Dear colleagues, pediatric surgeons,

Recently, the Journal of Pediatric Surgery published an article by Gertler et al., titled "Functional and Health-Related Quality of Life Outcomes into Adulthood for Females Surgically Treated for Anorectal Malformation" [1]. The aim of this study was to investigate bowel function, bladder function, and health-related quality of life (HRQoL) in females operated on for anorectal malformations (ARMs). It is surprising that the first author, Joshua Gertler is listed as the corresponding author despite not having previously published articles about the ARMs.

Of particular interest is the assessment of quality of life, which is very dependent on the basic psychological attitudes received by parents from pediatric surgeons before surgical treatment. Most often, parents repeatedly say their child that she was born without an anal canal without which person cannot carry out fecal retention. Therefore, after an operation, if the patient, using enemas and laxatives, prevents the leakage of feces and urine, she thinks that she is lucky and will have high self-esteem and good mood. In the article Hassink et al after pull-through operation normal spontaneous bowel movement was in 24%. Only 22% reported no soiling at all. The authors showed that after correction ARM nobody reached normal fecal continence. Nevertheless, of all 58 patients, 84% were satisfied with their level of cleanliness [2]. However, what will the patient feel if she learns that she had a perineal ectopia ani with a normally functioning anal canal that was destroyed during a posterior sagittal anorectoplasty (PSARP). If she finds out that if instead of PSARP a cutback procedure had been performed that preserves the anal canal, and she could live a normal life her quality-of-life score would significantly decrease, as will her trust in her physicians.

Methodology

Selection to the control group. A control group of 2518 healthy age-matched individuals were randomly selected by Statistics Sweden from the Sweden Population Registry and invited to respond to the BFS and LUTS questionnaires. One hundred-ninetynine (8%) controls responded and 111 of them (55%) were female and thus used for comparison. Figure 2 from the article shows that the control group included patients with chronic constipation, soiling, and other symptoms suggestive of anorectal problems. These were probably patients with functional constipation (functional megacolon). Since the control group included

sick individuals, then, firstly, all comparisons with this control group make no sense. Secondly, BFS and LUTS questionnaires, based on which an erroneous selection was made, cannot be considered reliable, i.e., scientific.

Analysis of subjective data only.

The authors based their conclusions on the analysis of questionnaires returned by patients. They neither examined the patients nor saw them, raising doubts about whether the questionnaires were filled out by the patients themselves or their parents. Can a sick person, who has no idea about the normal function of fecal continence and defecation, who has no medical education, and who is depressed, correctly assess his symptoms?

Selection of patients for analysis.

Selection of Patients for Analysis: Given the study's aim and its serious objectives, one would expect the authors to present the treatment outcomes for girls with ARM. However, the majority of the 142 patients, without scientifically sound reasons, were excluded from the final analysis:

1. Eight (6%) patients died. The article does not provide data on how many of them died after surgery, which should be considered poor surgical outcomes.

2. Sixteen (11%) were not operated on. Why? Did their parents take them to another hospital? Or did they have a wide enough ectopic anus that allowed for acceptable fecal evacuation?

3. Twelve (8.4%) girls with cloacal ARM were excluded. Poor results in these children may be due to a misunderstanding of the pathological anatomy and physiology of this defect. These children have normal bladder and ureteral function, but severe impairment occurred due to damage during unnecessary surgeries. Patients with ectopy of the anus into the vagina, characterized by a long

rigid canal in the vagina, should be included in discussions for a complete understanding of the fate of patients with ARM in females.

4. In three cases (2%), the address was not known.

5. Four cases (2.8%) involved patients who refused to participate.

6. Fifty-five (39%) patients did not respond. Grateful patients do not behave this way, suggesting that some may have gone to another hospital.

7. Forty-four (31%) responded.

- "Further, patients with Currarino syndrome, Down syndrome, and other persons with severe intellectual disabilities were excluded from the study."
- "Patients with urinary diversion or who underwent clean intermittent catheterization (CIC) were excluded before data analysis."
- "Patients with enterostomies were excluded before data analysis."
- "One patient had a colostomy and was excluded from the analysis regarding BFS."

What purpose and on what basis were complicated cases excluded from the analysis?

Definitions

In different parts of the article, the definitions of fecal continence quality vary and do not align with the pathological physiology of the condition.

1. "A well-preserved bowel function with a BFS of 17/20 was found in 32.6% (14/43)" [1].

Fecal continence and the process of defecation depend on the state of the anal canal. Continence is maintained by the internal anal sphincter (IAS), three parts of the external anal sphincter (EAS), and the puborectalis muscle (PRM).

