INFORMED CONSENT IN PEDIATRIC GASTROINTESTINAL ENDOSCOPY

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ABSTRACT

Informed consent has become a major, but also mandatory component in medical praxis nowadays. A great number of forums and publications emphasize its ethical and psychological commands, the most adequate way to obtain it and especially its legal implications.

In pediatrics, the implications of this procedure are complex, sometimes confusing or not well understood. Thus, in clinical consultations or simple medical acts, the consent could be seen as implicit; when we talk about manoeuvres that lead to psychological or physical discomfort, invasive investigations, including endoscopy or therapeutical acts with possible risks or complications, informed consent from parents or legal tutors, respectively an intellectually, psychologically and socially evolved, educated child's consent (acceptance) becomes mandatory. We must, however, clarify the nuances between consent and acceptance, not only from the semantic point of view, the proportion of either of the two terms in the final decision, the minor patient's ability to discern at different age stages and finally the role and the importance of the doctor in such decision makings.

Key words: informed consent, gastrointestinal endoscopy

INTRODUCTION

Historical background

Our approach is a continuation of a series of general approaches within this publication regarding informed consent in pediatrics and oncopediatrics. (1,2,3) Our topic includes a double component: beside the ethical and legal characteristics of informed consent regarding the diagnosis and therapeutical techniques of digestive endoscopy, obviously invasive procedures we are interested about the specificity of their practice in infant medicine. Moreover, the discussion includes the possibilities and the effects of communication in a trinomial represented on one side by the child – central element of concern – and his/her parents and on the other by the doctor dedicated to the practice of these investigational methods that gain more and more therapeutical importance

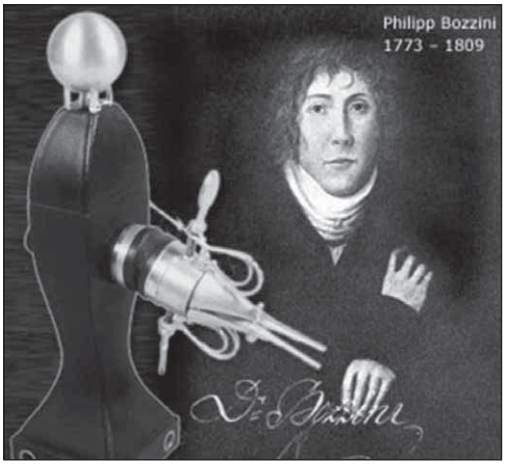

FIGURE 1. *P. Bozzini, the inventor of light conductor*

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Following the pioneers of **endoscopic digestive exploration**, P Bozzini (1796) and his *lichtleiter* (light conductor) (Fig. 1), AJ Desormeaux who, in 1835 uses the term endoscope for the first time, and A. Kussmaul, who in 1868 does the first human gastroscopy, the use of optical instruments adapted to these procedures is improved by successive innovations by using a closed tube (Rosenheim and Schindler in 1885), of an open tube (Ch. Jackson in 1907), respectively of a semi-flexible examination device (Schindler and Wolf in 1932). Decisive modernization of these instruments belongs to B. Hirschowitz, who in 1958 and 1961 succeeds in clinically applying the "transport of images" in endoscopy through optical fibres. Nowadays, the transmission, the magnifying and the electronic processing of the images is being permanently improved, according to the multiplication of the interventional techniques and also as a result of a hard competition between the producers of this technology. (4,5)

The development of the areas of exploration in the oesophagus, stomach and duodenum, respectively rectum and sigmoid to the entire colon and then to the lower intestine, the biliary and pancreatic ducts was the consequence of perfecting the technical tools and accessories, of the evolution from diagnosis to therapeutic endoscopy, of the extension of the indications to an even more various pathology, as well of the introduction of these methods in younger children, new-born and premature.

