

Research Article

Informed Consent: An Evaluation of the Parents of Children Suffering From the Tropical Form of Vernal Keratoconjunctivitis in Bamako (Mali)

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Abstract: We carried out a prospective cross-sectional study in the Health referral Center of the 4th Commune of Bamako. The purpose was to study the clinical and legal aspects of the tropical form of vernal keratoconjunctivitis in children. The study included 339 children of 0-15 years old. The parents or the legal guardians of the children were administered a questionnaire. The children of 0-3 years old accounted for 43.4 % (n=147). The mean age was 9.02 years. The vernal keratoconjunctivitis of grade 1 and 2 were the most frequent, they accounted respectively for 49.9 % and 34.8 %. On the legal hand, there was a lack of informed consent of the parents; only 14% of the parents knew the true nature of the disease of their children.

Keywords: Informed consent, Children, Vernal Keratoconjunctivitis.

INTRODUCTION

The medical paternalism which governed the doctor-patient relationships in past centuries is no longer allowed nowadays. The medical care is now based on transparency in respect of the patient rights to fair information. The Malian Charter of the patient states in its articles 13 and 14 [1]:

- Article 13: The patient has the right to be informed. This information should allow obtaining a complete overview of all the medical aspects of his condition and the decisions making that can have consequences on his well-being.
- Article 14: The patient or his guardians has the right to be fully informed of the risks prior to any diagnosis or treatment. His consent may be withdrawn at any time.

The information of the patient is a legal requirement; any breach can end in lawsuit. In France, act on the rights of the patient and health care system states: "Any person has the right to be informed of his health. This information relates to the different investigations, treatments or preventive actions that are proposed, their usefulness, their urgency, their consequences..." [2].

Vernal keratoconjunctivitis is a chronic, bilateral allergic disease of the external eye that leads to chronic irritation, watering, and discharge. It occurs universally but is more common in hot and dry environments. It typically affects children in their first two decades [3].

Diallo has proposed a classification in four grades based on the severity of the disease. The chronic evolution of the disease can result in blindness [4].

Some drugs (particularly the corticosteroids) used for the treatment, can cause complications among others: cataract and glaucoma; so the informed consent of the parents or the legal guardians should be obtained prior to the treatment. The aim of our study was to find out the clinical aspects of the VKC, the quality of information and the informed consent of the parents prior to treatment.

METHODOLOGY

It was a prospective cross-sectional study in the Health referral Center of the 4th Commune of Bamako from May 2010 to April 2011. The patients included in the study were those of 0-15 years old suffering from VKC and who already consulted an ophthalmologist prior to our study.

Sampling: we performed a simple random sampling.

Sample calculation: $N = P.Q. (\epsilon\alpha/e)^2$, P is the prevalence of VKC in a previous study = 32, 9% [5], $\alpha=95\%$, $\epsilon\alpha=1,96$, $e=5\%$, thus the sample size is 339 patients.

Data collection: an individual questionnaire was used to collect the data.

Ethical issues: the informed consent of the parents was obtained.

Sample analysis: the data were analyzed with software SPSS 10.0

RESULTS

- Our study included 339 cases of VKC. The males accounted for 54% (n=183) with a sex ratio male/female = 1.17; the patients of 0- 3 years old accounted for 43.4 (n=147). The age

of the patients ranged from 1-15 years with a mean age of 9.02 years. The males accounted for 54% (Table 1).

- The VKC of grade 1 accounted for 49.9% (Table 2)
- Prior to our study, 48, 96% of the children were under steroid eye drop (n=166) and 44, 54 (n=151) were under a combination of steroid+anti-histamine eye drop (Table 3).
- 86% of the parents did not receive any information pertaining to the nature of the disease.
- 4% of the parents received information on the disease among them 18, 10 % did not understand the content and 9.10% declared they were not satisfied.
- Only 9% of the parents who were informed on the disease knew the likelihood of complications, and only 6% knew the likelihood of side effects.

Table 1: Age range of the patients

Age range (year)	N	%
0-3	147	43.4
4-7	108	31.8
8-11	61	18.0
12-15	23	6.8
Total	339	100

Table 2: Distribution of patients according to the grading of VKC

Grade	N	%
Grade 1	118	34.8
Grade 2	169	49.9
Grade 3	51	15.0
Grade 4	1	0.3
Total	339	100

Table 3: Distribution of the patients according to the medication prior to our study

Type of Medication	N	%
Anti-histamine drops	21	6.20
Corticosteroid drops	166	48.96
Anti-histamine tablets	01	0.30
Anti-histamine+corticosteroid drops	151	44.54
Total	339	100

DISCUSSION

Among the 339 cases of VKC the patients of 0- 3 years old accounted for 43.4 (n=147). The age of the patients ranged from 1-15 years with a mean age was 9.02 years. Chenge B *et al.* in the Republic of Congo, obtained a mean age of 6.4 years [6]. The males accounted for 54% (n=183) with a sex ratio male/female = 1.17. Similarly, Moukouri *et al.* in Cameroun found in their study 53.72% of males [7]. Sunny and dusty areas like tropical countries may

increase the risk of VKC particularly in male who usually play on the ground.

The disease was lasting less than 1 year in 61.36% of the patients and between 1- 4 years (25.37%). The VKC of grade 2 was the most frequent; it accounted for 49.9 %, followed by the grade 1 (34.8%). Our results are nearly the same with those of Chenge *et al.* who found 51% of grade 2 and 39% of grade 1 [6].

The young age of our patients may be an explanation of the relatively short duration of the VKC and the frequency of the grade 1 and 2; because the grades 3 and 4 occur later during the evolution of the disease.

In our study, only 14% of the parents were informed of the diagnosis of the disease of their children. This lack of information is encountered in other medical specialties; for instance Triantafyllou *et al.* in their study found that only 23% of the patients who underwent digestive endoscopy knew their diagnosis [8]. According to the provision of the French code of public health the information of the patient is mandatory in the medical practice. This information should involve all the aspects of the medical care: the diagnosis, the nature of the investigations and their haphazards [9]. The failure to give fair information to the patient or his legal guardians is a violation of the principle of autonomy. Without fair information, there is no informed consent. Definitely the 86% of the parents who did not receive any information on the disease of their children neither gave their informed consent for the treatment.

Among the parents who were informed on the disease of their children, only 8.9 % were satisfied. 90% of the parents did not receive any information on the complications of the VKC.

Jukic *et al.*, in Croatia obtained 33% of patients who received the required information during their study [10]. In the study of Williams *et al.* in New Zealand only 21% of the patients were satisfied of the information they received [11]. The lack of information of the patients by the medical personnel can be due among others to the lack of time; sometimes they have too many patients to examine. In the other hand, it may be ignorance of the law.

The informed consent can be defined as the authorization of the doctor by the patient to undertake medical care after fair and appropriate information [9]. Moreover before any medical care of a child, the medical practitioner should insure that his parents or legal guardians consented. In case of emergency and when the parents are not reachable, the doctor can provide the medical care under his own responsibility. But we must bear in mind that the consent of the child should be obtained if he is able to understand [12].

Williams *et al.* in their study assumed that they received the informed consent of their patients in 91%; while Chee *et al.* obtained the consent of their patients in 37% [11, 13].

CONCLUSION

The VKC was more frequent in males than in females, particularly those of 0-3 years old. The VKC of grade 2 was prevalent. There was a lack of information of the parents of the patients; their informed consent was not commonly obtained. The

training of the medical practitioners in medical law is required.

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