the fact that ED

350 patients are highly motivated to take their treatment, as their medical condition is often painful

351 or could deteriorate. Often they have waited several hours for the consultation (some patients

352 leave the ED before seeing a doctor), they are stressed, anxious and want to get better.

353 Moreover, medical treatment for an AC is usually of short duration, contributing to better

354 adherence.[21] Nevertheless, the patients' responses showed that PILs given out in the context of

355 an AC help patients to better respect the schedule for taking their medication. Furthermore, with

356 PILs, they reconsult less for the same pathology and are less likely to return to the ED. If they

357 do reconsult, they tend to visit their primary care physician/general practitioner rather than the

358 ED.

359 We also observed that even though the results were not significant, the group without PILs

360 tended to follow the recommendations and advice of the physician better than the PILs group.

361 One may wonder whether the doctor gave less oral information when he/she gave the patient a

362 PIL or if some information was lost due to information overload in patients who received two

363 sources of information (oral information and written). This result should be confirmed by a study

364 involving a larger number of patients and/or by an analysis of audio recordings of the

365 consultations.

366

367 **Doctor behaviours**

27

368 Like Little et al., we found that physicians tended to increase the number of laboratory analyses

369 and examinationss ordered[35] and reduce the number of drug prescriptions when they used

370 PILs.[25, 36-38] It may be that PILs act as reminders for over-worked physicians and also help

371 structure the dialogue, resulting in less drug prescriptions and more tests (laboratory analyses,

372 imaging examinations etc). In a future study it would be interesting to check whether these

373 changes in the behaviour of the doctors, as perceived by the patients: 1) are real by analysing

374 audio or video recordings of the consultations; 2) follow the recommendations (sometimes for

375 further tests) contained in the PILs; 3) are correlated with an improvement in outcomes. This

376 would allow us to know whether better outcomes are directly linked to PILs or only indirectly by

377 the change in behaviour of the doctor when using PILs.

378

379 **Strengths and Limitations**

380 Regarding the improvement in the DPC score, we failed to obtain the expected 6-point gain.

381 Nevertheless, the improvement in DPC was significant and associated with better outcomes

382 such as satisfaction or fewer re-consultations in an ED for the same condition.

383

384 In this multicenter prospective interventional study, we used several different PILs for different

385 acute conditions in two hospital EDs with a relatively large series of patients. Our choice of

386 objectives is supported by a recent study, in which qualitative semistructured interviews were

28

387 performed a few days following discharge from ED. The four outcomes that were valued by

388 patients were: understanding the cause and expected trajectory of their symptoms; reassurance;

389 symptom relief; and having a plan to manage their symptoms, resolve their issues, or pursue

390 further medical care.[39] In the ED context, PILs can be a valuable tool both for the patient,

391 helping them to respect the instructions given by the doctor when they return home, and for

392 doctors, to better inform their patient in the short timespan of an emergency consultation.[5] In

393 our study, all 6 PILs were developed according to the same rigorous methodology and generic

394 questionnaires were used, as recommended.[11,28]

395

396 The AC included in the study were all non-severe, thus we cannot generalize our findings to

397 the entire range of pathologies seen in an ED. We note that the level of severity of a disease

398 impacts on satisfaction, in particular the more severe the pathology, the less importance the

399 patient gives to the infrastructure and the more satisfied he/she is.[38]

400

401 The study coordinator received no non-inclusion forms, which might be explained by the lack of

402 time in ED.[5] It is impossible to tell whether patients lost to follow-up (who could not be

403 contacted by telephone after 3 attempts) were the least satisfied, and/or least adherent. These

404 biases might have led to an over-estimation of the results.

405

406 Although the strongest interventional study design is a randomized controlled trial,[40] individual

407 patient randomization was not possible due to the major risk of contamination bias between

408 patients, between doctors (as the physicians shared office space) and a learning effect related

409 to the content of the leaflet (doctors unconsciously adapting what they say to 'control' group

410 patients). Our choice of a prospective controlled before-after trial allowed us to have the same

411 doctors in both groups. Doctors were not told the precise objectives of the study; however we

412 cannot completely exclude a Hawthorne effect bias during phase 2 of the study.

413

414 The investigators were independent of the ED physicians. In ED, interventional studies are

415 relatively scarce, probably due to difficulties in implementing them. In a systematic review of the

416 effectiveness of interventions to decrease ED visits by frequent adult users (one of our

417 outcomes),[41] among the 31 articles analysed the majority (21) were non-controlled studies.

418 Among the 10 interventional studies considered as providing a strong level of evidence, 4 were

419 controlled before-after studies and 6 were randomized controlled trials. In our study, the two

420 groups were comparable at baseline, confirmed statistically after adjustment on the main

421 characteristics of the patients. To minimize biases related to the different temporal contexts of

422 the two phases, we chose two identical periods of the year. Although our choice of design

423 seems to be well adapted to our objective, our findings should be confirmed in a large-scale

424 cluster randomized trial involving many EDs.

425

30

426 **Sustainbility of the intervention in everyday pratice**

427 To facilitate the feasibility of our study, the PILs were printed in advance, to allow patients to

428 read them without having to have an Internet connection. In fact all the PILs are available in

429 electronic format on a medical website and are commonly used by French speaking primary

430 care general practitioners during consultations. Thus, we do not see any obstacle to their use in

431 EDs, especially as it is often the same pathologies that are encountered. Regarding the

432 feasibility of using PILs in EDs: it would have been interesting to check 6 months after the

433 study if doctors and medical students had continued to use them and whether they downloaded

434 and used the other PILs available on the internet site; but this was not the purpose of our

435 study. Nevertheless, a future study should test whether PILs have an impact on the consultation

436 time and whether the emergency physicians who participate in the study continue to use them

437 after the study. To broaden usability we are planning to translate the PILs into English.

438

439 **Practice implications**

440 In ED, PILs could be an easy-to-use tool for improving DPC, benefiting both the doctor and the

441 patient.

442

443 **Data sharing**

444 Extra data is available by emailing Dr Mélanie Sustersic: melanie.sustersic@gmail.com.

31

445

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448

449 **Competing interests statement**

450 None declared.

451

452

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570

571   **Figure 1**. Patient flow chart.

572

573   **Figure 2.** Doctor-patient communication scores.