Defecation occurs due to the contraction of the levator plates, which open the anal canal, and the contraction of the rectum, which expels feces. During this process, other muscles involved in fecal continence relax [5]. The term "bowel function" as used here has no specific physiological meaning.

During PSARP, the authors removed the IAS in all patients under the guise of a fistula or rectal pouch, cut the striated muscles of the deep and superficial parts of the EAS, and the puborectalis muscle (PRM). In place of the removed IAS, surgeons lowered the bloodless and denervated rectum, which, unlike the IAS, cannot maintain constant contraction to hold feces. To lower the rectum, it was separated from the levator plates, which can no longer open the anal canal when contracted. Additionally, the final nerve pathways that provided reflex connections between different muscles and nuclei in S2-S4 of the spinal cord were severed, disrupting the reflexes of the anorectal zone. Notably, the presence of the anal canal in low types of ARMs was proven by Stephens (1953) [6], and this was widely known until 1982, when Peña began to assert that the anal canal was absent in ARM cases and referred to it as a fistula. However, Peña never published a scientific study proving this assertion. His articles primarily describe his experience with unsubstantiated operations.

Question: So, what function of the intestine did the authors preserve?

Answer: They destroyed the anal canal, destroying or damaging all the muscles involved in fecal retention and defecation, which were normal before the surgeons' intervention.

2. Elsewhere, the authors use a different definition: “The children and adults in the study reported **acceptable bowel function** in 34.5 % and 28.6 % of cases, respectively” [1]. As written in this article, “Bowel function was generally impaired over all age groups in females treated for ARM”. “Half of the adult patients scored within the “severe distress” bracket” [1]. This means that the patients were in a hopeless situation, which they rated as acceptable, only because they hoped for improvement. And yet, the authors concluded that “the children and adolescents in the present study reported an essentially comparable HRQoL compared to norm data” [1].

Objective and extensive scientific studies publish less favorable results of surgical treatment of ARMs.

A Systematic Review of 455 patients with a history of anorectal malformation repair, were included for analysis. The range of reported prevalence of long-term active problems was as follows: fecal incontinence, 16.7% to 76.7%; chronic constipation, 22.2% to 86.7%; urinary incontinence, 1.7% to 30.5%; ejaculatory dysfunction, 15.6% to 41.2%; and erectile dysfunction, 5.6% to 11.8% [7].

This study provides objective information, firstly, because it analyzes many patients. Secondly, the article was not published in the journal Pediatric Surgery, which blocks articles that contradict the "experience of Peña, Levitt, Wood, etc.". Thirdly, the wide range of figures indicates the low quality of the subjective analysis, i.e., the questionnaires.

It is widely known that post-reconstruction (PSARP), ARMs commonly result in constipation and fecal incontinence [8]. Borg et al showed that the radiological signs of rectal dilatation and sigmoid elongation diagnosed at in 33% of the ARM children [9]. This figure is significantly less than the true one, as it was determined by eye, i.e., with a very significant megarectosigmoid. The results of the study of 55 (23 females, 32 males) patients with ARM, ages ranging from 18 to 56 years, with an objective assessment of the condition differ sharply from what is shown in the peer-reviewed article. Twenty-one (38%) patients suffered from mucosal prolapse, 18 (33%) had had megasigmoid/megacolon. Stenosis of the neo-anus occurred in 13 (42 %) males and 4 (18 %) females, permanent neurogenic bladder dysfunction in 10 (32 %) males and 4 (18 %) females, recurrent urinary tract infections in 10 (32 %) males and 13 (59 %) females. Thirty-seven (70 %) patients had to be reoperated. Forty-one (75 %) patients needed means of aftercare to achieve social continence [10]. The authors' assumption about the possibility of improving the retention function bowel and urinary outcomes with age are inconsistent with the pathophysiology of the anorectum after destruction of the anal canal. Long-term results in adults have shown deterioration of function. In 74 adult patients with a diagnosis of ARM bowel and urinary outcomes appear to be worse than suggested in pediatric reports, with high levels of both urinary and fecal incontinence [11]. Also, Hashish et al showed that in contrast to previous perceptions, their study showed that stooling patterns are perceived to worsen with age [12]. Clinical results show a significant deterioration compared to questionnaires. In the article by Schmiedeke et al complete continence was found in 27 %, perineal fistula in 40 %, rectourethral/vesical in 10 %, vestibular in 24 %, cloaca in 0 %.

