Ethical aspects of care in the newborn surgical patient

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ABSTRACT

This article places focus on three main subjects that are all related to the ethical aspects of care of newborns undergoing major surgical interventions. The first concerns the communication between the surgeon, as a representative of the treatment team, and the parents. The second is the way to handle new developments in neonatal surgery. The third issue covers several aspects of the ethical decision-making process with regard to forgoing life support in surgical neonates. These issues will be discussed on the basis of two clinical case reports.

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Introduction

When discussing ethical aspects of the care for newborns, it would seem important to first define the actual meaning of medical ethics. Medical ethics can be seen as a system of moral principles, values, and judgments that apply to the practice of medicine in a cultural background. It is a discipline that gives the best possible reflection of different facets of the medical profession. The last decade has seen substantive shifts within medical ethics, mainly as a result of technological and scientific but also social developments. The field of medical ethics is now much more concerned with the meaningfulness of medical practice. Meaningful medical practice, we feel, is based on a dual concept. On the one hand, the good of medicine, with medical knowledge and technical progress determining the advisable course aimed at improving the patient's condition. On the other hand, the good of life, which means taking into account the current social views on quality of life. Medical ethics covers many different subjects, therefore only some aspects can be highlighted.

This article places focus on three main subjects related to the ethical aspects of care of newborns undergoing major surgical interventions. The first concerns the communication between the surgeon, as a representative of the treatment team, and the parents. The second is the way to handle new developments in neonatal surgery. The third issue covers several aspects of the ethical decision-making process with regard to forgoing life support in surgical neonates.

All these issues have been subject of discussion and clinical research in our pediatric surgical department for many years.1–4

These issues will be discussed on the basis of two clinical case reports.

Clinical case report 1

A male infant was born after a pregnancy of 38 weeks with a birth weight of 3860 g. Prenatal ultrasound revealed no structural anomalies except from a slight hydramnion. Due to inability to swallow saliva, choking on the first feeding, and failure to pass a naso-gastric tube into his stomach, he was admitted to the ICU of our level 3 children's hospital. The diagnosis of esophageal atresia with tracheoesophageal fistula was made, and no other associated anomalies (VACTERL) were detected.

The parents were very shocked by this unexpected postnatal course and had many questions about causes and consequences of this anatomical anomaly. Diagnosis, the necessary surgery, complications, and the expected postoperative course were discussed, and the parents gave consent to plan surgical correction. Through a minimal access thoracoscopic approach, the tracheoesophageal fistula was divided, and a tension-free anastomosis was constructed. The postoperative course was undisturbed except for a slight stricture of the anastomosis that responded well to several dilatations. The boy is now over 3 years old and participates in the interdisciplinary follow-up program for surgical newborns. He initially showed growth delay and psychosocial developmental delay, but at least the developmental delay has already been resolved to some extent.

Medical ethical considerations in response to this case report are as follows:

1. Pediatric surgeons have a special relationship with their surgical neonates; after all, the parents assume that they represent the best interest of their child.

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2. Minimal access surgery is a relative new innovative surgical technique introduced by individual surgeons and adopted in many pediatric surgical centers without evidence of its benefit.

3. Survival alone should no longer be the only parameter for successful treatment, but long-term follow-up of surgical neonates is equally important.

Re 1. Communication between patient, parents, and the pediatric surgeon

Medical specialists who treat children, like pediatricians and pediatric surgeons, have a special relationship with their patients. Taking into account the parents, there are at least three decision-makers. The child’s role is largely defined by its age and decision-making abilities.5,6 It goes without saying that the parents will act as surrogate decision-makers for newborn and other pre-verbal children. Decision-making belongs to their role as parents, and they will make their decisions based primarily on the best interest of the child. Since many anomalies are diagnosed prenatally nowadays, the initial conversations between parents and pediatric surgeon will often take place already before the child’s birth. In this context, the surgeon, as member of the prenatal team, communicates with the parents about the diagnosis, the therapeutic options, possible complications, and short- and long-term outcome. Parents naturally tend to be greatly shocked when they hear that their unborn child has one or more serious birth defects. Often more than one conversation with the parents is necessary to let them understand the possible consequences. It is therefore of great importance that the parents are informed as clearly and consistently as possible based on large experience and without contradictory answers to their questions. This will help to reduce their stress in the final stage of the pregnancy.7 In our pediatric surgical department, it is good practice that after a second consultation in the prenatal period the parents are invited to visit the ICU, where they are acquainted with the intensivists and nurses, so that they can familiarize themselves with the proceedings and the setting beforehand. Many parents gladly accept this invitation.

