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The effect of written information on adherence to antibiotic treatment in acute sore throat

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Abstract

A randomised clinical trial was conducted to establish whether written instructions, in addition to verbal ones, significantly improve adherence to antibiotic treatment for acute sore throat in comparison with verbal instructions only. Patients were selected by consecutive sampling at seven primary healthcare surgeries. The pill count average was 87.4 ± 25.2% and it was higher in the intervention group (93.7 ± 24.5%) than in the control group (81.1 ± 24.5%) ($P < 0.05$). Absolute risk reduction was 14% (95% confidence interval (CI), −3.77 to 26.56); relative risk reduction was 24.9% (95% CI, −11.04 to 58.28); the number needed to treat was 8.77. Written instructions, in addition to verbal ones, significantly improve compliance with antibiotic treatment in tonsillitis of acute sore throat in comparison with verbal instructions only.

Keywords: Therapeutic compliance; Health education; Pharyngitis/tonsillitis; Clinical trial; Antibiotics

1. Introduction

At least once a week, a general practitioner (GP) is confronted with a patient with an acute sore throat [1]. Penicillin has been the drug of choice for the treatment of group A β-haemolytic streptococci pharyngitis for more than four decades.

Adherence may be defined as the extent to which a patient's behaviour (in terms of taking medication, following a diet, modifying habits, or attending clinics) matches medical or health advice [2,3]. If a patient is prescribed an antibiotic for an infection to be taken as one tablet four times a day for a week, but takes only two tablets a day for 5 days, the adherence would be 36% (10/28). The term adherence is intended to be non-judgmental, i.e. a statement of fact rather than of blame on the prescriber, patient or treatment. Compliance and concordance are synonyms for adherence [4].

Adherence to physician's instructions, including taking medication as prescribed, is essential. However, compliance with a drug regimen of 10 days to be taken three to four times a day is difficult for most patients [5]. Non-adherence can be in many forms, including failure to have prescriptions filled, omission of doses, errors in administration and premature discontinuation [6].

It has been reported that written information, in addition to the usual verbal instructions given by the GP, achieves better compliance with antibiotic treatment in acute pharyngitis in children [7]. However, in various acute infectious diseases, if the usual verbal information is thorough, this difference is not observed [8,9].

If it is possible to demonstrate better compliance with written information in addition to verbal information, we must assume that introducing written information in daily practice will result in a better quality in general practice.

This study aims at assessing whether written instructions, in addition to thorough verbal ones, significantly improve the adherence to antibiotic treatment in tonsillitis of possible

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infectious or bacterial aetiology compared with verbal instructions only.

2. Participants and methods

An open, randomised, controlled trial was designed. Patients were selected by consecutive sampling as they presented to five different primary care centres in San Antonio, and to two more primary care centres in San Rafael and San José, all of which are located on the Balearic Island of Ibiza, Spain. Participants were enrolled by the GP.

2.1. Inclusion and exclusion criteria

Inclusion criteria were not very restrictive, as the object was to perform the trial in conditions of real clinical practice in order for the results to be extrapolated to the target population. The inclusion criteria were: (i) over 18 years old; (ii) presenting to the GP because of sore throat for less than 7 days and at least three of the four Centor criteria (history of fever, absence of cough, swollen tender anterior cervical nodes and tonsillar exudates [10]); (iii) according to medical opinion, antibiotic treatment required; (iv) ability to read and write correctly; (v) ability to understand the verbal instructions given; and (vi) on the panel of a GP taking part in the research.

The exclusion criteria were: (i) refusal of treatment; (ii) mental or social problems that may prevent the patient from complying with treatment; (iii) illiteracy or cognitive deficiency; (iv) allergy to the drugs prescribed in the protocol; (v) refusal to take part in the research; (vi) pregnancy, breastfeeding or any illness that may affect short-term prognosis; and (vii) not fulfilling any of the inclusion criteria.

To calculate the sample size, we assumed an alpha error of 5%, a beta error of 20% and the fact that, after applying the intervention, differences of 10% would be obtained in favour of the intervention group. This latter percentage was chosen because it is the mean effect or that of absolute risk reduction (ARR) between both groups in a study carried out by Colcher and Bass [7]. When the formula of qualitative variables of comparison of proportions was applied, it was established that the sample size had to be 76 patients per group (total 152).

2.2. Antibiotic treatment

All patients in both groups were treated with 250 mg of oral penicillin V or G every 6 h for 10 days, or the same dose of oral erythromycin for the same number of days if the patient was allergic to penicillin.

2.3. Intervention

The GP randomly assigned patients to the intervention group or to the control group. A computer program generated the allocation sequence and no restrictions were applied. Numbered containers were used to implement the random allocation sequence. The intervention was to give written information at the time of the first visit. This written information emphasised the importance of completing the antibiotic treatment, of respecting intervals between doses and the drawbacks of an early dropout, and was given only once at the time of initial consultation. The patient's ability to understand was tested when written instructions were given by asking them to read and repeat those instructions out loud. The control group was given verbal information only. All the patients were asked for their permission to be included in the trial. Because the intervention is based on educational measures, no blinding techniques were applied.

2.4. Follow-up

All the patients received two visits: first, at the time of consulting the doctor owing to sore throat; and second, a home visit made by a nurse on the 9–12th day after the first visit.

2.5. Measure of compliance

The primary outcome variable was adherence/compliance. To assess compliance, the pill count in a spot-check at the patient's house was used. The following formula was applied:

$$\text{Pill count} = \frac{\text{pills allegedly taken by the patient}}{\text{pills prescribed by the GP}} \times 100$$

Patients with a pill count between $\geq$80% and $\leq$110% were considered as compliant. A pill count of <80% was synonymous with under-compliance, and a count of >110% indicated over-compliance [11]. Two boxes of antibiotic, with 24 pills each, were prescribed to each patient. Since the total dose for 10 days was 40 pills, the patient had a surplus of eight pills. After agreeing to take part in the trial, the patients were informed that they would be visited at home to check their clinical condition. They were not told which day the visit would take place. In general, the visit took place between 14:00 hours and 15:00 hours, since the patient was more likely to be at home at that time, and on the 9–12th day after starting the treatment. After carrying out the pill count, the patient was asked whether an improvement or even a cure had taken place. Subjective cure of disease was defined by the complete resolution of symptoms. When an under-compliant patient was found from the pill count, the reasons were inquired into. The protocol to do so included six possible reasons: subjective cure (resolution of symptoms); side effects; oversight; distrust of treatment; low economic resources; and 'others'.

The clinical significance of the intervention was assessed by calculating the following indicators [11,12]: (a) absolute risk reduction (ARR), by deducting the percentage of non-compliance in the intervention group from the percentage of non-compliance in the control group; (b) relative risk