Pediatric endoscopy inaugurated by Kremer, Ottenjann (1970), Kremer (1974), initially with adult devices, subsequently with tools adapted to pediatric size, has continuously evolved, both by researching more new anatomy territories and by varying the spectrum of pathology approached and successfully treated. (5,6,7,8) All of this led to the creation of an increasing experience for more and more specialists and to the knowledge, the diagnosis and the treatment of numerous illnesses related to pediatrics. It has therefore become the subject of numerous publications and scientific events that have contributed to the development of a new field of medical expertise – pediatric digestive endoscopy – where interventional aspects tend to overcome the exploration and diagnosis ones.(9)

Endoscopic procedures are a major and indispensable component, through their precision and volume of informations offered to the diagnosis, treatment and monitoring; they have to be performed by an expert who knows both digestive pathology at children and the practice of various specific gestures and manoeuvres. We should underline that these techniques are invasive, suppose risks and the possibility of complications and failures. These include: the anaesthetic technique, the increased complexity of the procedures, especially the therapeutical ones and finally the ones determined by the field and pathology specific to their age. In such conditions we should mention the series of procedures practiced in present, as wel as their indications and contraindications.

Esofagoscopy: extraction of foreign bodies, diagnosis and assessment of caustic wounds – dilatations, strictures, tumours – biopsies, placement of stents, screening and monitoring of Barett esophagus, evaluation of reflux esophagitis, the assessment of disphagia, odinophagia and non cardiac thoracic pains. (10,11)

Gastro(duodeno)scopy, the oldest and most frequently used procedure used in various circumstances: foreign bodies, dissolution of bezoars, digestive hemorrhagies (hematemesis, melena), abdominal pains including suggestive systemic signs for an organic pain (weight loss, anemia, fever), nausea and persistent vomiting, precocious satiety, anorexia or refusal of food, refractory iron deficiency anemia, growth delay, assessment of some imagistic modifications; recently, PEG placement. (11,12)

Enteroscopy, an investigation that registered the most spectacular modernisations ("pushed" technique with one or double balloon or with the capsule – Fig. 2) is useful when mentioning the origin of certain digestive bleedings, in Crohn's disease, celiac disease, intestinal polyposis, but also when placing feeding tubes or rarely in monitoring the evolution of an intestinal transplant (13,14,15)

FIGURE 2. *Wireless video capsule*

(Recto)colonoscopy is also indicated at children for the diagnosis and the control of hemorrhagic episodes (melena, hematochezia), chronic diarrhea, anaemic and painful syndromes clinically significant, but unexplainable, the diagnosis and the monitoring of polyposis (biopsy, polipectomy) and more rarely when dilating certain stenosis, the as-

sessment of surgical lesions or of intestinal transplants. (16,17)

Advanced exploration are rare in children : ERCP for cholestasis syndromes and pancreatic pathology, EUS for pancreatic masses and for rare tumours of the upper digestive tract. Contraindications of the endoscopic exploration in pediatric practice are provided by cardiovascular collapse, respiratory distress or neurological deterioration, perforation or intestinal obstruction, peritonitis and also extreme prematurity, recent food ingestion, hypoglycemia in diabetic children. According with a geometric progression of the number and difficulty of these exams and also with a spectacular lowering of the age at which they are practiced, it has been described the existence of possible complications even in the expert execution (≈ 1%) related either to sedation / anesthesia or to the procedure itself. (18) General anesthesia – considered safe and effective, is recommended for young ages as well as conscious sedation is preferred at older ages; each may generate specific incidents: O_2 desaturation, respiratory depression, apnea, hypotension, bradycardia and even cardiovascular collapse and death (0.06%). (19) Other complications can be minor nausea, transient hypoxia and swallowing, bleeding episodes more or less important, infections (*Salmonella*, *Mycobacterium*, *H. pylori*), and perforation, fistula (after PEG placement) or capsule retention. The presentation of the possibilities and indications but also of the technology of these explorations defines their invasive nature and argues obligation and importance of obtaining an informed consent from parents, legal tutors of children but also the child's agreement – especially in those with appropriate physical and intellectual development (different age groups) that become active decision makers in authorization of diagnostic, therapeutic (and even research) practice on their person. Obtaining informed consent in pediatric affording new understanding in ethical and legal standards. It is still defined as a willing agreement or acquiescence given by a person of discernment that is not obtained by fraud and is consistent between the internal and the declared will of the patient containing both ways: voluntary option (never presumed) and the need for authorization both legal and institutional effective. Discernment is the individuals' ability to understand, appreciate and judge their actions (intellectual moment) and anticipating their consequences to decide on the optimum (volitional moment). Consent becomes an action (and finally a document) derived from the ethical principle of respect for patient's autonomy and self-determination, respectively the right to decide on procedures and treatments offered.