574

```
┌──────────────────────┐      ┌──────────────┐      ┌──────────────────────┐
│ 189 recruited patients│◄────►│  0 withdrew  │◄────►│ 211 recruited patients│
│                      │      │participation │      │                      │
└──────────────────────┘      └──────────────┘      └──────────────────────┘
```

0 withdrew participation

189 recruited patients

211 recruited patients

12 recruited in error

15 recruited in error
(11 hospitalised> 48h, 2 did not speak XXX, 2<15 years old)

177 eligible patients

196 eligible patients

21 lost to follow-up
-19 unreachable
-2 withdrew participation

28 lost to follow-up
-25 unreachable
-3 withdrew participation

156 analysed patients

168 analysed patients

Patient flow chart

161x95mm (300 x 300 DPI)

Doctor-patient communication scores.

146x106mm (300 x 300 DPI)

Colite infectieuse

Les points clés

Il s'agit d'une inflammation du colon.
Liée à un virus, bactérie ou un parasite, on parle de colite infectieuse.
Elle peut aussi avoir d'autres causes (médicaments, radiothérapie ; trouble vasculaire du colon etc.).

COLON TRANSVERSE
COLON DROIT
COLON GAUCHE

Les symptômes
➢ Douleurs abdominales;
➢ Diarrhée (+/-glaires ou sang) ;
➢ Fièvre modérée ;
➢ Fatigue ou soif intense si déshydratation.

Les causes
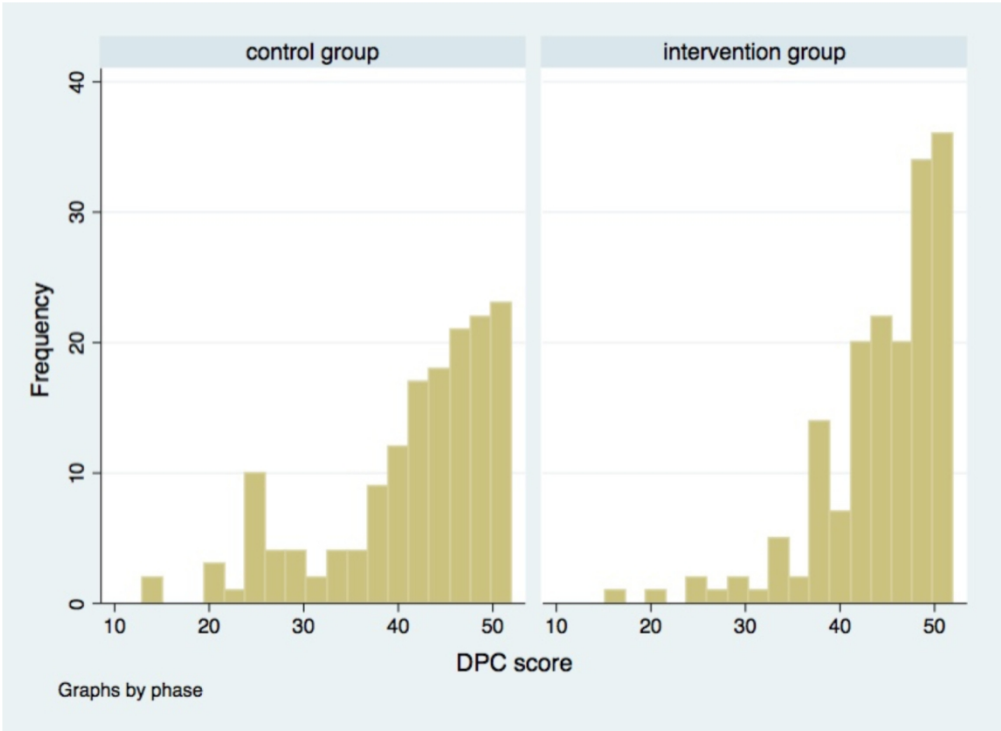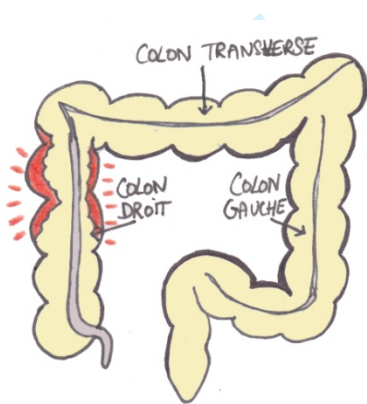La colite infectieuse est causée par la présence anormale de germes dans l'intestin (virus, bactérie, parasite).

L'évolution
Le plus souvent favorable en quelques jours.

Les complications
Elles sont rares :
- Déshydratation (si diarrhée abondante)
- Hémorragie (si diarrhée sanglante)

Le diagnostic

Par un examen clinique et des examens complémentaires :
➢ Prise de sang (recherche d'une infection) ;
➢ +/- coprocultures (analyse des selles) à la recherche de germes ;
➢ +/- un scanner abdominal.

Le traitement

- **ANTIBIOTIQUES SELON LES CAS** : pas toujours utiles et selon le germe en cause (ex : salmonelles et Campylobacter Pylori). Respecter la durée prescrite (7 à 10 jours selon les cas).
Ne pas les arrêter sans avis médical.
-**GLACE** sur le ventre si cela vous soulage ;
-**PARACETAMOL**: toutes les 6 heures si fièvre ou douleur.

Les conseils hygiéno-diététiques

- **RESTER A JEUN**: quelques heures après le début de la crise. Puis:
- **REGIME SANS RESIDUS** pendant 10 à 15 jours, pour mettre l'intestin au repos.
- **BIEN BOIRE** les jours qui suivent le début de la crise

Le suivi

Revoir votre médecin traitant dans les 2 à 3 jours qui suivent la crise.
Le but : s'assurer de la bonne évolution de la maladie.

Quand reconsulter ?

➢Si la fièvre persiste 48-72h après le début de la crise ;
➢Si les signes réapparaissent;
➢Si votre état ne s'améliore pas ou s'aggrave.

Nom et signature du médecin:

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.

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1

2 **Impact of Patient Information Leaflets on Doctor-Patient Communication in the context of acute**

3 **conditions: a prospective controlled before-after study in two French emergency departments.**

4

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15 **Study registration:** ClinicalTrials.gov: NCT02246361

16

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24

25 **Keywords:** Doctor-Patient Communication, Patient Information Leaflet, acute condition, emergency

26 department, satisfaction, patient behavior, doctor behavior, adherence.

