# The anal canal and urinary system with an imperforate anus. Evidence-based medicine versus A. Peña's experience

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Before comparing different methods of medical research, I propose to dwell on philosophical definitions.

## I. Introduction

### Philosophical Definition of Evidence-Based Medicine

Evidence-based medicine is an approach within medical epistemology (the theory of knowledge) according to which the validity of medical knowledge is determined not by authority, tradition, or individual experience, but by the results of systematic, reproducible, and controlled scientific investigations. In other words: Evidence-based medicine is a system of clinical decision-making based on the critical appraisal of objective data obtained through the scientific method.

**Clinical experience is inductive knowledge formed through personal observations and medical practice**.

This type of knowledge has several characteristics: (1) it depends on the number of cases observed; (2) it depends on the physician's memory; (3) it depends on the physician's interpretation of events; (4) it is susceptible to cognitive biases and errors.

For example, a surgeon may have performed 100 operations and consider a particular procedure highly successful. However, the surgeon may: (a) lack a control group; (b) be unaware of long-term outcomes; (c) fail to account for patients lost to follow-up; (d) remember successful cases more vividly than unsuccessful ones.

### The Main Philosophical Difference

| Evidence-Based Medicine | Clinical Experience |
|---|---|
| Based on collective knowledge | Based on individual knowledge |
| Relies on systematic research | Based on personal observations |
| Attempts to minimize subjectivity | Inevitably contains subjectivity |
| Verifiable and reproducible | Often difficult to verify |
| Evaluates average outcomes in populations | Evaluates patients personally encountered by the physician |

In 1982, deVries and Peña described a pull-through operation using a posterior sagittal approach for high anorectal malformations (ARMs). Previously, the sacrococcygeal route of Kraske, adapted by Stephens for surgical treatment of ARMs, was used for high types. This approach provides a posterior approach to the supralevator space to identify the puborectalis muscle (PRM). The muscle is separated from the urethra or vagina, and gradually a tunnel is created through the sling and external sphincter. The gentle and proper pull of the bowel through an undamaged PRM allows for the preservation of its function as a rectal sphincter and receptor [1]. The posterior sagittal approach differs from other approaches in that the PRM is transected to expose the rectum. The important role of the PRM in fecal continence is a generally accepted axiom. Two months after his first article, Peña published a second article, in which the number of patients he operated on increased by 20. The frequency of high types was significantly higher than low types, which contradicts the patterns in all described classifications. In his second article, Peña argued that the role of the PRM is exaggerated because he was unable to identify it during surgery. He claimed to be the first to discover the important role of the external sphincter, meaning the subcutaneous portion of the external anal sphincter (EAS), which plays no significant role in fecal continence since its dissection during cutback procedure does not cause fecal incontinence. Peña also claims to have achieved good results using posterior sagittal anorectoplasty (PSARP). Since then, Peña has claimed in numerous articles that PSARP is the ideal procedure for all types of ARM. As in his first article, he does not compare his treatment results with other methods. Therefore, this claim is untrue. Furthermore, without studying the pathological anatomy and physiology of ARM and without citing other scientific studies, he alters anatomical names and publishes claims about anatomy and physiology that contradict reliable scientific facts. All this is called the "Peña experience" [1].

## II. About hypotheses that contradict scientific data from the very beginning and have no relation to clinical experience

### 1. Anal canal or rectal pouch (fistula)

**A).** All pull-through surgeries, regardless of access, involve removal of the distal portion of the intestine, called the fistula or rectal pouch. A host of pediatric surgeons have documented that this portion of the intestine is so damaged that it cannot be used for ARM reconstruction, as this would cause functional impairment.

