INFORMATION BRIEF (RAPID REVIEW)

NERVE STIMULATOR FOR ANORECTAL MALFORMATION SURGERY IN PAEDIATRIC PATIENTS

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NERVE STIMULATOR FOR ANORECTAL MALFORMATION SURGERY IN PAEDIATRIC PATIENTS

PURPOSE

To evaluate the effectiveness, safety profile and cost implications of using nerve stimulators as intraoperative guidance tools during paediatric anorectal malformation (ARM) surgery, following request from a paediatric surgeon in Hospital Tengku Ampuan Afzan.

BACKGROUND

Globally, ARM affects approximately two to five per 10,000 live births, with higher prevalence in males.[1] A 2025 analysis of congenital digestive anomalies reported persistent disparities in ARM-related morbidity and mortality, particularly in low- and middle-income countries. Meanwhile in Asia, incidence remains comparable but access to specialised paediatric colorectal care is uneven.[2]

In the Malaysian cohort, the male-to-female patient ratio was 2:1, with Malay ethnicity accounting for 97.0% of cases. Of the total patients, 52 (53.0%) underwent definitive surgical correction for low-type ARM, primarily through mini-posterior sagittal anorectoplasty (PSARP) (69.2%), followed by anoplasty (25.0%) and anal shift procedures (5.8%). The overall postoperative mortality rate associated with definitive surgical intervention was 4.0%.[3] These cohort findings underscore the clinical burden of ARM in Malaysia and provide context for understanding the congenital nature of these anomalies.

As shown in **Figure 1**, the congenital anomalies affecting the distal gastrointestinal tract, characterised by absent or ectopic anal openings, fistulas to the urogenital tract, and variable involvement of pelvic musculature and nerves. These defects arise from abnormal cloacal development during early gestation and often co-occur with syndromic features such as VACTERL association.[4] Most ARM are diagnosed in the new-born period. In addition to a mandatory perineal and anal assessment, the examination should include evaluation of the heart, limbs and genitourinary system. A normal anus is defined by its correct location within the anal muscle complex and age-appropriate size, approximately a 10 to 12 Hegar dilator in full-term infants and 15 in 12-month-olds. Accurate assessment of anal position often requires examination under anaesthesia.[5]

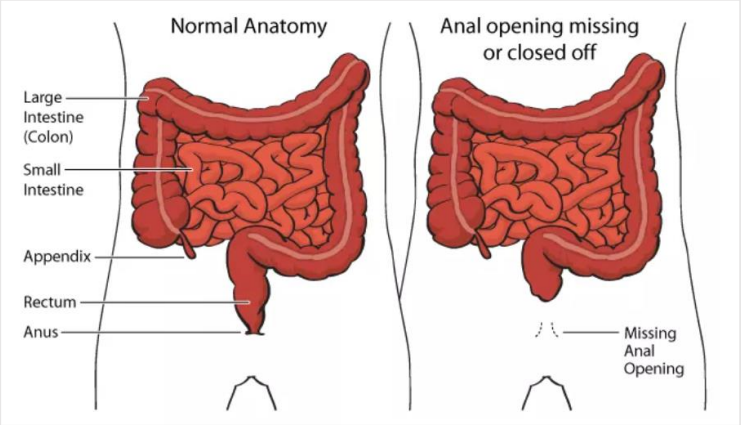


Figure 1: Forms of anorectal malformation – frontal view.[6]

The major long-term challenge and burden of disease for children with ARMs is gastrointestinal dysfunction, including chronic faecal incontinence and refractory constipation. These issues persist despite successful anatomical repair, significantly impacting the child's quality of life, psychosocial development and integration into society.[7]

In terms of treatment availability, the gold standard for the repair of ARM is the PSARP, which is often preceded by a colostomy in complex cases. Despite achieving anatomical correction, postoperative functional outcomes remain suboptimal, with up to 79.0% of patients experiencing constipation and 48.0% reporting faecal soiling, thereby requiring lifelong bowel management programs. These programs commonly involve the use of laxatives and enemas, trans-anal irrigations, or antegrade continence enemas (Malone procedure). However, such interventions are labour-intensive, impose significant psychosocial burdens and frequently fail to achieve voluntary continence, particularly among patients with associated sacral or spinal anomalies.[3] The limitations and challenges of existing treatment approaches for ARM are presented in **Table 1**.

Table 1: Current available treatments and limitations.[8,9]

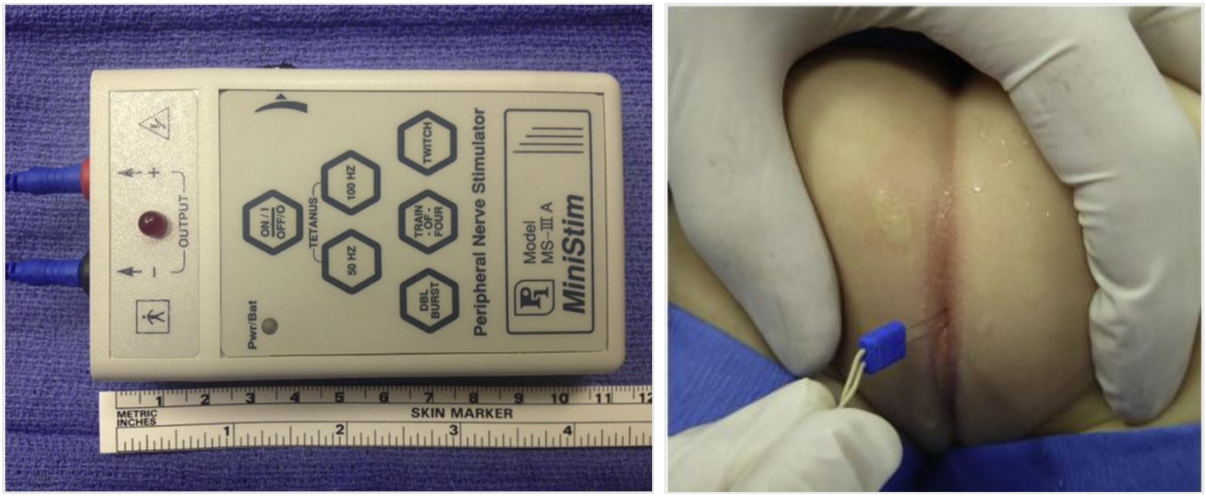
TREATMENT MODALITY	DESCRIPTION	LIMITATIONS/ DISADVANTAGES
Bowel management program	First-line: Dietary modification, osmotic laxatives (e.g., polyethylene glycol), and structured toilet training. For refractory cases, daily enemas are used to maintain social continence.	Requires lifelong, rigid adherence; high cost and psychological burden of daily enemas; can be socially stigmatising.
Pharmacological therapy	Use of laxatives or motility agents.	Often ineffective for severe neurogenic or anatomical deficits; side effects.
Surgical interventions	Reoperation (e.g., redo-PSARP) or procedures like the Malone Antegrade Continence Enema.	Invasive with associated surgical risks; outcomes can still be unpredictable as they do not address the underlying neuropathic deficits.
Biofeedback/ pelvic floor exercises	Used to strengthen pelvic floor muscles and improve rectoanal coordination.	Requires patient compliance and a functioning puborectalis/ external sphincter complex; often limited by the poor nerve and muscle development inherent to complex ARMs.

ARM, anorectal malformation; PSARP, posterior sagittal anorectoplasty

Following the surgical correction of ARM in children, it presents multifaceted challenges due to anatomical variability, associated congenital anomalies and the need for individualised operative strategies. The wide spectrum of ARM; from low-type defects to complex cloacal anomalies complicates preoperative planning and intraoperative decision-making, often requiring tailored approaches based on precise anatomical and neuromuscular mapping.[10] Intraoperative identifications of sphincter structures is critical for achieving functional outcomes, yet remains difficult in neonates and infants due to immature muscle development and atypical innervation patterns.[11] These challenges are further compounded in resource-limited settings, where access to advanced neuromonitoring tools and standardised protocols may be restricted, potentially affecting surgical precision and outcomes.

In response to these limitations, recent advancements in nerve stimulation technologies have significantly reshaped the surgical management of ARM in paediatric populations, enabling more precise, minimally invasive and anatomically tailored interventions aimed at restoring bowel continence. Intraoperative nerve stimulation serves a critical role in accurately identifying and preserving the external anal sphincter complex, thereby facilitating optimal placement of the neo-anus within the functional muscle ring. This targeted approach is essential for achieving voluntary postoperative bowel control and minimising long-term functional deficits. **(see Figure 3).**[12]

In intraoperative nerve stimulation for ARM repair, the stimulator is applied intermittently to prevent muscle fatigue or overstimulation. Following a midline sagittal incision, the levator ani and external anal sphincter muscles are exposed, and the probe is systematically applied to different muscle bundles to elicit contraction. Visible perineal skin movement or muscle twitching confirms functional response, and the point of maximal contraction is marked as the optimal site for neo-anus placement. After rectal pull-through, stimulation is repeated to verify proper positioning within the muscle complex. This technique is claimed to enhance anatomical precision during PSARP, reduce the risk of neo-anus misplacement, improve continence outcomes and support surgical training, particularly in resource-limited settings where low-cost stimulators can be utilised effectively. However, interpretation remains operator-dependent, and false negatives may occur in patients with poor sacral development or tethered cord.[13,14]



(a) (b)

Figure 3: a) Nerve stimulator, b) perineal region during stimulation.[12]

Beyond intraoperative application and operator-dependent interpretation, the functional reliability of nerve stimulators also hinges on their underlying battery design and power management systems, which determine usability, maintenance requirements and long-term clinical performance:[15]

- Implant types: Systems are available in recharge-free (non-rechargeable) and rechargeable implantable pulse generators (IPGs). Recharge-free models provide gentle stimulation continuously without patient recharging; rechargeable models require periodic external charging via manufacturer-specific equipment.

- External components: A smart programmer (handheld or app-based) and a communicator interface allow patients and clinicians to adjust therapy parameters (on/ off, amplitude, program selection) and check system status. The communicator itself has a battery that must be charged for use.

- Battery care: For rechargeable IPGs, routine charging is part of maintenance; for recharge-free IPGs, battery longevity depends on programmed settings and duty cycle and replacement occurs when depletion is detected during clinical follow-up.

The functional capacity of these stimulators is not only determined by battery longevity and external programmer interfaces, but also by the specific energy characteristics they generate, which define how electrical pulses interact with neural tissue to achieve therapeutic modulation. The energy characteristics are described below:

- Energy form: The device produces electrical energy-controlled, low-amplitude pulses delivered to neural tissue via implanted leads.[15]

- Parameters: Although exact ranges vary by system and clinical programming, nerve stimulators use adjustable current, pulse width (stimulus duration) and frequency to achieve therapeutic neuromodulation. The principle is akin to peripheral nerve stimulators where current, duration and frequency are tuned to reach threshold responses, but in sacral neuromodulation therapeutic goals prioritise comfortable, effective modulation rather than visible motor contraction.[16]

- Comparison to surface stimulators: Like transcutaneous electrical nerve stimulation units, which are battery-powered devices delivering transcutaneous impulses through electrodes, sacral neuromodulation delivers impulses more directly to nerves via implanted leads, enabling lower energy and more precise targeting than through skin electrodes.[17]

Translating these energy parameters into safe and effective therapy requires structured implantation and programming by trained clinicians, followed by coordinated patient participation and systematic maintenance protocols to ensure sustained neuromodulation performance. Implantation and programming are performed by trained clinicians, typically colorectal surgeons, urologists or specialised neuromodulation teams who conduct the implant procedure and complete the initial device programming, with postoperative adjustments made using the programmer and communicator to optimise stimulation settings and therapeutic programs.[15]

Maintenance and follow-up involve routine checks of the programmer and communicator to verify stimulation status, adjust parameters and manage operational modes with system notifications (e.g., device not responding, communicator low battery), and to guide troubleshooting through repositioning or charging. Safety checks and servicing include regular functional testing, parameter verification and adherence to structured maintenance schedules.[16]

While structured maintenance protocols ensure device reliability and safety, the broader clinical imperative lies in addressing persistent continence challenges, where nerve stimulation may serve as a neuromodulatory adjunct aligned with Malaysia's child health priorities. Its potential to improve postoperative quality of life is consistent with the strategic objectives outlined in Malaysia's National Child Health Plan (2021-2030), which priorities reductions in under-five morbidity and supports holistic child development.[17] A formal evaluation of intraoperative nerve stimulator use in ARM surgery among Malaysian paediatric patients is warranted. By integrating nerve stimulator into major paediatric centres would help localise expertise and tailor protocols to reflect Malaysia's clinical profile.

EVIDENCE SUMMARY

A systematic review was conducted. A total of 34 titles were retrieved through the Embase, PubMed and United States of Food and Administration (US FDA). Google was used to search for additional web-based materials and information. There was no language limitation in the search and the last search was conducted on 3 November 2025. Two included studies were conducted in United States and German. This review was developed with support from several artificial intelligence tools to improve content generation, organisation and refinement. Google Gemini was used to draft initial sections and outline key themes. Microsoft Copilot assisted in editing, ensuring clarity, consistency and alignment with regulatory standards. GoogleBook

LM helped locate and summarise relevant academic sources from digital libraries to support evidence-based writing.

EFFECTIVENESS

Two studies retrieved from the scientific database, evaluating the effectiveness of nerve stimulators in enhancing surgical precision during ARM correction.

Short C et al. (2013; United States) conducted a prospective comparative case series on a modified peripheral nerve stimulator against the [redacted] Muscle Stimulator in six paediatric patients (five boys, one girl; 5.9 kg to 11.0 kg). All patients underwent PSARP for various ARM, including four prostatic fistulae, one bulbar fistula and one vestibular fistula. Both devices were used sequentially during each procedure to identify pelvic and anal muscle groups, with performance documented via video. Energy delivery was measured using a digital oscilloscope at operative settings, revealing comparable outputs of 23.5 mW (peripheral nerve stimulator) and 25.3 mW [redacted] Muscle Stimulator) respectively. Both devices produced square wave pulses of 200 µs duration, with peripheral nerve stimulator operating at 100 Hz and [redacted] at 50 Hz. The findings indicated unanimous consensus among the operating team that both the improvised peripheral nerve stimulator and the [redacted] Muscle Stimulator demonstrated equivalent efficacy in intraoperative delineation of pelvic and anal musculature essential for accurate neo-anus placement during PSARP, although the ergonomics of the peripheral nerve stimulator's probe were comparatively less favourable. At follow-up (five months post-PSARP and two to three-months post-colostomy closure), all patients achieved daily stooling with a senna-based bowel regimen.[14]

Hasselbeck C et al. (2012; German) conducted a retrospective study to assess neuromuscular integrity and guide anoproctoplasty in children with ARM. In the study, sacral nerve stimulation was initiated at the S3 level; recognised as the primary contributor to external anal sphincter contraction by using a stimulator (20 Hz, 200 µs pulse, 1 V to 10 V range). Needle placement was verified via foot muscle responses, followed by sphincter response observation and innervation mapping. The [redacted] method (a medical imaging method for evaluating ARM) was concurrently employed to identify contractile muscle tissue. Seven children (aged 23 days to 8 years) underwent sacral nerve stimulation, with ARM types classified per Krickenbeck and Wingspread criteria. Notably, crossover innervation patterns were identified in two cases, including one with Okihiro syndrome, suggesting atypical neuromuscular configurations. A previously unreported congenital anomaly involving strictly contralateral EAS and plantar flexion responses to S3 stimulation was also observed in one patient.[17]

The findings showed that, this procedure enabled precise localisation of sphincter muscles without direct current application. Additionally, it was utilised intraoperatively for sphincter mapping and detection of primary innervation anomalies, as well as postoperatively to assess secondary deficits, thereby facilitating anatomically tailored surgical intervention.[17]

SAFETY

One study investigated the safety of nerve stimulation in enhancing surgical precision during the repair of ARM. There was no intraoperative or postoperative complication reported, including tissue burns. The procedure allowed precise muscle identification without direct stimulation.[18]

From a regulatory perspective, the United States of Food and Administration (US FDA) had not issued ARM-specific approvals for nerve stimulators, but several sacral nerve stimulation

devices were FDA-approved for bowel control applications, which include faecal incontinence often associated with ARM.[20] In ARM surgery, intraoperative nerve stimulation (e.g., mapping sphincter muscles) often used modified or improvised stimulators. These might not be FDA-approved for ARM-specific use but were adapted from approved neuromodulation platforms.

In addition, there were two devices registered with the Medical Device Authority (MDA) for intraoperative use in locating, identifying and stimulating motor nerves. These devices assisted surgeons in mapping motor nerve pathways by utilising evoked potentials, electromyographic signals and direct muscle stimulation to enhance surgical precision and neuromuscular integrity assessment.[21]

ECONOMIC IMPLICATION

No cost-effectiveness studies were retrieved for nerve stimulators specifically for ARM correction. One study highlighted a substantial cost advantage of the modified peripheral nerve stimulator, which was priced at USD162 (MYR671.49) versus USD12,371 (MYR51,277.79) for the [redacted] Muscle Stimulator. Despite similar intraoperative performance and safety profiles, the modified device's affordability suggested strong potential as a cost-saving alternative for neuromuscular mapping in resource-limited surgical settings.[18]

CONCLUSION

The limited evidence retrieved had demonstrated comparable performance in muscle identification during PSARP, with no reported complications. Sacral nerve stimulation further enabled precise sphincter mapping and revealed atypical innervation patterns. The modified stimulator’s significantly lower cost suggested strong potential for resource-limited settings. From a regulatory standpoint, the US FDA has not approved nerve stimulators specifically for ARM repair, though several sacral neuromodulation devices are cleared for bowel control indications including faecal incontinence. The MDA has registered two devices for intraoperative motor nerve localisation and stimulation.

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