27

1

35 **Contributorship statement**

36 MS, AG and JLB conceived the project.

37 MS, JT and MT conducted the study.

38 CV and JLB performed the statistical analyses, interpreted the results and prepared the figures.

39 MS, JLB, JT, MT, AG and AF wrote the article.

40

41 **ABSTRACT**

42 **Objectives:** In the context of acute conditions seen in an emergency department, where communication may be

43 difficult, Patient Information Leaflets (PILs) could improve Doctor-Patient Communication (DPC) and may

44 have an impact on other outcomes of the consultation. Our objective was to assess the impact of PILs on DPC,

45 patient satisfaction and adherence, and on patient and doctor behaviours.

46 **Design:** Prospective controlled before-after trial between November 2013 and June 2015.

47 **Settings:** Two French emergency departments.

48 **Participants:** Adults and adolescents > 15 years diagnosed with ankle sprain, or an infection (diverticulitis,

49 infectious colitis, pyelonephritis, pneumonia or prostatitis).

50 **Intervention:** Physicians in the intervention group gave patients a PIL about their condition along with an oral

51 explanation.

52 **Main outcome mesures:** Seven to 10 days later, patients were contacted by phone to answer questionnaires.

53 Results were derived from questions scored using a 4-point Likert scale.

54 **Main findings**: Analysis of the 324 patients showed that PILs improved the mean DPC score (range from 13 to

55 52): with 46 [42-49] for 168 patients with PILs versus 44 [38-48] for 156 patients withouta PIL (p-value< 0.01).

56 The adjusted Odds Ratio for good communication (having a score >35/52) was 2.54 [1.27-5.06]. The overall

57 satisfaction and adherence scores did not show significant differences. In contrast, satisfaction with healthcare

58 professionnals and timing of medication intake were improved with PILs. The overall satisfaction score

59 improved significantly on per-protocol analysis. When using PILs, the doctors prescribed fewer drugs and more

2

60 examinations (radiology, biology, appointment with a specialist); the need for a new medical consultation for the

61 same pathology was reduced from 32.1% to 17.9% (OR 0.46 [0.27-0.77]) particularly re-visiting the ED.

62 **Conclusions**: In emergency departments, PILs given by the doctor improve DPC, increase patients' satisfaction

63 with healthcare professionals, reduce the number of emergency reconsultations for the same pathology and

64 modify the doctor's behaviour.

65

66 **STRENGTHS AND LIMITATIONS**

67 • A simple way to improve Doctor-Patient Communication and physician behaviour in EDs.

68 • All scores used in the methodology were generic and based on the same solid theoretical model

69   describing a consultation for an acute condition.

70 • The only study design possible was a before-after study to avoid a biais of contamination between

71   physicians in the particular context of an ED.

72 • No non-inclusion form was registred by physicians, which may be a bias of patient selection.

73
74

75 **INTRODUCTION**

76 Acute conditions (AC) are a very common reason for consultation in primary care, both in general practice and

77 in emergency departments (ED). An AC can be defined as being a condition of short duration.[1] Faced with an

78 AC "the primary goal of the physician is to improve health and effectiveness largely depends on time-sensitive

79 and, frequently, rapid intervention".[2]

80 In an ED, the combination of frequent interruptions and multiple concurrent doctor tasks may lead to clinical

81 errors.[3] The lack of familiarity between patients and physicians, and the complex, high-stress, unpredictability and

82 dynamic of the work,[4] present challenges for effective communication.

83 In this stressful context, giving patients information can be difficult as physicians have restricted time for each

84 patient and the patient's capacity to retain information is often limited.[5] Besides the condition itself, EDs are

85 frequently places where lack of comfort, high influx and overcrowding may be upsetting for the patient. Discharge

86 from the ED can be a period of vulnerablity for patients.[5,6] They run the risk of further clinical deterioration, may

87 experience side-effects from a newly prescribed drug, or even suffer from the consequences of a wrong

88 diagnosis.[5,7]

3

89   In the ED, the information delivered by the physician to the patient is crucial[8,9,10] and if it is insufficient, neglected

90   or misunderstood, the patient could suffer complications.[8,9] Patients Information Leaflets (PILs) appear to be

91   highly suited to this context. They have a role in the continuity of care by facilitating the hospital to home transition

92   and can be considered as a resource both for the patient and the doctor.[11] Indeed, PILs given during a consultation

93   play a important role in assisting patients in making informed choices, taking treatments appropriately or following

94   advice on lifestyle changes.[12,13] While PILs have become an integral part of everyday medical practice,[11] their use

95   in EDs has been relatively little studied.

96

97   Over the last few decades, many authors have attempted to evalute PILs.[11, 14-16] However, the heterogeneity of

98   research protocols, in particular in the choice of outcomes and the way they are measured, has made it impossible

99   to pool relevant data and to draw general conclusions about their effectiveness.[11, 17]

100

101   Primary outcomes have mainly concerned adherence to treatment, knowledge or patient satisfaction,[11,17-19] but

102   seldom communication effectiveness,[11,12] which has been identified as one of the six general competencies

103   essential for a physician[20] and as the ultimate criterion of PILs' assessement.[13] Whatever the outcome selected, it

104   is seldom defined with clarity and when it is, its definition never takes into account the other outcomes of interest,

105   which would make it possible to avoid redundancy.[9]

106

107   Although the literature on PILs is large, few studies have focused on acute conditions and/or been conducted in

108   ED.[10] Most of the studies dealing with PILs for AC have been focused on a specific condition[14-16,21-25] using

109   research protocols which combined several tools since no single tool was considered completely satisfactory.[26]

110   Most of these tools were not generic and don't allow comparisons between studies.[11,26]

111

112   To overcome all those obstacles, we started from a theoretical multidisciplinary model describing the main

113   outcomes of a consultation found in the literature.[11] We then used generic scales usable in the context of acute

114   conditions and measuring Doctor-Patient Communication (DPC),[27] adherence, patient and doctor behaviours, and

115   patient satisfaction.

116

4

117 In the present study, based on this common model, we assess the impact of 6 PILs on Doctor-Patient

118 Communication in two French EDs. The secondary objectives were to assess the impact of the use of PILs on

119 patient satisfaction, patient adherence, and patient and doctor behaviours.