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In the article by Holschneider et al, the innervation patterns of the rectal pouch and fistula of 52 children with ARMs were investigated. Abnormal innervation patterns were found in 96% of the specimens. All fistulas were found to be aganglionic, including the adjacent part of the rectum involving the internal sphincter equivalent. In the authors' opinion, the recommendation to use the distal rectal pouch and parts of the fistula in the reconstruction of anorectal malformations should be reconsidered [2]. This article is puzzling because the authors should have known that the internal anal sphincter (IAS) normally lacks the intermuscular nervous plexus. At the request of the renowned pediatric surgeon Duhamel (1969), histological examinations of the anal canal were performed in 100 children without anorectal pathology. The study revealed that the IAS lacks autonomic innervation, in contrast to the rest of the digestive tract [3]. This has been confirmed by modern research. For example, a study by Uemura et al showed that epithelial and ganglionic distribution was similar in the distal rectal end of ARMs and in a normal anal canal. The stratified columnar epithelium is the epithelial boundary between the rectum and skin in a normal anal canal. Its preservation could reproduce anal canal structure in ARM reconstruction [4]. Docter et al, using micro-CT imaging, concluded that the fistula, currently resected during surgical reconstruction for ARM, contains vital structures like the IAS, normal epithelial transition zone and normal ganglion cells. Although clinical functionality should be studied in the future, our results indicate that the fistula has a normal anal canal morphology and should be spared during ARMs reconstruction if possible [5]. It was already known in the 1940s and 1950s that a physiological zone with a reduced number of ganglion cells exists directly above the dentate line. This is why biopsies have begun to be taken significantly above them. The European ERNICA network recommends: "Biopsies should be taken from the posterior and/or lateral rectal wall at least 2 cm proximally to the dentate line or 3 cm from the anal orifice" [6]. By calling the distal segment of the intestine the "rectal pouch," the authors assumed that the intermuscular plexus should be the same as in the rectum. Consequently, they were unaware that this segment had long been referred to as anal canal ectopy, and that after the cutback procedure, fecal continence and defecation function in patients with perineal and vestibular ectopy were normal [7]. To assert that "the use of the distal rectal pouch and parts of the fistula in the reconstruction of anorectal malformations should be reconsidered," a comparison of the results of these two methods would be necessary. Pull-through surgery, regardless of approach, destroys the anal canal, leading to varying combinations of fecal incontinence and chronic constipation, which worsen with age [1]. This example demonstrates that clinical experience that disregards

evidence-based medicine leads to destruction of an initially functioning anal canal and poor functional outcomes.

**B).** The article by Levitt and Peña makes two statements regarding the anal canal in patients with ARM, which are are given without references and without evidence. (1) “Patients with anorectal malformations have abnormal voluntary striated muscles with varying degrees of hypodevelopment”; (2) “Except for patients with rectal atresia, most patients with anorectal malformations are born without an anal canal; therefore, the sensation does not exist or is rudimentary” [8]. Firstly, in 1960-1982, in cases of ectopic anus, simple cutback procedure was considered sufficient to make the imperfect anus large enough for its normal function in the location where it was located [9]. Wilkinson wrote: "Since the fistula passed through the branches of the puborectalis loop, if a sufficiently wide channel was created by dilation (after dissection), the child was continent" [10]. The results of the dissection procedure for low types of ARMs in both boys and girls, based on the Wingspread classification, were good in 90% of patients, while after PSARP, using the same assessment method, they were poor in 100% [1]. Since preservation of the anal canal, and not the rectal pouch, is accompanied by normal function, therefore, the muscles are normally developed, and anal canal sensitivity does not differ from normal. Secondly, manometric studies in patients with visible fistulas in each case revealed normal resting pressure and relaxation of the IAS in response to increased rectal pressure, indicating normal sensitivity of the rectum and anal canal [11, 12, 13]. Relaxation of the IAS in response to rectal distension, which is a diagnostic test for Hirschsprung's disease, is often mistakenly referred to as the anorectal inhibitory reflex. Physiologists call this rectoanal inhibitopy reflex because, in response to increased rectal pressure, the IAS relaxes with a simultaneous contraction of the PRM and EAS, which prevent (inhibit) the exit of feces. This event occurs each time peristalsis brings a new portion of feces into the rectum. During IAS relaxation, solid feces remain in the rectum, and gas and liquid penetrate the upper anal canal. Sensors located there allow one to determine the composition of the contents. If liquid has entered, the IAS contracts and forces the liquid into the rectum, and if gas has entered, the person decides what to do with it depending on the circumstances. Lin and Chen observed "rectoanal relaxation" in patients with high and intermediate types of ARMs after pull-through surgery without IAS saving. They suggested that the IAS-saving procedure is not essential for the development of the rectoanal relaxation reflex and that compensation or adaptation of the rectum likely contributes to the presence of the rectoanal relaxation reflex and may recreate postoperative continence [14]. In 1899, Bayliss and Starling published 3 classic and epoch-

making articles on the movements and innervation of the bowel. Their statement since quoted in physiological textbook, that “Excitation at any point of the gut excites contraction about, inhibition below. This is law of the intestine” [15]. This law, otherwise called the “myenteric reflex,” explains the peristalsis of all parts of the digestive tract, except for the small intestine [16].

Thus, a transient decrease in rectal pressure in response to a rise in proximal pressure is a manifestation of peristalsis. However, the IAS is not involved in peristalsis. It opens simultaneously along the entire length because of contraction of the levator muscles. Contraction of the IAS accounts for 50% of fecal continence. This is why it must be preserved during ARM correction. Assumptions made without understanding the underlying physiology led to chaos in pediatric colorectal surgery. Below is radiographic evidence of normal anal canal function in ectopia ani with visible openings on the perineum and vestibule with a normal rectoanal inhibitory reflex demonstrating normal rectoanal sensation (**Figure 1).**

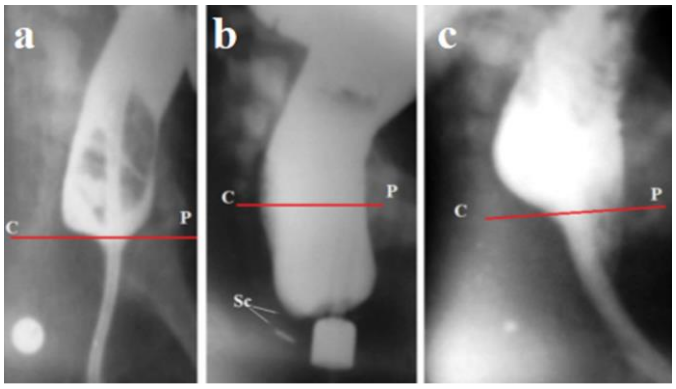


**Figure 1.** Lateral radiographs of the anorectal area of patients with visible openings of ectopic ani. **(a).** Anterior displacement of the anus relative to the anal dimple, to which a button was glued. Barium suspension was injected through a catheter inserted into the rectum. The anal canal located distal to the pubococcygeal line (red) is closed. It provides normal barium (stool) retention, despite the absence of the subcutaneous part of the EAS around it, since it is located above the button. **(b).** Upon readmission, an attempt at defecation occurred with wide opening of the anal canal. The subcutaneous part of the EAS (Sc) is located between the wall of the anal canal and the pushpin near the anal dimple. It is approximately 0.4 mm, as the true diameter of the radiopaque marker located near the ectopic anus is known to be 1.6 cm. This gap, along with the subcutaneous portion of the EAS, also contains skin and subcutaneous tissue. **(c).** After barium was administered to the rectum, the IAS relaxed, and the barium entered the anal

canal anterior to the endotracheal tube, the balloon of which the pressure decreased was recorded. A decrease in pressure in the upper anal canal occurred simultaneously with contraction of the PRM and EAS. Therefore, the barium remained in the upper anal canal. The barium did not penetrate the anal canal behind the tube because the loop of PRM pressed the posterior wall of the anal canal against the tube. This is a radiographic image of the rectoanal inhibitory reflex.

Thus, radiographic examination confirmed the presence of a normally functioning anal canal, with preserved sensitivity and reflexes: fecal continence and defecation. Secondly, it was shown that the subcutaneous portion of the EAS, which Peña called the external sphincter and considered, without evidence, crucial for fecal continence, is not involved in fecal continence. Finally, den Hollander et al, found that "the IAS, present at the distal end of the fistula, should be spared as much as possible to preserve anal sensibility. In this way, aiming to maintain the best possible fecal continent. Furthermore, the outcomes of this study demonstrate that anal sensibility is regulated by transmural nerves" [17].

**2. Persistent cloaca or vaginal ectopy of the anus with narrow vagina?**.

True cloaca is a very rare congenital abnormality in girls, where the embryonic development of the anorectum stops at the cloacal stage, as observed in birds and reptiles. As a result, the bladder, uterus, and rectum open into a wide cavity called the cloaca. They lack a urethra, vagina, and anal canal. For many years, two forms of ARM with a vaginal fistula were recognized. In some cases, the vagina has normal size, with a wide cavity, while in others, it is narrow. Currently, following the initiative of Hendren and Peña, patients with narrow vagina are diagnosed with persistent cloaca and are treated as if they had a true cloaca. It is believed that this pathology arises after the formation of the urethra, vagina, and anal canal, which then merges into a common canal [8, 18]. However, this idea contradicts the laws of embryology. Embryonic growth occurs only through division. The joining of already formed structures (not cells) is fundamentally impossible. Peña proposed surgical corrections of the urinary tract without any data on its condition. He did not conduct any studies to assess the function of the urinary system, and there were no studies in the literature. In 1997, Peña proposed the total urogenital mobilization (TUM) operation to repair cloaca. During the presentation of Peña's article, Hendren asked, "Do you think the external urethral sphincter is of any importance in these patients? And if it is, do you think this mobilization risks any injury to the external sphincter?" Peña responded, "My experience in managing cloaca is that girls who suffer from

urinary incontinence do so not because of a lack of urinary sphincter but rather due to the lack of bladder contractility" [18].

All of Peña's articles were devoted to describing his experience treating patients with ARM. He did not conduct any research on the function of the anorectal area. Therefore, he had no knowledge of the pathological physiology of so-called persistent cloaca. Meanwhile, there is convincing evidence in the literature that in patients with so-called persistent cloaca, urinary tract function is normal unless the operations proposed by Peña are performed [19,20]. Based on this, it becomes obvious that no studies of urinary tract function in vaginal fistulas have been performed because there were no urinary tract complaints in such patients before the name change. An example of how persistent cloaca is treated as recommended by Peña is described in the article by Wael et al [21].

A one-year-old girl, diagnosed with persistent cloaca after birth and receiving an end colostomy, was admitted for definitive correction of the defect. No urinary tract complaints were described. Catheters were inserted into the bladder and vagina (Figure 2a). The posterior sagittal anorectoplasty with total urinary mobilization was performed, wherein the urethra and vagina were separated as one structure (Figure 2b). A new rectum was performed from the proximal loop of the colon [21]. After six months, there were no problems with urination or bowel movements, except for occasional episodes of diarrhea. Kidney function tests were normal.

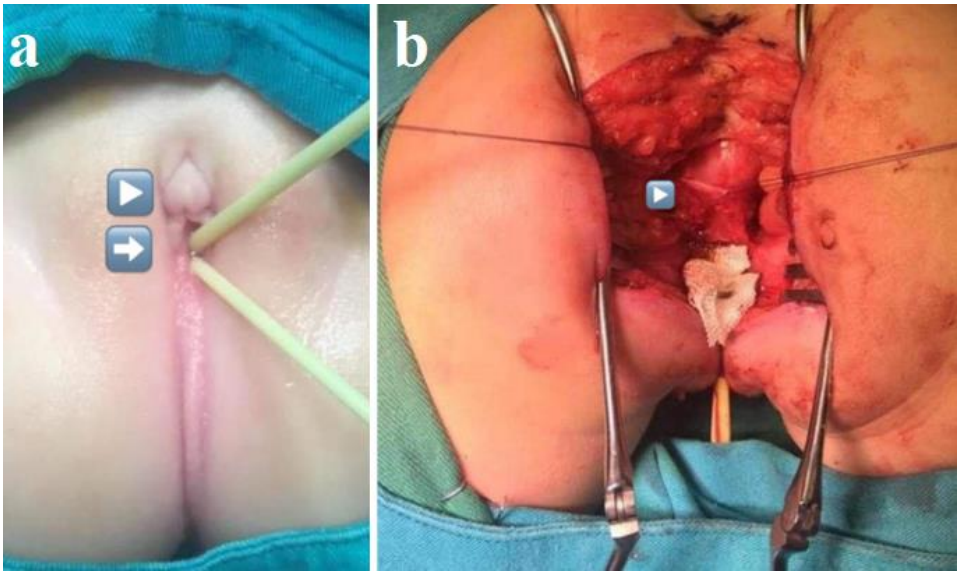

**Figure 2.** From the article by Wael et al [21]. (a). A large clitoris is shown by the arrowhead. The arrow indicates catheters inserted into the bladder and vagina. (b). PSARP stage.

**Analysis of this observation.** Firstly, the description of the case is of low quality, and the reliability of some facts is questionable. The article states that endoscopic cystoscopy was used to assess the level of fusion, which was distal to the lower edge of the pubic symphysis with a short common canal <3 cm. However, this method is not used to determine the level of fusion. Moreover, there is no fusion [22]. The results of treatment cannot be judged 4 months after the operation, especially since good results after correction of persistent cloaca have not been described. Evaluating only objective data, the following facts can be noted: (1) for a year, i.e. initially, the girl had no problems with the urinary system; (2) one catheter was inserted into the bladder and the other into the vagina; (3) a large perineal wound during PSARP. Everything was done as recommended by Peña based on his "experience" [8].

There is a significant difference between the professions of a tailor and a surgeon. A surgeon's work relies on a deep understanding of normal and pathological anatomy and physiology. If, in ARMs, the distal intestinal tract has the histological appearance of a normal anal canal [4,5], exhibits the reflexes of fecal retention and defecation [11,12,13], and functions as an anal canal [6,7,9,10], then it is an anal canal, not a fistula or rectal pouch. Secondly, if the urethra and vagina, located caudal to the pubococcygeal line, are already formed during the embryonic period, then the anal canal, not the rectum, is located caudal to this line. To understand what happens to the urethra after total urogenital mobilization and to the anal canal after PSARP, it is important to understand that their function is provided by invisible nerve branches that connect all the pelvic organs with each other and with the nerve centers in the spinal cord S3-4 [23]. Thus, it is not a congenital pathology of the urinary system, as Peña baselessly asserted, but iatrogenic denervation of the urethra and bladder after which necessitates permanent bladder catheterization and problems of the urinary system arise up to the development of renal failure. During PSARP, after resection of the IAS called fistula, the feeding vessels are removed (devascularization) and invisible nerve branches are cut (denervation) to mobilize the rectum.

Peña and his colleagues claim that PSARP is the ideal procedure for all types of ARMs. To explain the poor results, which cannot be ignored, Peña asserted that they are caused by impaired innervation due to sacral vertebral pathology. Firstly, the association of ARM with vertebral pathology does not imply a cause-and-effect relationship. Secondly, this ignores the fact that anal-preserving surgeries produce normal results, regardless of cardiac, renal, or sacral

vertebral defects. Nevertheless, it is currently common practice to perform spinal X-rays to predict poor outcomes.

**Conclusion**

In his articles, Peña describes the use of the posterior sagittal approach in pull-through surgery. This approach offers no advantages over other approaches. The claim that PSARP is an ideal procedure is false, as it has not been compared with anal-preserving procedures.

All of Peña's other claims cannot be considered his own experience, as they initially did not correspond to existing reliable, i.e., scientific, facts. They contained no evidence but were invented to justify his operations.

1. What he called a fistula or rectal pouch, which his followers still remove today, is an ectopic anus with a functioning anal canal, which is present in all types of imperforate anus. All pull-through surgeries destroy the anal canal, without which fecal continence and defecation cannot be normal and deteriorate with age.

2. To justify transecting the PRM, he claimed it was of little importance and called the subcutaneous portion of the EAS the external sphincter, which he claimed had been underestimated, although in fact, transecting it does not lead to fecal incontinence. Since then, pediatric surgeons have been unaware of the presence of the IAS when performing PSARP. The PRM, along with the deep and superficial portions of the EAS, are called the muscular complex. And the subcutaneous portion of the EAS, which makes up 1/10th of the EAS, is called the external sphincter. All of these contradicts known anatomy and physiology of the anorectal zone, which is the same for people of different ages.

3. The claim that there is no sensitivity in the rectum with ARM was initially contrary to scientific facts.

3. The claim that poor results after PSARP are due to impaired innervation due to malformation of the sacral vertebrae is not true.

4. The name "persistent cloaca" doesn't reflect the pathophysiology of the defect. It has nothing to do with the cloaca. This pathology arises during the embryonic period, when an ectopic anus penetrates the vagina, which has not yet formed a cavity. Consequently, a thin channel forms

in the vagina next to the urethra and anal canal. By calling this defect a "cloaca," the authors, without scientific justification, assumed that these patients have a pathology of the urinary system and began performing surgeries like those performed for a true cloaca. These surgeries damage the normally functioning bladder and urethra. PSARP, on the other hand, destroys the anal canal.

5. What is the state of pediatric colorectal surgery, if doctors accept hypothesis that contradict scientific facts as truth?

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