Let us now go back to the case of the above-mentioned boy, in which the diagnosis was not made until after birth. Consequently, the discussions with the parents about diagnosis and prognosis needed to take place after admission to the ICU. This can be challenging within the hectic environment of the ICU. Usually there is enough time to inform the parents adequately and to seek a well-considered informed consent before the surgical correction is scheduled. According to Nwomeh and Caniano,8 the following four elements must be part of fully informed process: (a) the physician provides adequate information with which to make a decision to (b) a legal proxy who (c) indicates full understanding of the intervention, including the indications, risks, and possible alternatives and (d) voluntarily consents to the proposed intervention. Only in exceptional situations is asking informed consent not possible, for example, if immediate intervention is crucial because delay of the surgery could lead to serious harm to the child. After adequate information and recommendations about treatment, including potential benefits and risks, parents almost always give consent based primarily on the fact that they act in the best interest of their newborn. They often wonder about the cause of the anomaly; in most cases, however, we cannot answer this question satisfactorily. In a minority of diagnoses, genetic, environmental, or familial factors are identified and play an etiological role, but in most cases, the cause remains a mystery so far.

In an attempt to elucidate the causes of anomalies, a clinical geneticist evaluates all newborns with anatomical anomalies during the first admission. Whole genome arrays are performed on the geneticist’s recommendation. Blood from all patients and parents is collected after informed consent, for DNA-testing now or in the future. The information gained can be used to improve diagnostics and treatment of congenital anatomic anomalies.9,10

Parents will also like to know whether their child will survive, and if so, what quality of life can be expected. This question forces us to keep evaluating both our surgical and medical treatment modalities. With technical advancement progressing rapidly, we need to consider whether all these new modalities really contribute to optimal treatment of the child. Not only the evaluation of new surgical techniques is important but also long-term follow-up after surgery with attention to both physical and psychosocial functioning is equally important.10,11 So, what are important ethical issues in relation to well-considered treatment?

Re 2. Innovation in pediatric surgery

Over the decades, much progress has been made in the technical possibilities of pediatric surgery, pediatric anesthesiology, and pediatric intensive care. Progress can be distinguished into improvement and innovation. Improvement is enhancing an already existing and often widely used technique. For example, using adapted surgical instruments or suture materials is mostly low-risk improvements, and these hardly have ethical implications. Innovation, on the other hand, is the introduction of something completely new, such as minimal access surgical techniques or new surgical devices. The goal of innovation is to solve a clinical problem in a manner that provides direct benefit to an individual patient or group of patients with a specific condition.12

In the case of the boy described above, repair of the esophageal atresia was through minimal access surgery by a thoracoscopic approach. This new technique has potential advantages: less postoperative pain and less risk to develop scoliosis at a later age. These benefits are less obvious regarding leakage and stenosis of the anastomosis.

Quite a few traditional open surgical techniques have been replaced by minimal access techniques as the preferred surgical approach for many surgical diseases. These approaches were introduced in medical literature and at scientific meetings by individual surgeons, usually from single institutions, by reporting their experience, the benefits, complications, and only seldom the learning curve. Subsequently, other surgeons adopted these techniques with professional enthusiasm.

From an ethical point of view, an innovative treatment should at least be defined in a clinical research protocol, and later in a randomized clinical trial.

“No surgical innovation without evaluation” is the title and main topic of a study by McCulloch et al.13 McCulloch and colleagues propose recommendations for the assessment of surgery based on a five-stage description of the surgical development process. The first phase is the Idea (proof of concept) and sometimes needs ethical approval. Then, this phase must be followed by the phases of development, exploration (learning), and assessment. For these three phases, medical ethical approval is also required. The final phase is long-term outcome, for which ethical approval is not needed.13

In surgical disciplines, unlike the more contemplative medical professions, innovative surgical techniques are often introduced without evidence from (randomized) clinical trials. Yet these trials are considered as the “gold standard” in evaluating new therapeutic interventions. A study of Moss et al.14 showed that randomized clinical trials constitute 0.17% of all the pediatric surgical literature and that only one-third were related to surgical intervention. Caniano and Ells15 give several reasons for adopting operations without a (prospective) trial setting. The most relevant reasons are as follows: (a) suitable animal models may be lacking
for the anatomic condition, (b) the new operation represents an extension of standard accepted technique, and (c) it is often unclear when an operation should be tested in clinical trials.

In recent years, more and more publications have critically evaluated the already well-accepted minimal access surgery. Topics include perioperative outcome differences, review of levels of evidence, and selection criteria for open and thoracoscopic interventions.16-18 Ure19 argues that more clinical studies and reports are mandatory to determine the indications for minimal access surgery as well as for conventional open procedures. This could also put an end to the polarization between minimally access and conventional surgeons.

In an article about ethics and the pediatric surgeon, Fallat et al.20 argue that innovation is essential to make progress in pediatric surgery but that honesty, transparency, and truly informed consent are important in the discussion with parents about new surgical innovations.

Re 3. Importance of long-term follow-up of surgical neonates

Even though it appears difficult in practice to evaluate new surgical treatments through clinical trials, this does not absolve the pediatric surgeon from taking a critical look at the pros and cons, complications, and final results of a newly used technique. In other words, it is the pediatric surgeon's duty, but of course also that of all other members of the treatment team, to analyze how surgical neonates are doing in the long term, at least to adolescence.

Very often, parents need to take their child to outpatient clinics of various medical specialists, who tend to provide aftercare related to their own specialty. Consequently, parents receive often contradictory answers to their questions following their uncontrolled search on the internet. Various studies have shown that surgical neonates are at risk of impaired physical growth and psychological adjustment in late childhood and adolescence.21-23 Bearing in mind all this, we started in 1998 a supportive care team for surgical neonates and their parents with a focus on physical, developmental, and psychosocial needs. The aim, structure, and the first results of the follow-up program run by the team have been published previously.24 This supportive team has grown to an interdisciplinary structural follow-up team. The team's key figure is the coordinating pediatrician, who functions as an intermediary between patient and parents on the one side, and on the other side coordinates activities of the many team members, like pediatric surgical consultants, developmental psychologists, social workers, physical therapists, and more.25-32

The data generated by such a long-term follow-up program will not only benefit the child (state of physical functioning, early identification of developmental delay, etc.) but also the physicians, because in this way new developments in surgical technique and care are evaluated as well.4,33 Therefore, structural follow-up should nowadays be a state-of-art facility in all pediatric surgical centers.

Clinical case report 2

An infant male was born in a general hospital at 35 weeks gestation with a birth weight of 2160 g. He is the first child of parents, both born in the Netherlands, but of North African (Moroccan) descent. The first days after birth, increasing vomiting and bilious gastric retentions were noted, as well as failure to pass meconium in spite of enemas. These were indications for referral to our pediatric surgical center. A barium enema was performed and showed a picture consistent with jejunal atresia. Laparotomy revealed a stenosis at the level of the jejunooileal junction, through which meconium can pass however after gentle massaging. Still the abdominal distension and vomiting persisted after this intervention, and 3 days later, a second laparotomy was performed and biopsies of the colon and ileum were obtained and an ileostomy was placed. None of the biopsies shows ganglia, even the one taken at the level of the stoma. However, head ultrasound monitoring in this period shows a small periventricular hemorrhagic infarction. Because the stoma also is still aganglionic and there is no bowel movement in the weeks thereafter, another laparotomy is performed after 5 weeks with the aim of identifying to what level the aganglionosis extends and to place a higher jejuno-ileostomy. From frozen sections taken during the operation, it appears that the stomach is ganglionic, but that the jejunum is aganglionic from 3 cm distal to the ligament of Treitz. Peroperatively, an episode occurred during which the non-invasive blood pressure measurements at the legs were low, although other parameters such as CO2, SaO2, and heart rate were normal, as well as urine output. Postoperative monitoring took place in the ICU, and epileptic seizures were noted and subsequently treated. A brain ultrasound showed normally developed cerebrum and cerebellum, with no flaring, cysts, or bleeding. MRI scans 2 days later showed a picture of diffuse ischemia and supratentorial infarction. Prognosis of this advanced brain injury is severe mental and motor retardation, expected tetraparesis, hearing impairment, and defective to no cognitive ability.

From a discussion with the parents, it appeared that because of their religious beliefs they could not agree with a policy of withholding and withdrawing treatment. They wanted to have every possible treatment for their child, such as intensive care, bowel transplantation, etc.

In a large multidisciplinary meeting together with the end-of-life care review committee, the issue of medically futile therapy was discussed, as this concerned an infant with total aganglionosis of the bowel and very severe neurological injury. On the basis of these medical conditions, it was concluded that bowel transplantation was not indicated because of the severe neurological impairments and further medical treatment would be futile and that admission to the ICU for ventilator support or other supportive therapies would be abstained from. This was also confirmed by a second opinion from another pediatric surgical center. Parents wished to continue treatment as long as possible for religious reasons.

The medical team then decided to abstain from intensive care treatment, but to initiate medium care treatments such as TPN and antibiotics. The most important rationale was to prevent the child from having discomfort. After a number of difficult discussions, the parents finally accepted that it was inevitable that their child would die at some time.

After 1 month, the child was discharged home with home TPN. Later the child needed to be regularly admitted for infections or other problems. Eventually, end-stage liver failure with bleeding and hemolysis developed, and at 7 months of age, the boy died on his mother’s lap.

Medical ethical considerations in response to this case report are as follows:

1. Total intestinal aganglionosis is potentially treatable these days with life-long TPN and if possible small bowel transplantation at a later age. However, this child had total intestinal aganglionosis complicated by severe neurological impairment.

2. Parents may wish to continue treatment as long as possible for religious considerations. The medical team considers medical treatment futile and decided on restriction of ICU treatment options. Medical team agrees with further medium care treatment such as TPN and antibiotics, provided the child is not uncomfortable, realizing that this will not go on very long.

3. The review committee on end-of-life care acknowledges this and emphasizes that the child should receive treatment and supportive care if it is uncomfortable, even if this would lead to death.
Re 1. Dealing with a complicated and severe congenital anomaly

The congenital anatomical malformation of this patient, near-total intestinal aganglionosis, is a very rare and the most severe form of Hirschsprung disease. Initial surgery reveals a condition of ultra-short bowel syndrome which raised ethical dilemmas such as, is a meaningful treatment possible, and if so, is there a limit on the treatment in view of the best interest of the child? Ultra-short bowel syndrome has severe morbidity and a very high mortality because of complicated intestinal obstruction, malnutrition, and infection. Although long-term survival has improved with the introduction of new surgical procedures, but especially owing to advances in total parental nutrition, morbidity is still considerable. From a meta-analysis by Ruttenstock and Puri regarding clinical outcome in patients with total intestinal aganglionosis, it appears that especially patients with less than 20 cm of ganglionic small bowel carry a poor prognosis due to life-threatening complications related to long-term total parental nutrition. Intestinal transplantation is emerging as a potential option for these children. On the other hand, Diamanti et al. found good quality of life in a small group of children with ultra-short bowel syndrome. Although still dependent on parenteral nutrition, the children regularly attended school and none was listed for intestinal transplantation.

Today, intestinal transplantation for newborns with ultra-short bowel syndrome is certainly not standard practice. Cummings et al. asked neonatologists and pediatric surgeons whether they viewed intestinal transplant in neonates with severe short bowel syndrome as impermissible, optional, or obligatory. The majority of respondents felt that parents should be offered the option of parenteral nutrition with the goal of reaching the ethical permissible treatment option of intestinal transplantation. However, in practice, only a minority of respondents offer actual intestinal transplant when counseling parents. Although Lao et al. recently published promising outcomes in children with intestinal failure following listing for intestinal transplant, more outcome data and feasibility studies are needed. Intestinal transplant should only be considered ethically obligatory when the outcome data confirm short- and long-term benefits to the patients.

Yet, before seeking ethically justified parental permission regarding treatment of neonates with short bowel syndrome, the parents must be fully informed about diagnosis, all treatment options (comfort care only, various surgical procedures, or parenteral nutrition with possibly an intestinal transplantation), and prognosis.

For the patient in this case report, the medical team considered further treatment as futile, as he had total aganglionosis complicated by severe neurological injury. Within the medical profession, it is generally accepted that if a requested treatment is truly futile, it is ethically permissible to withhold it. “Futile” is defined as being unable to accomplish the desired goal, or as “having no useful result.” In other words, it is a treatment that would not be beneficial in curing the underlying disease or would not achieve survival.

What are the key points in the decision-making process to withdraw or withheld life support?

Re 2. Decision-making process to forego life support

We previously outlined guidelines to provide a framework for the treatment team regarding the different stages of the decision-making process. These guidelines, developed by medical and nursing staff, are, with some adaptations, still applicable.

In short, the stages of the decision-making process on forgoing life support treatment are as follows:

- Achieve consensus within treatment team. If not, identify possible conflicts and clarify conflicting opinions by further discussions.
- If necessary second opinion and/or advice from the medical ethical committee.
- Consensus achieved within treatment team.
- “Bad news talks” with the parents to explain the rationale of the decision.
- If there is a parents–physician conflict, additional communication, second opinion, and/or advice from the medical ethical committee is indicated.
- Consensus within treatment team and parents.
- DNR order written in patient's file.
- Clearly stated written agreements on restrictions of treatment.

The first step is reviewing all possible diagnoses and then to determine the most accurate prognosis and expected quality of life on the basis of the reported data, the clinical experience of the physicians and nurses, and data in the literature. In balancing possible pros and cons, pediatric surgeons need to consider not only what can be done but also how likely it is to help and what harms are associated with the various treatment options (i.e., the risks and benefits of treatment).

Consensus within the treatment team is essential. As ICU-nurses provide the greater part of patient care, they significantly contribute to the promptness and intensity of supportive care for high-risk infants. Indirectly, they have a major role in life support decision-making, and therefore we need to know their attitude toward life support management of their patients. Therefore, it is important that decisions about life support should be discussed at an early stage and with an open mind. This offers the opportunity of detecting and discussing different attitudes and prevents misunderstandings and burnout.

The next step in the decision-making protocol is what is called the “bad news talks” with the parents. The medical history is reviewed and the child’s current status and prognosis explained. It should be clear to the parents that continuation of treatment will not restore health, but will merely prolong an uncomfortable life or even only postpone inevitable death. The parents of the baby with total aganglionosis could, based on religious belief, not agree with a policy of withdrawal and withholding treatment. They wanted treatment to continue even though the treatment team doubted the rationale for persisting. In these circumstances, treatment can be continued, unless it causes the child unbearable suffering. Further discussions must be offered to the parents to let them understand and accept the actual prognosis regarding their child’s disease. Parental decisions will be influenced primarily by their love for their newborn baby. Whatever the parents decide, therefore, can be relied on, in almost all instances, to be a choice made for what they believe is in the best interest of the infant. The physician has a separate responsibility: to assess whether the proposed treatment is, in fact, the best option for the patient.

Parents and doctors together, therefore, should reach a consensus. But, when consensus is not reached and the discussion is ongoing, a second opinion or advice of an ethical care review committee may be very useful.

What is the specific role of an ethical care review committee?

Re 3. Role of hospital ethical committees

Medical ethics is given a prominent position in our children’s hospital and therefore several ethics committees are in place. First, the committee on medical ethical questions that deals with promotion, initiation, and coordination of ethical issues in the broadest sense. This committee also developed policy on issues like resuscitation and do-not-resuscitate orders. There is also an active ethical clinical case committee. Clinicians can submit their treatment decisions to this committee for review. This review usually takes place retrospectively and is educational.
The end-of-life care review committee’s primary mission is to serve the practitioners with advice regarding withholding or withdrawal of treatment. In the second case, the opinion of this committee was sought. The committee agreed with the treatment team that, given the serious and complicated clinical picture, curative treatment is not meaningful and not in the best interest of the child. Further treatment should focus exclusively on comfort care for the infant.

Clearly, ethical care committees must have a consultative role and do not carry any direct therapeutic decision-making authority. Therefore, they merely functioning as a sounding board for contemplating the ethical implications of daily practice and provide well-considered advice. The primary goals of an ethical committee are to help the treatment team understand which options are ethically required, which are ethically permissible, and which are ethically unacceptable. However, we agree with Mercurio that the opinion of such committee often carries with it some degree of influence or “moral authority.”

Final remarks

The ultimate goal of the treatment of neonates with (multiple) congenital anomalies is to let them lead a normal life with minimal residual disease and as independent as possible from the medical system. Advancements in prenatal screening, surgical techniques, and intensive care have greatly benefited the treatment of neonates with major congenital anomalies but have their limits and must be introduced carefully and, in most cases, with agreements of ethical boards. Yet, a proportion of the neonates with congenital anomalies probably will not survive, and surgeons and parents are facing decisions on foregoing life support.”

Indeed, the Hippocratic Oath says that it is the doctor’s task to alleviate the patient’s suffering and to effect cure, but not at the cost of all. In our age of technical progress survival alone is no longer the only parameter for successful treatment, but morbidity, which may influence quality of life, is equally important.

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