120

121 **MATERIALS AND METHODS**

122 **Study design and settings**

123 A prospective comparative interventional non-randomized study was conducted in France (region Rhone-Alps) in

124 two hospitals' EDs between September 2013 and June 2014 (phase 1, control group) and between September 2014

125 and June 2015 (phase 2, intervention group) in a controlled before-after design. The study was approved by the

126 regional ethics committee on 31 Oct 2013 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand).

127

128 **Cohort description**

129 The study had two arms: a control group with standard consultations (phase 1: no PILs) and an intervention group

130 with standard consultations plus PILs given by the physician (phase 2: with PILs).

131 For both groups, all consecutive outpatients (adults and adolescents >15 years) diagnosed with one of the following

132 conditions: ankle sprain, acute pyelonephritis, acute prostatitis, pneumonia, acute diverticulitis or infectious

133 colitis) and who would be contactable by telephone 7 to 10 days after the consultation, were informed of the study

134 by the physician (orally and through a patient information letter). The 6 diagnoses selected (covered by 6 different

135 PILS) concerned two different types of condition frequently encountered in an outpatient emergency department:

136 non life-threatening traumas and infections.

137 If they agreed to participate, the patients were asked to sign an informed consent form and the physician had to

138 complete a short inclusion-case report form describing the patient's profile. If the patient declined to participate,

139 we asked to the physicians to record this by completing a form. Patients who were hospitalised for more than 48

140 hours following the consultation were excluded.

141 The consent letter was identical for both groups. It explained that the purpose of the study was to assess doctor-

142 patient communication and patient satisfaction and that this study might help to improve these in the future.

143

144 **The intervention**

145 After establishing a diagnosis and including the patient in the study, the physician gave patients in the intervention

146 group a PIL corresponding to their condition. Physicians were instructed to refer to the PIL during the consultation.

5

147 The 6 PILs used had been selected from among one hundred PILs that had been written during last 3 years and are

148 available in French on a medical website (https://www.ssmg.be/fiches-dinformation-des-patients). An example of

149 the PILs used is shown in the supplementary file (colitis). The leaflet was A4 size (210 × 297 mm), featured an

150 illustration related to the condition and information on the causes of the condition, its symptoms, the risks, the

151 usual course of the disease, the treatments, and any persisting or new symptoms which would require a further

152 medical consultation. Each PIL had been elaborated following a rigourous methodology based on a synthesis of

153 the literature.[11,28] Their development had consisted of the 10 following steps: selection of the topic and the

154 objectives of the PIL, a literature review on the subject, definition of the sections, drafting, expert consensus on

155 the contents, assessment by patients, agreement on the layout, choice of the diffusion strategy, delivery to patients

156 and regular updates. Each PIL had been reviewed by at least two physicians to verify its coherence with evidence

157 based medicine and readability. In addition a Flesch readability score of 60 was required, corresponding to a junior

158 high school level of reading. The PILs for our study concerned 6 conditions that often require prescriptions for

159 medication, additional examinations, advice on lifestyle changes and instructions as to if and when to consult

160 again.

161 For the purposes of the study, we checked that the information was completely up-to-date and any corrections

162 were made. This took about 2 days for one of our research team members.

163

164 **Patient and public involvement statement**

165 All PILs were written according to the same methodology taking into account the patients' usual priorities,

166 experience, and preferences.[11,28] They were each read by at least two volonteer patients.[11,28] Patients were not

167 involved in the design of the study, nor in the conduct of the study. Answers to the questions were provided by

168 the patients themselves over the phone, they assumed the responsibility of reporting on their behaviour since the

169 consultation and whether to be truthful or not.

170

171 **Measurements**

172 Between 7 and 10 days after the consultation the patient was telephoned by an investigator who had not participated

173 in the patient recruitment, was not involved in their care, and who did not know *a priori* the patient's diagnosis or

174 which PIL they had been given. They were asked to answer several series of questions. If they were unreachable

175 the first time, the call was repeated twice. If the investigator was not able to contact them, a contact person

6

176 designated by the patient on the inclusion sheet was phoned. If this also failed, then the patient was considered as

177 lost to follow-up.

178

179 **Outcomes**

180 Data about the socio-demographic characteristics of the patients (9 questions), about the PIL received (16

181 questions) and about the doctor's behaviour (4 questions) were collected. For the DPC score, we used a validated

182 generic questionnaire for acute conditions (13 questions).[27] For satisfaction and adherence scores, we used the

183 short questionnaires we had previously developed: 5 questions about satisfaction, 6 questions on patient adherence

184 (including 3 items about drug adherence, one item about non-drug prescriptions, one about recommandations and

185 advice, and one about the way to use the health care system after the current consultation), 3 questions on the

186 patient's behaviour, and 4 questions on the doctor's behaviour. Each of the outcomes had been clearly defined

187 according to the same theoretical model[11] to study the correlations between them. DPC, satisfaction and adherence

188 scores were calculated from replies (scored on a 4-point Likert scale) to the phone questionnaires.

189

190 **Sample size calculation**

191 The main objective was to measure the impact of PILs given during the consultation on the DPC score. In the

192 absence of published data on the subject, we made the following assumptions: taking an average DPC score of 40

193 i.e. 75% of the maximum score and a minimum effect level of 15% i.e. a gain of 6 points (by analogy with the

194 recommended Minimally Clinically Important Improvement pain or function scales),[29] then for a standard

195 deviation (SD) of 16 points and a power of 90% (estimated sample size for two-sample comparison of means using

196 a t-test with Stata software), 150-patients per group were needed. With an estimated lost to follow-up rate of 12.5%

197 and erronous inclusions, we planned 200 patients per group i.e. 400 in total.