Krickenbeck grade 1 soiling: 42 %, grade 2 and 3: 31 %. Forty-nine percent of the incontinent patients practiced bowel management, reaching continence in 19 %. The statement of constipation (67 %) was validated with the last clinical findings, showing coprostasis in 46 %, "Not suffering constipation" was confirmed in 61 % and falsified in 29 % [13]. These results were unexpected and once again showed that one cannot count on objective assessment of symptoms by patients. Therefore, the results of the questionnaire females [1] and males with anorectal malformations after PSARP [14], obtained because of the analysis of questionnaires with the methodological violations, cannot be considered scientific and cannot be referred to.

This unscientific approach has become widespread. For example, ten pediatric surgeons decided to determine how bowel management programs affect patient experience. Analysis of the responses showed that achieving cleanliness was associated with positive patient experience of bowel management programs. "This finding suggests that achieving cleanliness, regardless of regimen, may allow patients the best functional and experiential outcomes" [15].

Such findings make no scientific sense, since it is obvious that people who control their excretion have friends, do better in school, and are more successful in sexual relationships. Then another question arises. Why do numerous authors publishing such studies compare the results of operations with obviously unhealthy control individuals, and not with the results of operations preserving the anal canal? For example, all males treated for low ARMs by cutback procedure outcomes by bowel function scores were good at 85% and satisfactory in 15%. Each of them had normal fecal continence, and mild constipation passed with age [16]. Meanwhile, after PSARP constipation in "low" ARM has been reported in 42%-70% of cases. Vestibular fistulas seem to have the highest rate of constipation (not less than 61.4%) [17].

The same authors who described their memoirs about the treatment results of females with ARM published another article about males with ARM, again with numerous methodological violations [14]. The analysis of these selectively chosen mild cases is rife with contradictions: "The bowel function of males treated for ARM was grossly impaired across all age groups when compared to healthy controls," "yet supposedly improves significantly with age". They report, "Second to soiling issues reported in 64.9% of our cohort, 63.2% of patients had some degree of constipation. Urinary tract function was affected, but overall comparable to the controls". The authors did not explain, and this statement cannot be explained, why patients with the bowel function and urinary tract ware grossly impaired across all age groups, reported similar or, in some domains, better HRQoL outcomes when compared to normative European

data." The study by Beattie et al., using the PedsQL tool, found a significantly impaired quality of life in children with ARMs [18]. This result cannot be different, since the destroyed anal canal, which the authors of the peer-reviewed article are unaware of, cannot be restored, and neoanus function inevitably deteriorates with age because of worsening megacolon [3].

Persistent cloaca as an important part of ARMs in females

Örtqvist et al. recently reported in a multi-center Nordic study that even patients operated on for a cloacal malformation had similar HRQoL compared to healthy a Swedish population [19]. In this article, the authors report that well-preserved spontaneous bowel control was rare, six (23%) patients had a permanent urinary diversion or used clean intermittent catheterization (CIC), while majority (70%) of the remaining patients were urinary continent. The reported HRQoL was comparable to healthy Swedish children [14].

These results, obtained with numerous methodological violations, are in contradiction with the objective results. First, the name “persistent cloaca” and the concept of its embryology, pathophysiology and treatment, which were described by Hendren and Peña, do not correspond to scientific data. The assertion that during embryonic development, the already formed urethra, vagina and rectum merge into the common channel is unproven and contradicts embryonic studies. The dysfunction of the bladder and urethra that occurs after surgery has not been studied before surgery and it is not observed unless the operations proposed by these authors are performed [4]. The description of radiological studies contradicts the objective symptoms **(Figure 1).**

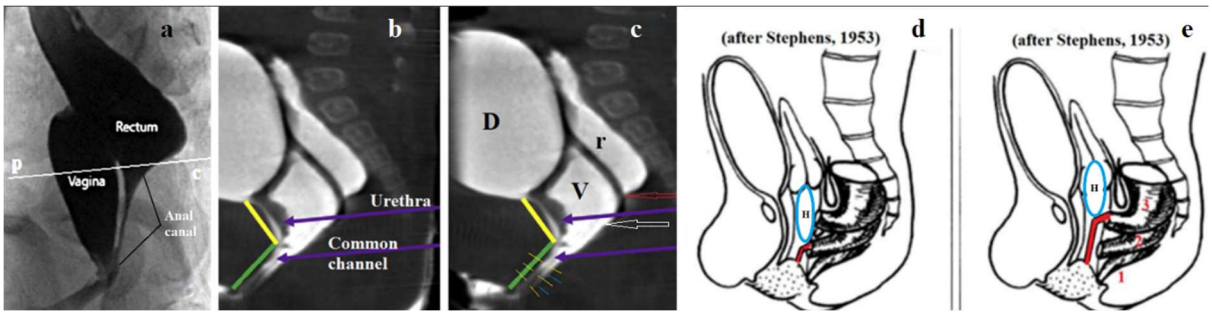

Figure 1. (a) ARM with anal ectopy in the lower part of the vagina. Contrast medium, introduced through a colostomy without the use of high pressure, revealed the vagina of normal width. At the time of the radiograph, the anal canal had time to contract. **(b)** MRI study from the article by Wood et al. [20], with the caption "Short common channel cloaca with adequate urethra." The authors suggest that, in the angle between the yellow and green lines, the urethra merges with the vagina to form a common channel. **(c).** In the copy of the same image (b), I

have shown the presence of two channels: between the yellow lines, you can see the continuation of the urethra to the perineum, and next to it, the blue lines indicate the narrow vaginal canal. Between them, a dark dividing line can be observed, representing the fusion of the walls of the urethra and vagina. The upper part of the vagina (V) is dilated (hydrocolpos). The red arrow points to a rectum above the anal canal. The white arrow is located at the site of ectopic anus in the vagina. The short contracted anal canal is located between the red and white arrows. **(d-e)** On the diagram of fistula locations in girls, proposed by Stephens (1-vestibular; 2-vaginal low; 3-vaginal high), I have drawn a channel in red, which is created by the IAS in the vagina in cases where an internal cavity has not yet developed. A narrow, long fistula blocks the opening to the vagina, resulting in fluid retention in the upper part of the vagina (hydrocolpos -H) (blue oval).

As demonstrated by Stephens, anal ectopy in the vagina can occur at either a low or high position, which means the site of vaginal blockage can be at different levels. However, there is no sign of fusion between the vagina and the urethra, and even less so of any impairment in urinary function.

More accurate long-term results of treatment of cloacal malformations are given by systematic reviews:

Voluntary bowel movements were reported in 108 of 188 (57%), soiling in 146 of 205 (71%), and constipation in 31 of 61 patients (51%). Spontaneous voiding was reported for 138 of 299 patients (46%). 141 of 332 patients (42%) used intermittent catheterization, and 53 of 237 patients (22%) had a urinary diversion. Normal menstruations were reported for 25 of 71 patients (35%). Centers with limited experience reported similar outcome compared to centers with more experience (≥1 patients/year) [21]. Responses from 113 institutions in Japan reported 466 persistent cloaca cases. As a result, the bladder dysfunction was in 32.6%, clean intermittent catheterization - in 22.5%, and permanent enterostomy were in 7.3% [22]. Among fifty-five cloaca patients' urodynamic evaluation revealed an inadequate detrusor contraction pattern in 65.4% of the cases. The article by Ruiz et al shows that a total of 50 patients (91%) achieved urinary continence, but only 30.9% had volitional voiding and 56% needed major urological reconstructive surgeries. Eighteen patients (32.7%) were in stage 2 or more of chronic kidney disease (<90 ml/min/1.73 m2) at the last follow-up visit [23]. Versteegh et al study urogenital function after cloacal reconstruction. At follow-up spontaneous voiding was seen in 29 patients (69%). Clean intermittent catheterization was needed in 33%; a urinary diversion was created in 24%. In total 32 (76%) were dry no involuntary loss of urine per

urethra. Recurrent urinary tract infections were seen in 55%. Normal menstruation was in 55% [24]. Warne et al in 41 patients were evaluated at puberty, and 28 (68%) had uterine function, 13 (32%) were menstruating normally and 15 (36%) presented with hematometra/hematocolpos. All 15 girls with an obstructed uterus required surgery, which included hysterectomy in 2, partial hysterectomy with vaginoplasty in 3 and vaginoplasty in 9. There was 1 complex case of fistula. Etiology of the obstructed uterus was vaginal stenosis after reconstruction in 3 cases, stenosis of persistent urogenital sinus (no previous reconstruction) in 11 and cervical stenosis in 1. Ten patients experienced primary amenorrhoea, which was confirmed in 8 (20%) while 2 (5%) continue to be followed for possible cryptic obstruction. In 10 girls the diagnosis of absent/vestigial uterus was made at early laparotomy, but this was erroneous in 6 in whom uterine function developed at puberty [25].

An objective analysis of the remote results of surgical treatment of the so-called "persistent cloaca", using methods as if these were patients with a classic cloaca, indicates a severe lesion of the urinary system, with a high percentage of chronic constipation and fecal incontinence, as well as gynecological complications. Instead of examining the function of the urinary system before surgery, and finding out the presence of an anal canal in these patients in order to preserve everything created by nature, the authors try to justify destructive operations by the supposedly happy life of these women.

Conclusion

1) Although PSARP was one of the approaches to the pull-through operation in ARM, Dr. Peña made it his brand, on which his career and fortune were based. This approach gained recognition due to the easy detection of the rectum. In order to justify the destruction of the anal canal, and the PRM, Peña, without any evidence, began to claim that there was no anal canal in ARM. According to Peña, the PRM cannot play a significant role in fecal continence, since he could not identify it during the operation. Typically for Peña, he ignored the fact that pediatric surgeons before him found the PRM and passed the rectum through its loop, because numerous studies have shown that the PRM plays an important role in fecal continence. In 2005, Peña organized an international conference for the development of standards for the treatment of anorectal malformations, which adopted the Krinkenbeck classification [26]. From this classification, the division of ARM into high and low types disappeared. In the Wingspread classification, low types meant perineal and vestibular fistulas, which were known to have an anal canal. In the wake of numerous articles by Peña about the remarkable results after PSARP,

which did not compare the results with the cutback procedure, surgeons decided to recommend PSARP for all types of ARM.

Since then, PSARP has become a mandatory protocol. All studies that contradicted this "ideal" operation were not published in pediatric medical journals.

2) Manometric and radiographic studies of patients with ARM indicate that almost all types of ARM, except for the true cloaca, have a normally functioning anal canal [4,27,28]. Recently, the ARM-Net Consortium Consensus confirmed that “According to present knowledge, the “fistula” in ARM represents an ectopic anal canal and should be preserved as far as possible to improve the chance for fecal continence” [29]. It follows that severe constipation, fecal incontinence, urological and sexual problems after PSARP are due to destruction of the anal canal and disruption of the neural regulation of pelvic reflexes.

3) Hendren and Peña, without scientific justification, changed the name of the ARM with vaginal fistula to "persistent cloaca" and began to operate on these children as if they were patients with a true cloaca. They did not conduct any studies of the bladder and urethra before the operation and explained the poor results by a congenital dysfunction. An analysis of the literature shows that this pathology is caused by ectopia of the anus in the vagina with the formation of a long fistula. Instead of expanding the rigid fistula in the vagina and preserving the anal canal, most surgeries are still being produced to destroy the anal canal with damage of the urinary function.

4) Recently, numerous articles have appeared in which the authors analyze the answers of patients to questionnaires after the correction of the ARM. As shown above, patients cannot correctly assess their condition because they have no idea of the norm, do not have sufficient knowledge, and are often in distress. These articles are written with violations of the methodology unacceptable for scientific research. Only patients who did not have complications are selected. The selection of control subjects with anorectal diseases (constipation and fecal incontinence) is a deliberate violation to prove that after the operation, patients are almost as happy as those who do not regularly do antegrade cleansing enemas, periodic catheterization of the bladder, and are not afraid to appear in a group because of the unpleasant odor emanating from them.

5) The current trend is created and modeled by Levitt and Wood, who, following in Peña's footsteps, created the "Pediatric Colorectal and Pelvic Learning Consortium." In numerous articles featuring their supporters, they describe treatment protocols based on Peña's

experience. These articles, ignoring scientific facts, are designed to maintain the status quo and create the impression that these protocols are universally scientifically supported. They are designed to protect the authors from legal action their patients who, because of surgery have lost the natural functions of the anorectum and urinary system.

6) Another reason pediatric surgeons are reluctant to change their surgical approach to treating ARM is the belief that PSARP is the ideal procedure. For decades, they followed the Peña experience, where scientific research and debate were not considered. Nowadays, the need to study anatomy, physiology, and pathology has become a concern. Moreover, the idea that any surgeon can perform simpler procedures with better functional outcomes has created a fear of losing their jobs in an unnecessary colorectal unit.

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Dear colleagues from the Unit of Pediatric Surgery, Karolinska University Hospital, Stockholm, Sweden; Department of Women's and Children's Health, Karolinska Institutet, Stockholm, Sweden.

I have analyzed your articles on anorectal anomalies. Before I publish my analysis on my website and send it to pediatric surgeons, I would like to receive answers to the following questions, without which I do not understand the purpose of your publications.

1. Who is Joshua Gertler (joshua.gertler@ki.se)? I have not found any articles on ARM with his participation, except for two from yours. I have not found him in the list of doctors at your institution.

2. Who commissioned these articles and justified the proposal for grants?

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3. I am ready to take your comments and explanations into account in the final version of my analysis of your articles.

Respectfully yours

Michael D. Levin