The doctrine of informed consent includes the principle of benefit – only those practices that can bring good to the patient are indicated as well as the principle of fairness – the same measures for the same disease in each patient. Differences exist from doctor to doctor and according to specific departments on the quantity and quality of information content and especially on the way in which they are exposed. The involvement of the medical staff is nonuniform sometimes superficial, contradictory and even chaotic. In children the legal concept evolved particularly in some European countries and the USA assuming – in addition to a better understanding of how the doctor must work with parents – obtaining the minor patient's agreement, which is essential. Parental consent is rather an informal explicit permission to which is added mandatory the consent of a minor patient. It is accepted that since the age of 7 a child can understand the purpose of exploration, at 10 years the risks and the right of refusal and after 14 years the moral and intellectual maturity, the ability to understand, the abstract thinking and the hypothetical assessment approach the adult ones allowing responsible decisions. (21,22)

In our country the obtaining of an informed consent is stipulated by Law No. 46/21 January 2003 on patients' rights to receive information about health services and their mode of applying as well as about the identity and professional status of health care provider. The patient has the right to receive complete information about his health, the benefits of medical treatments and interventions (including exploratory procedures) that can help restore or improve his health and to be or not to be informed about his disease if the revealing would cause distress. The informing should be so complete as to allow a conscious patient to take a decision and the refusal must be respected but as with consent, the assumed responsibility must recorded in writing by the patient, while for children by parents or legal tutors. The terms of legislation cannot cover many circumstances encountered in clinical practice and the legal and ethical dilemmas or even conflict situations. Thus from the start can be a lack of mutual empathy between parents and physician and lack of social code, intellectual, cultural and even language barriers. The relationship between parents and children can be affected by excessive authoritarianism or tolerance, by the parents' doubts about the right and the ability of children to decide or by differences of opinion between parents (divorce, adoption), etc.

The legal authorisation involves, as in adults, the patient's right to know and understand what is happening and the obligation of doctors to present the required, expected and necessary information that leads to an "educated decision" on their condition. The ability to understand is extremely diverse both in caregivers and children and should be carefully evaluated by the doctor in order to opt for a more rational and convincing information, depending on many different factors: the intellectual and educational level, temper, trust, suspicion or fear, any previous experience but also influences of other physicians or qualified persons, relationships between parents and their own children; the latter proving to be confident or reluctant and sometimes fearing more the investigation than the disease. Depending on these factors and many others it has to be decided the level of information concerning the rates of morbidity / mortality of the suggested procedure – too many details can frighten the subjects leading to refusal of the investigation / treatment, too little may expose the doctor at charges of an incorrect way of getting the acceptance. The specialist should opt for a "rational" informing with an exposure of significantly frequent or severe risks in order to convince a rational patient. On the other hand presenting only the major elements of risk may displease those who want an exhaustive presentation of them.