198

199 **Analysis**

200 Statistical analysis was performed with the recommended procedures of data management and database freezing

201 using Stata version 13.0 software (Stata Corp, College Station, Texas) OSX. We planned an intention-to-treat

202 analysis (all patients in both Phase 1 and 2) and a strictly per-protocol analysis (patients without PILs in Phase 1

203 versus those patients who recieved PILs with an oral explanation given by doctor in Phase 2). Statistical tests were

204 carried out with an alpha risk of error of 0.05. Variables are described by numbers and percentages, and continuous

205 variables by median and IQR [25th and 75th percentiles]. For quantitative variables, the Mann-Whitney test was

7

206　used to compare two groups. For qualitative variables, the Chi2 test was used if applicable; otherwise the Fisher

207　exact test was used. The DPC scores were classified as high (>50), intermediate (36-50) or low (≤35) to test the

208　difference between the two groups. Multivariate analysis was performed by logistic regression to give an OR (and

209　95% CI) for good communication (score > 35) adjusted on age, sex, marital status and type of condition. The

210　replacement of missing values for the DPC score (the main outcome) was performed for patients with less than

211　20% of missing answers, i.e. two missing out of 13 at most. Replacement was done using the answers obtained to

212　the other questions (11 patients out of 324 (3.4%) including 9 patients with 1 missing item and 2 patients with 2

213　missing items out of 13). If 3 or more responses were missing, the patient was excluded from the analysis.

214

215　**RESULTS**

216　**Characteristics of study subjects**

217　Four hundred patients were included in our study and 324 sets of answers were analysed: 156 patients without

218　PILs and 168 with PILs. More patients presented with ankle sprain (183) than with an infectious disease (141).

219　Figure 1 shows the patient flow chart. No non-inclusion form was registered. Table 1 presents a comparison of

220　baseline characteristics and shows no statistically significant difference between groups.

221

222　**Table 1**. Comparison of baseline characteristics of patients between groups who received a Patient Information

223　Leaflet during the emergency department consultation and those who did not. Values are numbers (percentages)

224　or medians (interquartile range).

Variables	Control Group without PILs (N=156)	Intervention Group with PILs (N=168)	p-value
Condition			
Ankle sprain	83 (53.2 %)	100 (59.5 %)	0.25
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

8

Education level achieved			
Junior high school	62 (39.7 %)	62 (36.9 %)	
			0.55
High school	39 (25 %)	37 (22 %)	
University	55 (35.3 %)	69 (41.1 %)	
Socio-professional category			
Farmers/artisans/tradesmen	7 (4.5 %)	6 (3.6 %)	
Intellectuals/managers	30 (19.2 %)	32 (19 %)	0.90
Employees/workers	43 (27.6 %)	52 (31 %)	
Retirees/students etc.	76 (48.7 %)	78 (46.4 %)	
Marital status			
Single	79 (50.6 %)	67 (39.9 %)	0.05
Living as a couple	77 (49.4 %)	101 (60.1 %)	

225

226 Values are numbers (percentages) or median (interquartile range)

227

228 **Main results**

229 In ED, PILs given by the doctor improve the DPC score, in all comparisons (medians compared or classes

230 compared). Figure 2 presents the Doctor-Patient Communication scores. This result is identical after adjusting for

231 age, sex, family status and pathology. It is reinforced in the strictly per-protocol population. Table 2 shows the

232 DPC scores.

233

234 **Table 2**. Comparison of Doctor-Patient Communication (DPC) scores between the two groups without and with

235 PILs.

SCORES	Control Group without PILs	Intervention group with PILs	Odds Ratio (OR) with 95% confidence interval	p-value
Intention to treat analysis				

9

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 [1.39-5.35]	**<0.01**
> 35	25/156 (80.1%)	154/168 (91.7%)	Adjusted* OR for good communication (score >35): 2.54 [1.27-5.06]	
		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 [1.98-22.6]	**<0.01**
> 35	125/156 (80.1%)	81/84 (96.4%)	Adjusted* OR for good communication (score >35): 5.60 [1.63-19.2]	

236 * adjusted for age, sex, family situation and pathology

237

238 **Secondary objectives**

239 Table 3 shows comparisons of overall scores and of patients' responses about their satisfaction, adherence, and

240 patient and doctor behaviours in the two phases.

241

10

242   **Table 3.** Secondary objectives: satisfaction, adherence, and patients' and doctors' behaviours (ITT analysis).

243

A. Satisfaction	Control group without PILs n=156	Intervention group with PILs n=168	OR [95%CI]	p-value
I. Satisfaction with infrastructure (reception, food, waiting time)	92/156 (59 %)	91/168 (54.2%)	0.82 [0.53-1.28]	0.38
II. Satisfaction with nurses and care assistants	112/156(71.8%)	137/168 (81.6%)	1.74 [1.03-2.93]	**0.04**
III. Satisfaction with the doctor	103/156 (66%)	131/168 (78%)	1.82 [1.11-2.98]	**0.016**
IV. Satisfaction with the medical consultation	93/156 (59.6%)	129/168 (76.8%)	2.24 [1.39-3.62]	**<.0.01**
V. Would you recommend the ED to friends or family?	119/156 (76.3%)	135/168 (80.4%)	1.27 [0.75-2.16]	0.37
Total satisfaction score:	19 [16-20]	19[17-20]		0.20
B. Adherence* (according to doctor behaviours)	**Control group without PILs**	**Intervention group with PILs**	**OR [95%CI]**	**p-value**
I- Have you taken the whole course of the prescribed treatment?	108/134 (80.6%)	107/130 (82%)	1.12 [0.60-2.09]	0.72
II- Did you respect the prescribed doses?	127/134 (94.8%)	122/124 (98.4%)	3.36 [0.68-16.5]	0.18
III- Did you comply with the regimen and conditions (time at which you should take the	113/134 (84.3%)	116/124 (93.5%)	2.69 [1.15-6.33]	**0.02**

11

medication, if you were fasted or not, during meals

etc.)?

IV- Did you have additional examinations or a

specialized consultation prescribed by your doctor

(imagery, laboratory analyses, an appointment | 87/98 (88.8%) | 119/141 (84.4%) | 0.68 [0.32-1.48] | 0.34

with a specialist)?

V- Did you follow the recommendations and the

advice given (have you changed any habits as a | 82/89 (92.1%) | 104/123 (84.6%) | 0.47 [0.19-1.17] | 0.10

result of the consultation)?

VI- Did you follow health monitoring instructions

and advice given by your doctor on if and when to | 75/78 (96.2%) | 81/83 (97.6%) | 1.62 [0.26-9.96] | 0.67

reconsult a healthcare professional?

