Journal of Pediatric Surgery xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

The position of a written document in preoperative information for pediatric surgery: A randomized controlled trial on parental anxiety, knowledge and satisfaction

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ARTICLE INFO

Article history:
Received 2 February 2017
Received in revised form 21 March 2017
Accepted 17 April 2017
Available online xxxx

Key words:
Pediatric surgery
Communication
Office visits
Anxiety
Patient education

ABSTRACT

Introduction: Preoperative information is a legal and ethical obligation. Very little studies have evaluated the preoperative information method in pediatrics. Having a child operated on is stressful for the parents. Improving information is a way to lower their anxiety. Our study aims to measure the impact of a leaflet, which supports spoken information on parental anxiety, the comprehension–memorization of the information and their satisfaction.
Materials & methods: Prospective study including 178 patients of outpatient surgery, randomized in two groups: spoken information versus spoken information supported by a leaflet, which is then handed out to the parents. The messages were identical: physiopathology, risks without treatment, surgical technique and its possible complications, description of the hospitalization day, and postoperative care. Parental evaluation was made with self-questionnaires after the preoperative consultation, then on the day of surgery. At each moment we evaluated the level of anxiety, satisfaction of information quality and the comprehension–memorization of the data.
Results: Written information significantly improves the scores of comprehension–memorization, parental satisfaction and significantly decreases the level of anxiety.
Conclusion: Significant impact of the written document as communication support in pediatric surgery, validating the method and encouraging it to be generalized to other pediatric surgery acts.
Level of evidence: Level I.
Type of study: Prognosis study.

Following the French Code of Medical Ethics, it is indispensable that the physician delivers "clear, loyal and appropriate" information, before all informed consent. On a juridical level, this information is a legal obligation; the physician must provide proof that it was given. There are different ways to deliver the information; the use of a written document is not compulsory.

The patient being minor in pediatrics is represented by their parents or legal guardian.

The physician must insure that the latter have understood the information they have given them.

Spoken information has its limits. Indeed only half the data are memorized during the consultation, even though the information is considered satisfactory and understood. Kessels [1] reveals in a study that 40 to 80% of the information given by doctors is immediately forgotten. The higher the amount of information, the lower the proportion of data remembered. Nearly 50% of the memorized information is incorrect. The principal causes for mistake are, oral information mode, technical vocabulary and patient's level of education. Parent's apprehension also interferes with the assimilation of the data. In addition there is often only one parent at the consultation, which leads to the risk of incomplete and/or incorrect transmission of the information. An unanswered question, data forgotten after the consultation or simply by giving a surgical indication, generates anxiety in parents [2], with an inevitable impact on their children. In fact the more the parents are anxious on the day of the operation, the more the experience is traumatic for their child (more intense pain and anxiety) [3–5].

It is so legitimate to think that in the aim for better general care, improving preoperative information, especially during the consultation is a way to decrease the anxiety of the parents and their children [6,7]. Thereupon, Otal et al. [8] tested with success a simple and rapid tool evaluating the comprehension of the medical language (the Newest Vital Sign), underlining the necessity of a clear and effective communication with the parents [9].

Preoperative information is mostly spoken. Written material dedicated to the pathology is rarely used. Its classic vocation is to complete the discussed information without replacing it, to help patients understand the pathology and its management. It is usually handed out at

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http://dx.doi.org/10.1016/j.jpedsurg.2017.04.009
0022-3468/

the end of the consultation in a leaflet format. The "Haute Autorité de Santé" (HAS, French National Health Authority) in France recommends the distribution of written information suitable for all.

Very few studies have evaluated preoperative pediatric information and its implications, while the requirement level in this area is particularly high. Improvement of this information seems essential to us for the optimization of overall care.

This study therefore analyzes the impact of a written document used to support preoperative communication, on the understanding and integration of information by parents and on their level of anxiety and satisfaction.

1. Materials and methods

A comparative prospective monocentric study was established from January to December 2016. It received an approval from the Ethics Committee in Human Research and was recorded with the national Commission of IT and Liberty under the number 2016-028. Three pediatric surgeons included 178 children for regulated ambulatory surgery, randomized into two groups. The first received "conventional" spoken information only (group 1), and the second received spoken information supported by a leaflet resuming the same information handed to them at the end of the consultation (group 2).

The inclusion criteria were: a targeted regular indication for ambulatory pediatric surgery: Inguinal hernia (boy or girl), hydrocele, spermatic cord cysts, umbilical hernia, ectopic testicle, phimosis and protruding ears, the participation of the same parent for the evaluation on the day of the consultation and during hospitalization and finally, a written consent, that is requested at the end of the consultation, in order not to distract the attention which is necessary to assimilate the information.

The exclusion criteria were: the difficulty in understanding the French language, the parent's refusal to participate in the study, uncompleted questionnaires or badly filled in or filled in by two different people.

Written documents were made for each pathology following standardized framework based on the recommendations of good practice of the HAS to combine the compulsory information given during the consultation. Different points were herewith covered: physiopathology of the illness, the risks involved in the absence of care, and surgical techniques—its complications and the possible alternatives, description of a typical hospitalization day and postoperative cares. The documents were presented in an A5 brochure format of 4 pages. A tool adapted to French texts tested their readability: Scolarius (Influence Communication, 2010) also inspired by the Flesch Reading Ease Formula and Flesch–Kincaid Grade Level (Rudolph Flesch, 1951) [10]. The documents were considered easy to read, with a 12–15 year old grade level required to understand the text. Illustrations adapted to each pathology were completed during the consultation, directly onto the document while giving explanations on the physiopathology and surgical treatment.

In order to ensure comparability between groups, the content of the consultation was in each case identical. Illustrations were elucidated on the study's document if applicable and on a separate sheet of paper in the other group. All three surgeons received the same training to deliver the information during the preoperative consultation.

The parents were evaluated through self-questionnaires at the end of the preoperative consultation, in order to evaluate that they received and understood the information (subjective assessment). On the day of the hospitalization, we evaluated the comprehension and memorization of the information through a multiple-choice questionnaire of ten items based on all the information given to the parents.

At the end of the consultation and on the day of hospitalization, we also evaluated:

- Parent's anxiety through the Visual Analog Scale (VAS, 0 = minimum to 100 = maximum) and through the Amsterdam Preoperative Anxiety and Information Scale (APAIS, anxiety score out of 20 and information desire out of 10, making a total of 30) [11]. The reasons for anxiety were also informed.
- Satisfaction with the quality of the information through a numerical scale (0 = minimum to 10 = maximum).

In between the preoperative consultation and the hospitalization, the parents were free to contact the medical and paramedical team if they had any questions. The preanesthetic consultation was in general a week before the operation. It followed a very standardized framework and was therefore comparable between the two groups. At the end of the consultation, parents gave their written consent for both surgery and anesthesia.

The statistical analysis was descriptive and comparative between the two groups concerning parental anxiety, satisfaction, knowledge and consultation on the Internet and was accomplished with the help of Epi Info® software (version 3.5.4).

2. Results

2.1. Epidemiology

178 parents were included in the study, randomized into two groups (Fig. 1).

164 parents were finally selected for analysis, 84 in group 1 ("conventional" spoken information) and 80 in group 2 (spoken information supported by the leaflet).

The epidemiological characteristics were comparable in both groups (Table 1). Mothers mostly represented the parents (78.7%), with an average educational level of 0 to 3 years of higher education (i.e., after the secondary cycle) (Fig. 2).

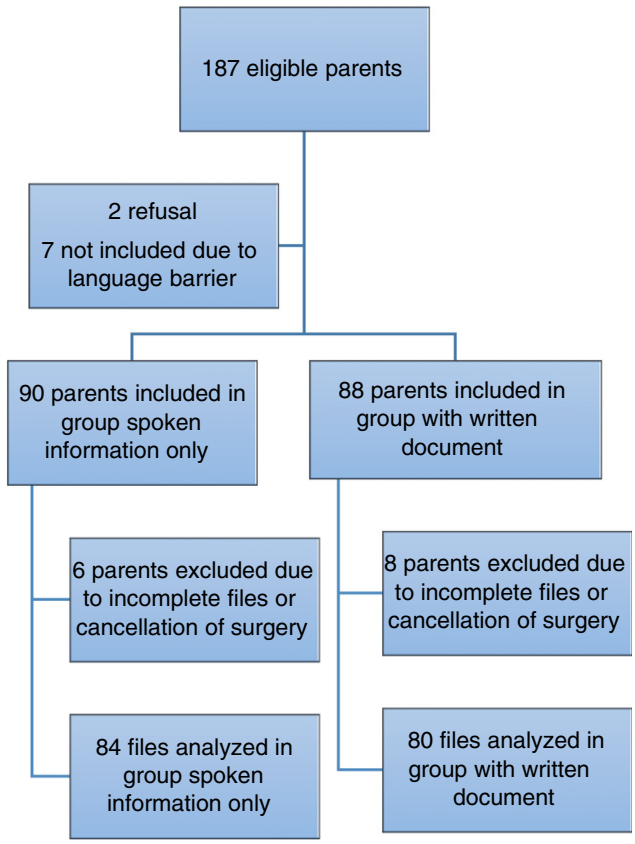

Fig. 1. Flowchart. «Spoken information only» group = group 1, 84 patients. «Spoken information supported by blooklet» group = group 2, 80 patients.

Please cite this article as: Landier M, et al, The position of a written document in preoperative information for pediatric surgery: A randomized controlled trial on parental an..., J Pediatr Surg (2017), http://dx.doi.org/10.1016/j.jpedsurg.2017.04.009