Communication and obtainment of the child's consent is often influenced by the presence or absence of relatives or other persons responsible for him. Special conditions are encountered in children with impaired intellectual development or psychiatric disorders, orphans, deprived of legal representatives or institutionalized, alcohol or drugs consumers, members of religious sects as well as in emergency situations where there is practically no time to obtain the consent of relatives or in cases of impaired status of small patients in which an early endoscopy can contribute to the diagnosis and management of these conditions. It can also be mentioned the declination by the child of the initial consent, in which case it has to be requested from the parents or even through legal mandate in rare situations when public interests exceed the rights of the patient. (22,23,24)

Informed consent is a legal part of the observation sheet, it must be signed and dated and its content necessarily includes

- a complete diagnosis and prognosis of the disease that requires an endoscopy;
- type and description of the procedure including conscious sedation / anesthesia;
- the indications and the benefits of the procedure;
- the physical discomfort and complications: severity, incidence, risk;
- the alternative possibilities, the results and their reasonable risks;
- the prognosis in case of refusal. (25,26,27)

The physician should be aware of subjective and objective obstacles of obtaining this document – a difficult moment both for minor and for family; he must exploit his interpersonal communication skills and the spirit of compassion. Discussions (sometimes repeated) with the child and relatives involve -especially when the procedure includes a therapeutic part- an objective assessment of the intellectual, educational, and social level of the interlocutors. We have to take into account the fact that small infants and toddlers, sometimes older children and even teenagers can't describe the causes, nature and character of their suffering so that the discussion should be appropriate to the age of the subject. The dialogue will be held in a special room providing an intimate atmosphere of trust and collaboration, using a friendly, encouraging and attractive language with simple and comprehensive terms, providing informations and "common sense" arguments according to the capacity of the interlocutors to understand and to the opportunity to ask questions and get answers. Further efforts are needed to reduce natural reluctance and anxiety of children and parents. An appropriate amount of informations has to be presented in order to explain the steps and stages of the procedure and the interventional maneuvers: diet, bowell preparation, venous puncture for anesthesia, duration etc. Communication of disagreements, risks and potential complications are "keystone" in obtaining the informed consent, this requiring patience, tact and positive approach and a highlight of the doctor's experience and success rate. On contrary, the benefits of endoscopic exploration will be exposed.

The discussion will always respect the autonomy of decision, the dignity of the patient and will provide insurances about data confidentiality. Finally, understanding of the presented data should be checked, providing a reasonable time of reflection and decision both from parents and child. We don't have to forget to take the opinion for the eventual use of data obtained from endoscopic procedures in research purposes. (21,23,28) Same coordinates should be considered when the physician is confronted with resistance or persistent refusal of the parents or of the (non) "emancipated" child which should be respected both ethically and legally.

The decision of a minor may not be rejected by any parental authority and can even be named an "informed refusal." The situation becomes more complicated when this option comes immediately before the beginning or during the endoscopy; this can lead to stop of the procedure and to a new counselling. Sometimes a good doctor or parents can encourage and persuade in a reasonable time the subject to accept the continuation of the investigation. Sometimes the presence of a psychologist is useful. At lower ages (under 7-10 yrs) parents and caregivers have the entire legal responsibility of refusal or cessation of the procedure.

CONCLUSIONS

Accelerated progress in the last 3-4 decades of gastrointestinal endoscopy techniques, both diagnostic and therapeutic, associated with developing innovative endoscopic accessories and their introduction in pediatric practice contributed to a new subspecialty – Pediatric Gastroenterology. Diagnosis and identification of new aspects in child's digestive pathology also coincided with the development of new opportunities for effective nonsurgical treatment of various lesions. The invasive nature of these practices raised numerous and complex legal and ethical issues concerning their knowledge and acceptance by parents and minor patients in the informed consent. The large variety of clinical situations raise many dilemmas to medical staff between autonomy of the decision versus optimal approach in the interest of the small patient, divergence between parental consent and child's refusal / acceptance, difficulties of considering the child's opinion according to age group and "competence" and the optimal attitude in emergency situations, particular social context or "informed refusal " of the minor/ caregivers. In all cases the decision will be taken by the doctor in the patient's best interest and in respect of the rules of ethics and legality.

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