Total adherence score:	0.93 [0.80-1]	0.89 [0.76-0.97]		0.21
	(n=154)	(n=165)		
C- Patient behaviours	**Control group without PILs**	**Intervention group with PILs**	**OR [95%CI]**	**p-value**
I-Did you need a new medical consultation for the same condition?	50/156 (32.1%)	30/168 (17.9%)	0.46 [0.27-0.77]	**< 0.01**
I.1- Did you consult an ED physician?	42/156 (26.9%)	14/168 (8.3%)	0.25 [0.13-0.47]	**<0.01**
I.2- Did you consult your primary care physician?	11/156 (7.1%)	17/168 (10.1%)	1.48 [0.67-2.28]	0.32
D- Doctor behaviours				
I-Drug prescriptions?	134/156 (85.9%)	130/168 (77.4%)	0.56 [0.32-1.00]	**0.049**
II- Prescriptions of further tests (laboratory analysis, imaging, appointment with specialists)?	98/156 (62.8%)	141/168 (83.9%)	3.09 [1.83-5.22]	**<0.01**
III- Given advice to follow?	89/155 (57.4%)	123/168 (73.2%)	2.03 [1.27-3.23]	**<0.01**
IV- Information on if and when to consult a	79/155 (51.0%)	84/165 (50.9%)	1.00 [0.64-1.55]	0.99

12

doctor again?

244

245 *Two patients in phase 1 (control) and three patients in phase 2 (with PILs) didn't receive any prescription and

246 weren't included in the adherence analysis.

247

248 There were no significant differences in overall satisfaction and adherence scores across the entire population

249 (ITT). All three satisfaction' items related to healthcare professionals and, for adherence, the item related to timing

250 of medication intake, were significantly improved. The overall satisfaction score significantly improved on per-

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

252

253 **Table 4.** Answers to questions concerning the Patient Information Leaflet (numbers and percentages).

Questions	Yes	Does not remember
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

13

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%)

254

255 The comparison of DPC and satisfaction scores, each in 2 classes (DPC ≤ 35 or > 35; satisfaction score ≤16 or

256 >16) and whether the PIL was given to the patient by the physician (n=127/159, 79.9%) or by a nurse (28/159,

257 18.2%), did not show significant differences. DPC and satisfaction scores were higher when patients received the

258 PIL with an explanation (p=0.02). The need for a new medical consultation for the same pathology was reduced

259 with PILs from 32.1% to 17.9% (OR 0.46 [0.27-0.77] p < 0.01).

260

261 **DISCUSSION**

262 Emergency medicine is largely a communication activity and medical incidents occurring in this context are too

263 often the result of poor communication processes.[4,30] Developing tools that improve communication in EDs is a

264 real public health need.

265

266 **Main results**

267 Our study shows that patient information leaflets handed out during emergency department consultations improve

268 DPC (the number of patients who considered DPC to be very good doubled and the number of patients who thought

269 that DPC was insufficient halved). Regarding patient satisfaction, all three items concerning healthcare

270 professionals improved with PILs. Concerning adherence, PILs also improved the respect of medication intake

271 schedules. PILs reduced the need for consultations for the same pathology, particularly a return to the ED. When

272 doctors used PILs, they prescribed fewer medications and more additional diagnostic tests.

273

274 **Doctor-Patient Communication**

275 In 2010, Ha and Longnecker wrote that ¨most complaints about doctors are related to issues of communication,

276 not clinical competency'' and that "effective DPC is a central clinical function in building a therapeutic doctor-

14

277 patient relationship".[26] Although in our study the physician was instructed to personally give the PIL to the patient

278 during the consultation along with oral information, some delegated the task a nurse. Nonetheless, irrespective of

279 who handed over the PIL, DPC and satisfaction increased when the leaflet was explained to the patient. This is

280 consistent with other studies.[31,32] While this suggests that explaining the PIL to the patient could be a task done by

281 other medical or paramedical staff, we believe it is preferable that the PIL is personally delivered during the

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

283

284 **Satisfaction**

285 Patient satisfaction was partially improved by PILs. Among the 5 items included in the satisfaction score, all three

286 items about healthcare professionals underwent a statistically significant improvement. One item, concerning

287 whether the patient would recommend the ED to a friend or family, tended to be improved. Another item, related

288 to the infrastructure and organization of the ED (reception, waiting time), could not be influenced by the use of

289 PILs. In a systematic review, the authors found that key interventions to improve patient satisfaction in ED are

290 those that develop the interpersonal and attitudinal skills of staff, increase the information provided, and reduce

291 the perceived waiting time.[33]

292 We note that in the literature, results concerning satisfaction linked to PILs are not unanimous. One explanation is

293 the heterogeneity of the questions among different satisfaction scales. For example, the scale developed by Arnold

294 et al. explores accessibility of care, the attitude of medical and paramedical staff, quality of care, waiting times,

295 practical information delivered (costs of care etc.) and in a study of groups receiving PILs or not, concluded that

296 both groups had high scores for each dimension of patient satisfaction and that there was no evidence that the PIL

297 was associated with any change in satisfaction.[34] In their satisfaction scale, Little et al. assessed items similar to

298 those we explored through our DPC scale (relieving distress, intention to comply with care management decisions,

299 communication, amount of information delivered, confidence in the doctor, relationships) and he concluded that

300 a leaflet increased patient satisfaction.[21] Different satisfaction scales explore different dimensions and a detailed

301 comparison with the contents of various scale, showed that our results are consistent with the literature.

302

303 **Adherence and patient behaviours**

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

305 in our results, it was very difficult to improve adherence. Good adherence to treatment and to the doctor's advice

306 can be explained by the fact that ED patients are highly motivated to take their treatment, as their medical condition

15

307   is often painful or could deteriorate. Often they have waited several hours for the consultation (some patients leave

308   the ED before seeing a doctor), they are stressed, anxious and want to get better. Moreover, medical treatment for

309   an AC is usually of short duration, contributing to better adherence.[21] Nevertheless, the patients' responses showed

310   that PILs given out in the context of an AC help patients to better respect the schedule for taking their medication.

311   Furthermore, with PILs, they reconsult less for the same pathology and are less likely to return to the ED. If they

312   do reconsult, they tend to visit their primary care physician/general practitioner rather than the ED.

313   We also observed that even though the results were not significant, the group without PILs tended to follow the

314   recommendations and advice of the physician better than the PILs group. One may wonder whether the doctor

315   gave less oral information when he/she gave the patient a PIL or if some information was lost due to information

316   overload in patients who received two sources of information (oral information and written). This result should be

317   confirmed by a study involving a larger number of patients and/or by an analysis of audio recordings of the

318   consultations.

319

320   **Doctor behaviours**

321   Like Little et al., we found that physicians tended to increase the number of laboratory analyses and examinations

322   ordered[35] and reduce the number of drug prescriptions when they used PILs.[25, 36-38] It may be that PILs act as

323   reminders for over-worked physicians and also help structure the dialogue, resulting in less drug prescriptions and

324   more tests (laboratory analyses, imaging examinations etc). In a future study, it would be interesting to check

325   whether these changes in the behaviour of the doctors, as perceived by the patients: 1/ are real by analysing audio

326   or video recordings of the consultations; 2/ follow the recommendations (sometimes for further tests) contained in

327   the PILs; 3/ are correlated with an improvement in outcomes. This would allow us to know whether better

328   outcomes are directly linked to PILs or only indirectly by the change in behaviour of the doctor when using PILs.

329

330   **Strengths and limitations**

331   Regarding the improvement in the DPC score, we failed to obtain the expected 6-points gain. Nevertheless, the

332   improvement in DPC was significant and associated with better outcomes such as satisfaction or fewer re-

333   consultations in an ED for the same condition.

334

335   In this multicenter prospective interventional study, we used several different PILs for different acute conditions

336   in two hospital EDs with a relatively large series of patients. Our choice of objectives is supported by a recent

16

337 study, in which qualitative semistructured interviews were performed a few days following discharge from ED.

338 The four outcomes that were valued by patients were: understanding the cause and expected trajectory of their

339 symptoms; reassurance; symptom relief; and having a plan to manage their symptoms, resolve their issues, or

340 pursue further medical care.[39] In the ED context, PILs can be a valuable tool both for the patient, helping them to

341 respect the instructions given by the doctor when they return home, and for doctors, to better inform their patient

342 in the short timespan of an emergency consultation.[5] In our study, all 6 PILs were developed according to the

343 same rigorous methodology and generic questionnaires were used, as recommended.[11,28]

344

345 The AC included in the study were all non-severe, thus we cannot generalize our findings to the entire range of

346 pathologies seen in an ED. We note that the level of severity of a disease impacts on satisfaction, in particular the

347 more severe the pathology, the less importance the patient gives to the infrastructure and the more satisfied he/she

348 is.[38]

349

350 The study coordinator received no non-inclusion forms, which might be explained by the lack of time in ED.[5] It

351 is impossible to tell whether patients lost to follow-up (who could not be contacted by phone after 3 attempts)

352 were the least satisfied, and/or least adherent. These biases might have led to an over-estimation of the results.

353

354 Although the strongest interventional study design is a randomized controlled trial,[40] individual patient

355 randomization was not possible due to the major risk of contamination bias between patients, between doctors (as

356 the physicians shared office space) and a learning effect related to the content of the leaflet (doctors unconsciously

357 adapting what they say to 'control' group patients). Our choice of a prospective controlled before-after trial

358 allowed us to have the same doctors in both groups. Doctors were not told the precise objectives of the study;

359 however we cannot completely exclude a Hawthorne effect bias during phase 2 of the study.

360

361 The investigators were independent of the ED physicians. In ED, interventional studies are relatively scarce,

362 probably due to difficulties in implementing them. In a systematic review of the effectiveness of interventions to

363 decrease ED visits by frequent adult users (one of our outcomes), [41] among the 31 articles analysed the majority

364 (21) were non-controlled studies. Among the 10 interventional studies considered as providing a strong level of

365 evidence, 4 were controlled before-after studies and 6 were randomized controlled trials. In our study, the two

366 groups were comparable at baseline, confirmed statistically after adjustment on the main characteristics of the

367 patients. To minimize biases related to the different temporal contexts of the two phases, we chose two identical

17

368   periods of the year. Although our choice of design seems to be well adapted to our objective, our findings should

369   be confirmed in a large-scale cluster randomized trial involving many EDs.

370

371   **Sustainbility of the intervention in everyday pratice**

372   To facilitate the feasibility of our study, the PILs were printed in advance, to allow patients to read them without

373   having an Internet connection. In fact all the PILs are available in electronic format on a medical website and are

374   commonly used by French speaking primary care general practitioners during consultations. Thus, we do not see

375   any obstacle to their use in EDs, especially as it is often the same pathologies that are encountered. Regarding the

376   feasibility of using PILs in EDs: it would have been interesting to check 6 months after the study if doctors and

377   medical students had continued to use them and whether they downloaded and used the other PILs available on

378   the internet site; but this was not the purpose of our study. Nevertheless, a future study should test whether PILs

379   have an impact on the consultation time and whether the emergency physicians who participate in the study

380   continue to use them after the study. To broaden usability we are planning to translate the PILs into English.

381

382   **Practice implications**

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

384

385   **Data sharing**

386   Extra data is available by emailing Dr Mélanie Sustersic: melanie.sustersic@gmail.com.

387

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390

391   **Competing interests' statement**

392   None declared.

393

394

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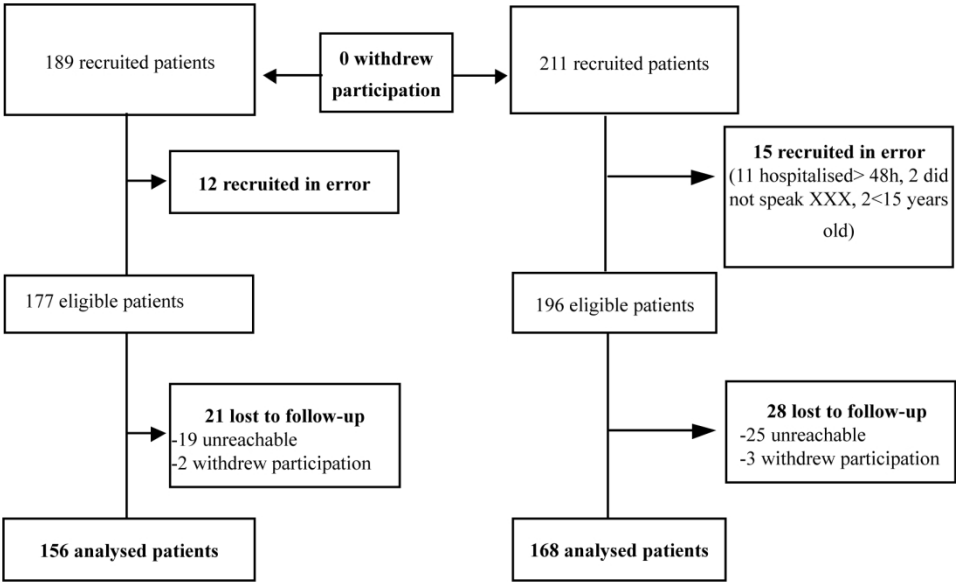
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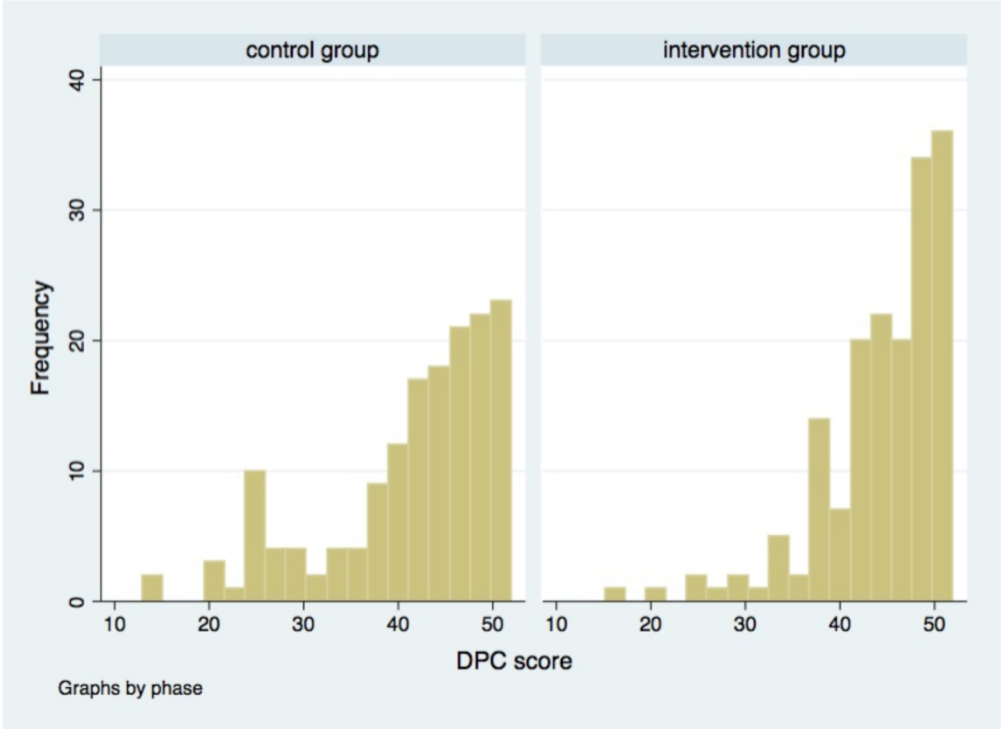493 2017; 24(1):40-52. doi: 10.1111/acem.13060.

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497 **Figure 1**. Patient flow chart.

498

499 **Figure 2.** Doctor-patient communication scores.

500

189 recruited patients

0 withdrew participation

211 recruited patients

12 recruited in error

15 recruited in error
(11 hospitalised> 48h, 2 did not speak XXX, 2<15 years old)

177 eligible patients

196 eligible patients

21 lost to follow-up
-19 unreachable
-2 withdrew participation

28 lost to follow-up
-25 unreachable
-3 withdrew participation

156 analysed patients

168 analysed patients

Patient flow chart

161x95mm (300 x 300 DPI)
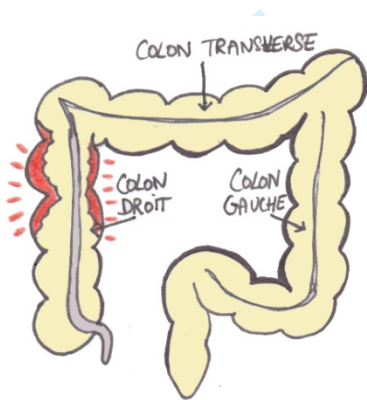
Doctor-patient communication scores.

146x106mm (300 x 300 DPI)

Colite infectieuse

Les points clés

Il s'agit d'une inflammation du colon.
Liée à un virus, bactérie ou un parasite, on parle de colite infectieuse.
Elle peut aussi avoir d'autres causes (médicaments, radiothérapie ; trouble vasculaire du colon etc.).

Les symptômes

- Douleurs abdominales;
- Diarrhée (+/-glaires ou sang) ;
- Fièvre modérée ;
- Fatigue ou soif intense si déshydratation.

Les causes

La colite infectieuse est causée par la présence anormale de germes dans l'intestin (virus, bactérie, parasite).

L'évolution

Le plus souvent favorable en quelques jours.

Les complications

Elles sont rares :
- Déshydratation (si diarrhée abondante)
- Hémorragie (si diarrhée sanglante)

Le diagnostic

Par un examen clinique et des examens complémentaires :
- Prise de sang (recherche d'une infection) ;
- +/- coprocultures (analyse des selles) à la recherche de germes ;
- +/- un scanner abdominal.

Le traitement

- **ANTIBIOTIQUES SELON LES CAS** : pas toujours utiles et selon le germe en cause (ex : salmonelles et Campylobacter Pylori). Respecter la durée prescrite (7 à 10 jours selon les cas).
Ne pas les arrêter sans avis médical.
-**GLACE** sur le ventre si cela vous soulage ;
-**PARACETAMOL**: toutes les 6 heures si fièvre ou douleur.

Les conseils hygiéno-diététiques

- **RESTER A JEUN**: quelques heures après le début de la crise. Puis:
- **REGIME SANS RESIDUS** pendant 10 à 15 jours, pour mettre l'intestin au repos.
- **BIEN BOIRE** les jours qui suivent le début de la crise

Le suivi

Revoir votre médecin traitant dans les 2 à 3 jours qui suivent la crise.
Le but : s'assurer de la bonne évolution de la maladie.

Quand reconsulter ?

- Si la fièvre persiste 48-72h après le début de la crise ;
- Si les signes réapparaissent;
- Si votre état ne s'améliore pas ou s'aggrave.

Nom et signature du médecin: