Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Rapid health technology assessment (HTA) on the use of vesicostomy buttons in children

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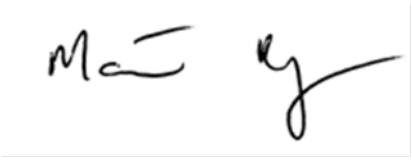
Foreword

A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. Children with these bladder problems are at an increased risk of complications including recurrent urinary tract infections, urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage. For some of these patients, surgical urinary intervention is required to prevent significant long-term clinical consequences. Urine storage and bladder emptying problems in children can be managed conservatively (for example with medicines) or via other non-surgical or surgical management options, depending on factors such as age, anatomy, bladder function and individual preference.

Vesicostomy button devices are low-profile silicone devices inserted percutaneously through the abdominal wall into the bladder to create a channel, allowing for intermittent urine drainage, without the need for a long external catheter. The vesicostomy button is a modified version of the gastrostomy button, originally designed for enteral feeding, that has been repurposed for urinary use.

The aim of this rapid HTA was to examine the clinical effectiveness and safety of the use of vesicostomy buttons in children to facilitate urine storage and bladder emptying.

Work on the rapid HTA was undertaken by an Evaluation Team from the HTA Directorate in HIQA. A multidisciplinary Expert Advisory Group was convened to advise the Evaluation Team during the course of the rapid HTA. HIQA would like to thank the Evaluation Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.



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Particular thanks are due to the Expert Advisory Group (EAG) and the individuals within the organisations listed below who provided advice and information.

The membership of the EAG was as follows:

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Organisations that assisted HIQA in providing information, in writing or through meetings, included:

Avanos Medical and Technopath provided a factual accuracy check on the description of the technology of the MiniONE® and MIC-KEY® devices.

The following members of the HTA Directorate contributed to the management, technical writing or dissemination of this report:

Lydia O'Sullivan (project lead), Marie Carrigan, Andrew Dullea, Elaine Foley, Sharon Kappala, Dane Moriarty, Kirsty O'Brien, Michelle O'Shea, Máirín Ryan, Debra Spillane, Susan Spillane, Kieran Walsh.

Conflicts of Interest

None reported.

Key findings and advice to the Minister for Health

At the request of the Department of Health, the Health Information and Quality Authority (HIQA) agreed to undertake a rapid health technology assessment (HTA) on the use of vesicostomy buttons in children. This rapid HTA aimed to assess the clinical effectiveness and safety of the use of vesicostomy buttons in children to facilitate urine storage and bladder emptying.

The key findings of this rapid HTA, which informed HIQA's advice to the Minister for Health, were:

- A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. However, these conditions are generally rare or uncommon. Some examples of these conditions include neurogenic bladder, anorectal malformations and posterior urethral valves.
- Children with these bladder problems are at an increased risk of complications including recurrent urinary tract infections, urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage. For some of these patients, surgical urinary intervention is required to prevent significant long-term clinical consequences.
- Urine storage and bladder emptying problems in children can be managed conservatively (for example with medicines) or via other non-surgical or surgical management options, depending on factors such as age, anatomy, bladder function and individual preference.
- Non-surgical management options include intermittent urinary catheterisation and indwelling urethral catheters.
    - Clean intermittent catheterisation (CIC) is the repeated insertion and removal of a small, flexible catheter several times daily to empty the bladder. It is the preferred long-term method when feasible, preserving bladder function and reducing infection risk.
    - Indwelling urethral catheters provide continuous drainage. Their use in children is generally limited to short-term perioperative (before, during or after an operation) management due to higher risk of infection and complications.
- Surgical management options are used in children when urethral catheterisation is not feasible, is poorly tolerated or would result in significant morbidity.
    - Suprapubic catheters are inserted percutaneously into the bladder via the abdominal wall, bypassing the urethra. They are typically used in

cases of a sensate urethra, urethral injury or obstruction, or following complex bladder surgery, but carry procedural risks such as bleeding and bowel injury.

  - Vesicostomy refers to the surgical creation of a tract from the skin to the bladder (usually in the lower abdomen) to allow for bladder drainage or catheterisation. It may be performed as a temporary urinary diversion or as part of long-term bladder management and can be open or closed (using a vesicostomy button device).
  - Mitrofanoff continent urinary diversion is a major surgical procedure that creates a channel from the skin to the bladder which enables intermittent catheterisation while maintaining continence. It is considered for children who require long-term CIC but cannot use the urethra.

- Vesicostomy button devices are low-profile silicone devices inserted percutaneously through the abdominal wall into the bladder to create a channel, allowing for intermittent urine drainage, without the need for a long external catheter. They are primarily used as a temporary solution in children who cannot reliably perform CIC, serving as a bridge to future definitive bladder management or reconstructive surgery. However, in selected cases such as children with cerebral palsy or with associated co-morbidities, the vesicostomy button can be considered a long-term solution.
- The vesicostomy button is a modified version of the gastrostomy button, originally designed for enteral feeding, that has been repurposed for urinary use. First described for urine storage and bladder emptying in 1996, it has since gained wider adoption in paediatric urology. Two CE marked devices are currently in use, the MiniONE® (Applied Medical Technologies) and MIC-KEY® (Avanos Medical); in both cases they are being used 'off-label' for this indication. The manufacturers and distributor of these devices were offered the opportunity to provide a factual accuracy check and to share their perspectives on the use of their device as a vesicostomy button in children. They reiterated that the use of these devices in this manner is 'off-label'.
- Compared to a 'standard' catheter, which has longer tubing and a catheter bag on the outside of the body, the vesicostomy button is small and can easily be hidden under clothes and allows children to participate more comfortably in everyday activities, including sports and swimming.
- While the use of the button device in this manner is considered 'off-label', it is not contraindicated. The devices are manufactured from medical-grade silicone, a biocompatible material that is widely used in urinary catheters and

other devices designed for the urinary tract, reflecting material compatibility across gastrointestinal and urinary applications.

- Clinicians within certain paediatric specialities often rely on the use of medical devices outside the manufacturer's intended purpose or instructions for use ('off-label') due to the relative scarcity of approved paediatric options. While the Medical Device Regulation 2017/745 obliges manufacturers to monitor systematic off-label use, the available data are typically low quality. Generating the robust clinical evidence needed to formally expand indications is often impractical in rare paediatric conditions, limiting evidence-based conclusions on safety and effectiveness.

- Any 'off-label' use of medical devices merits consideration of controlled risk management processes, clear governance structures and fully informed consent in accordance with legislation and the best available evidence. Patient and carer information leaflets should provide accessible information to support safe and effective care and a clear explanation of what 'off-label' means in this context.

- Four clinical guidelines from German, Canadian, European and International organisations, plus one expert consensus statement, were identified that specifically mentioned the use of vesicostomy buttons in children. Each of these note that vesicostomy buttons may be used as a management option for patients with urine storage and bladder emptying problems.

- A systematic review was conducted to identify and summarise the international evidence relating to the clinical effectiveness and safety of the use of vesicostomy buttons in children. The overall evidence base was very limited and comprised 15 publications from 14 case series; these studies included a total of 244 patients who had undergone button vesicostomy.

- Three case series were considered to be low quality, seven intermediate quality and four high quality. All case series were uncontrolled and none compared the use of vesicostomy buttons with alternative bladder management interventions.

- Eleven out of the 14 studies reported the sex of participants; of the 193 participants in these 11 studies, 131 (68%) were male. The age of participants varied widely across the studies, ranging from newborn infants to age 19, with a median age of five years.

- Eight studies reported the use of the MIC-KEY® device within nine publications, two reported the use of the MiniONE® device and one reported

use of a Bard device. Four studies did not specify the brand of device used, and one study used both MIC-KEY® and MiniONE® devices.

- Reporting of patient characteristics, diagnoses, indications and prior bladder management was heterogeneous, inconsistent, and often incomplete.
    - Common underlying diagnoses included spinal dysraphism (including spina bifida), posterior urethral valves, neurogenic bladder (not otherwise specified), and anorectal malformations.
    - Indications for vesicostomy buttons included poor bladder emptying, bladder assessment, management following previously attempted interventions, which may have failed, and temporary diversion to allow time before definitive treatment.
- Button removal rates varied widely (0% to 100%) and may reflect whether the device was intended as a temporary or permanent management option and that the follow-up time varied between studies. Reasons for button removal included patients moving to urethral continence or subsequent treatments, such as learning or complying with clean intermittent catheterisation (CIC) and or clean intermittent self-catheterisation (CISC), surgical interventions such as Mitrofanoff diversion, bladder augmentation, bladder reconstruction, renal transplant and artificial urinary sphincter implantation.
- Reports on bladder function outcomes following vesicostomy button placement were heterogeneous in terms of outcome selection, measurement and reporting. Six case series reported generally positive perceived outcomes related to bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. However, in the absence of comparator groups, no firm conclusions can be drawn regarding the relative effectiveness of vesicostomy buttons versus other bladder management strategies.
- Fourteen studies reported on the presence or absence of urinary tract infections (UTIs). The proportion of patients experiencing UTIs ranged from 0-54%. Five studies reported no UTIs with a range of follow-up times between six months and 10 years. Five studies reported on the incidence of symptomatic or febrile UTIs, ranging from 15-31%. In four studies, UTIs ranged between 21-54% but the authors didn't specify if they were symptomatic. In four studies where the incidence of UTIs were reported before and after vesicostomy button placement, more than half of the patients who had a UTI after button placement had a history of UTIs prior to button placement.

- The rate of infection at the site of the vesicostomy button ranged from 0-14% of patients over a wide range of follow-up periods. Overgranulation (excessive growth of tissue around the button insertion site) was reported in 13% and 24% of patients in two case series. One patient from a relatively large case series (n=35) had button-related skin ulceration requiring revision (correction of complications and or adjustment of the device), and removal of the device.
- Twelve case series reported on vesicostomy button leakage, with reported leakage rates of 0-28% across follow-up periods ranging from two months to 13 years. The reporting on this outcome was not standardised. However, seven case series reported a proportion of these leaks as 'major' or 'significant'.
- Device- or procedure-related complications were inconsistently reported. Where reported, events included mechanical malfunction, encrustation, blockage, dislodgement, retention of the device in the bladder neck, unplanned exchange or revision, difficulties with the drainage tubing, and lithiasis (formation of stones within the bladder due to the presence of the device). Four case series reported no device failures; six reported at least one device- or procedure-related issue.
- Patient or parent satisfaction was reported in nine case series. Only one study conducted a formal quality-of-life comparison between a subset of patients receiving a vesicostomy button and another sample of patients performing CIC; no statistically significant difference in any quality-of-life domains or overall mean score (69.8 versus 72.3, p=0.65) was observed, although the questionnaire used had been substantially modified from its validated form and due to the low participant number, the study likely did not have the statistical power to detect a difference. The remaining studies reported generally positive satisfaction but did not use formal assessment methods.
- Given the limitations of this evidence base it is not possible to draw definitive conclusions regarding the clinical effectiveness of vesicostomy button use in children, relative to other management options. However, no serious safety concerns were noted and generally positive outcomes are reported in relation to urine storage and bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. Patient and parent satisfaction appeared to be positive overall, and vesicostomy buttons appeared to be well tolerated.

Arising from the findings of this rapid HTA, HIQA's advice to the Minister for Health is as follows:

- A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. However, these conditions are generally rare or uncommon. Some examples of these conditions include neurogenic bladder, anorectal malformations and posterior urethral valves. Children with these bladder problems are at an increased risk of complications including recurrent urinary tract infections, urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage. For some of these patients, surgical urinary intervention is required to prevent significant long-term clinical consequences.
- The vesicostomy button device is a modified version of the gastrostomy button, which is used outside the manufacturer's intended purpose or instructions for use (also known as 'off-label') in a very small number of children with problems storing urine and emptying their bladders. Vesicostomy buttons often serve as a bridge to future definitive bladder management or reconstructive surgery. While the use of the button device in this manner is considered 'off-label', it is not contraindicated. The devices are manufactured from medical-grade silicone, a biocompatible material that is widely used in urinary catheters and other devices designed for the urinary tract, reflecting material compatibility across gastrointestinal and urinary applications.
- From 2018 to 2026, a total of 26 vesicostomy buttons were placed in patients at Children's Health Ireland (CHI) hospitals. This means that between two and four vesicostomy buttons have been placed each year for the past six years for a variety of indications.
- Clinicians within certain paediatric specialities often rely on the 'off-label' use of medical devices due to the relative scarcity of CE-marked paediatric options. Any 'off-label' use of medical devices merits consideration of controlled risk management processes, clear governance structures and fully informed consent in accordance with legislation and the best available evidence. Patient and carer information leaflets should provide accessible information to support safe and effective care and a clear explanation of what 'off-label' means in this context.
- The evidence identified in this systematic review is limited to 14 case series with small sample sizes and very limited comparative data. In addition, four clinical guidelines and one consensus statement relating to the use of vesicostomy buttons in children were identified, each of which provided very limited information.
- Given the limitations of the evidence base it is not possible to draw definitive conclusions regarding the clinical effectiveness and safety of vesicostomy button

use in children, relative to other management options. However, no serious safety concerns have been noted over the last 30 years of its use in clinical practice. Generally positive outcomes are reported in relation to patient and carer satisfaction, urine storage and bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. In addition, some of the adverse events, for example, UTIs, may also be attributed to the patients' underlying clinical conditions, rather than related to the use of the vesicostomy button.

- Based on the finding of this rapid HTA, vesicostomy buttons provide a continent, reversible option for urine storage and bladder emptying problems in some children for whom other management options are limited or not preferred by patients and carers. In these patients, damage to the urinary system may be avoided, while potentially preserving future management options. Further, it is noteworthy that vesicostomy buttons represent a more discreet, low-profile management option and may enhance social comfort and confidence. For example, they allow children to participate in activities, such as sports and swimming, and enable them to wear regular underwear, which patients and carers may prefer over open vesicostomy.

Executive summary

The aim of this rapid health technology assessment (HTA) was to examine the clinical effectiveness and safety of the use of vesicostomy buttons in children to facilitate urine storage and bladder emptying. This rapid HTA considered the following domains: description of the technology, the epidemiology and burden of disease, and clinical effectiveness and safety.

Background

Following a request from the Minister for Health, HIQA agreed to undertake a rapid Health Technology Assessment HTA on the use of vesicostomy buttons in children. This rapid HTA aims to identify and summarise the international evidence on the safety and effectiveness associated with the 'off-label' use of gastrostomy buttons as vesicostomy buttons in children. 'Off-label', in this context, refers to the use of medical devices outside the manufacturer's intended purpose or instructions for use.

Methods

This research was carried out in accordance with HIQA's quality assurance framework. In summary, the following took place:

- The terms of reference and deliverables for the rapid HTA were agreed between HIQA and the Department of Health.
- An Expert Advisory Group (EAG) was convened by HIQA comprising representation from relevant stakeholders. These included: clinicians with specialist expertise in paediatrics and paediatric urology; the Health Products Regulatory Authority; experts in medical devices; an advocacy group for people living with spina bifida and hydrocephalus and their carers; and a patient safety organisation. An Evaluation Team was appointed comprising HIQA staff.
- A description of the technology (vesicostomy buttons) was prepared.
- The manufacturers and distributor of these devices were offered the opportunity to provide a factual accuracy check and to share their perspectives on the use of their device as a vesicostomy button in children.
- The epidemiology and burden of urine storage and bladder emptying problems in Ireland and internationally was described.
- A systematic review of the clinical effectiveness and safety of the use of vesicostomy buttons in children was conducted.
- The draft report was circulated to the EAG for review.
- A draft report outlining the findings of this rapid HTA was discussed at a meeting of the EAG and subsequently amended, where appropriate.

- Informed by the feedback from the EAG, a revised draft report was prepared and circulated to the EAG for review.
- Following review by the EAG, the final draft of the rapid HTA was submitted to the Executive Management Team (EMT) in HIQA for approval.
- Following approval from the EMT in HIQA, the final rapid HTA was submitted to the Minister for Health as advice and published on the HIQA website.

Description of technology

Vesicostomy button devices are low-profile silicone devices inserted through the abdominal wall into the bladder to create a channel, allowing for intermittent urine drainage without the need for a long external catheter and a catheter bag. They are primarily used as a temporary solution in children who cannot reliably perform clean intermittent catheterisation, serving as a bridge to future definitive bladder management or reconstructive surgery. However, in selected cases such as children with cerebral palsy or with associated co-morbidities, the vesicostomy button can be considered a long-term solution.

The vesicostomy button is a modified version of the gastrostomy button, originally designed for enteral feeding, that has been repurposed for urinary use. First described for urine storage and bladder emptying in 1996, it has since gained wider adoption in paediatric urology. Two CE marked devices are currently in use, the MiniONE® (Applied Medical Technologies) and MIC-KEY® (Avanos Medical). In both cases they are being used 'off-label' for this indication, although use in the bladder or vesicostomy setting is not specifically listed as a contraindication. The manufacturers and distributor of these devices were contacted to provide a factual accuracy check and to share their perspectives on the use of their device as a vesicostomy button in children. They confirmed that the use of these devices in this manner is 'off-label'.

Four clinical guidelines from German, Canadian, European and International organisations, plus one expert consensus statement, were identified that specifically mentioned the use of vesicostomy buttons in children. Each of these note that vesicostomy buttons may be used as a management option for patients with urine storage and bladder emptying problems.

Epidemiology and burden of disease

A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. However, these conditions are generally rare or uncommon. Three key paediatric conditions which commonly lead to urine storage and bladder emptying problems requiring surgical urinary diversion: neurogenic bladder (predominantly due to congenital or acquired neurologic disorders), anorectal malformations, and posterior urethral valves.

Children with these bladder problems are at an increased risk of complications including recurrent urinary tract infections, urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage. For some patients, surgical urinary intervention is required to prevent significant long-term clinical consequences.

'Neurogenic bladder' refers to a disruption in normal bladder, bladder neck, or urinary sphincter function that arises from any disorder of the nervous system. Neurogenic bladder in children is most commonly caused by congenital neural tube defects, particularly spinal dysraphism, including spina bifida, with myelomeningocele representing the most severe and clinically significant form. Children with neurogenic bladder are at increased risk of recurrent urinary tract infections, urinary incontinence, and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage due to impaired bladder storage and emptying, often presenting with urgency, incontinence, or difficulty voiding. Long-term management focuses on protecting kidney function, improving continence where possible, and supporting independence.

Spina bifida

In Ireland, spina bifida is one of the most common forms of neural tube defect, aligning with the reported national rate of 10-11 per 10,000 births. According to a report published in 2014, approximately 40 new cases of spina bifida are identified annually in Ireland, and a high proportion of affected children (around 80-90%) experience bladder problems.

Anorectal malformations

Anorectal malformations are rare congenital conditions, with a birth prevalence of approximately one in 2,500 to 5,000 live births in Europe and include a wide spectrum of severity. Although anorectal malformations are uncommon, they are clinically significant and are frequently associated with lower urinary tract dysfunction, including neurogenic bladder in around 25% of cases. Despite their low prevalence, anorectal malformations carry a substantial long-term disease burden with many children requiring ongoing bladder management.

Posterior urethral valves

Posterior urethral valves are a rare congenital condition occurring exclusively in boys, with an estimated incidence in the UK and Ireland of one in 4,000 to 5,000 live male births. Posterior urethral valves are the most common cause of congenital lower urinary tract obstruction in boys. This often leads to lifelong complications, including bladder dysfunction, which requires intervention in up to 40% of cases,

and progressive renal impairment, with around one-third of affected boys developing end-stage renal disease.

Estimated vesicostomy button case volume

While precise estimation of the number of children requiring vesicostomy buttons is challenging due to limited population-level data, overall numbers are likely very low, given that the underlying conditions are rare and only a subset of affected children require this intervention.

From 2018 to 2026, a total of 26 vesicostomy buttons were placed in patients at Children's Health Ireland (CHI) hospitals. This means that between two and four vesicostomy buttons have been placed each year for the past six years for a variety of indications. The clinical indications for placement of vesicostomy buttons varied but were consistent with the clinical indications described in the case series reported in Chapter Four.

Clinical effectiveness and safety

A systematic review was conducted to identify and summarise the international evidence relating to the clinical effectiveness and safety of the use of vesicostomy buttons in children. The overall evidence base was very limited and comprised 15 publications from 14 case series; these studies included a total of 244 patients who had undergone a button vesicostomy procedure.

Reporting of patient characteristics, diagnoses, indications and prior bladder management was heterogeneous, inconsistent and often incomplete.

- Common underlying diagnoses included spinal dysraphism (including spina bifida), posterior urethral valves, neurogenic bladder (not otherwise specified), and anorectal malformations.
- Indications for vesicostomy buttons included poor bladder emptying, bladder assessment, management following previously attempted interventions which may have failed, and temporary diversion to allow time before definitive treatment.

Reports on bladder function outcomes following vesicostomy button placement were heterogeneous in terms of outcome selection, measurement and reporting. Six case series reported generally positive perceived outcomes related to bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence.

Fourteen studies reported on the presence or absence of urinary tract infections (UTIs). The proportion of patients experiencing UTIs ranged from 0-54%. Five

studies reported no UTIs with a range of follow-up times between six months and 10 years.

The rate of infection at the site of the vesicostomy button ranged from 0-14% of patients over a wide range of follow-up periods. Overgranulation (excessive growth of tissue around the button insertion site) was reported in 13% and 24% of patients in two case series.

Twelve case series reported on vesicostomy button leakage, with reported leakage rates of 0-28% across follow-up periods ranging from two months to 13 years. The reporting on this outcome was not standardised. However, seven case series reported a proportion of these leaks as 'major' or 'significant'.

Device- or procedure-related complications were inconsistently reported. Where reported, events included mechanical malfunction, encrustation, blockage, dislodgement, retention of the device in the bladder neck, unplanned exchange or revision, difficulties with the drainage tubing and lithiasis (formation of stones within the bladder due to the presence of the device). Four case series reported no device failures; six reported at least one device- or procedure-related issue.

Patient or parent satisfaction was reported in nine case series. Only one study conducted a formal quality-of-life comparison between a subset of patients using vesicostomy buttons and another sample of patients performing clean intermittent catheterisation; no statistically significant difference in any quality-of-life domains or overall mean score (69.8 versus 72.3, p=0.65) was observed, although the questionnaire used had been substantially modified from its validated form, and, due to the low participant number, the study likely did not have the statistical power to detect a difference. The remaining studies reported generally positive satisfaction but did not use formal assessment methods.

Conclusions

The evidence identified in the systematic review of clinical effectiveness and safety is limited to 14 case series with a total of 244 participants.

Given the limitations of this evidence base, it is not possible to draw definitive conclusions regarding the clinical effectiveness and safety of vesicostomy button use in children, relative to other management options. However, no serious safety concerns were noted and generally positive outcomes are reported in relation to urine storage and bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. Patient and parent satisfaction appeared to be positive overall, and vesicostomy buttons appeared to be well tolerated.

Plain language summary

What did we look at?

Children with certain health conditions can have problems storing urine and emptying their bladder. One of these health conditions is known as neurogenic bladder. This is where the nerves which control the bladder are damaged, for example due to spina bifida. Spina bifida is a condition where the spine and spinal cord do not form properly in the baby in the mother's womb during pregnancy. It can cause mild to serious disabilities, including problems with the bowel and bladder.

If urine storage and bladder emptying problems are not managed early, children may be more likely to get infections and may develop damage to the bladder and kidneys. There are different ways of managing these bladder problems. These depend on factors like how severe the condition is, what a patient or caregiver prefers, and whether a particular option is possible for an individual patient.

The Minister for Health asked the Health Information and Quality Authority (HIQA) to carry out a review to see whether using a medical device known as a vesicostomy button for the management of urine storage and bladder emptying problems in children works well and is safe. Since 2018, between two and four vesicostomy buttons were placed into children each year in Children's Health Ireland (CHI) hospitals.

What is a vesicostomy button?

A vesicostomy is a surgical procedure, performed while the child is under anaesthetic, to create a small opening on the abdomen just below the belly button. Through this opening, a 'catheter' or tube is passed to allow urine to drain out of the bladder. This helps to reduce urine going back up to the kidneys and improves emptying of the bladder. This in turn helps to reduce the risk of infections and damage to the kidneys. A vesicostomy button is a medical device, made from medical-grade silicone, which is placed into the bladder, through the vesicostomy (opening) and used to drain urine out of the bladder. The material used in these devices (medical-grade silicone) is the same material used in 'standard' catheters. Compared to a 'standard' catheter, which has longer tubing on the outside of the body, the vesicostomy button is small and can easily be hidden under clothes. It allows children to participate more comfortably in everyday activities, including sports and swimming.

These button devices are manufactured and licensed to be used in the stomach, not the bladder. Therefore, when these devices are used to help with storing urine and emptying the bladder, their use is considered 'off-label'. This means they are being

used differently to how they were originally intended to be used. However, it is quite common and appropriate in some circumstances for medical devices to be used 'off-label', particularly in children. In many cases, 'off-label' use of a device is often supported within the clinical community, based on scientific literature and clinical guidelines. To help ensure that patients are kept safe, extra safeguards are needed, including clear discussion of risks and benefits with the child and their family, and following relevant clinical guidelines or hospital policies. Information about the devices and support on the safe use of the device should also be provided to the child and their family.

What did we find?

We found that there wasn't a lot of medical literature published about the use of vesicostomy buttons in children. The 14 research studies which we found included a total of 244 children between them and came from the United Kingdom, Italy, the United States, France, the Netherlands and Argentina. Children in these research studies ranged in age from newborn babies to 19 years, but most children were about five years old when they had the vesicostomy button inserted. In the majority of studies, one of two types of vesicostomy buttons were used, known as the MIC-KEY® and MiniONE® devices.

Due to the very small amount of research studies published, it is not possible to draw firm conclusions about how well vesicostomy buttons work, or how safe they are, compared with other ways of managing problems with storing urine and emptying the bladder. Complications such as leakage from the button site, infections, and skin reactions were noted in these research studies. It is not possible to know whether these complications occur more often when using vesicostomy buttons compared with 'standard' catheters. However, this review indicates that vesicostomy buttons have been used since 1996 without any serious safety concerns. Overall, healthcare professionals, patients and caregivers from the research studies seem to agree that vesicostomy buttons work well, for certain children, in specific circumstances. These circumstances include those with severe bladder problems where standard catheterisation through the urethra (the tube that carries urine out of the body) is difficult, painful or not possible. They can also provide a short-term option until a better long-term way of emptying the bladder can be set up.

List of abbreviations used in this report

ARM-Net	European Anorectal Malformation Network
BAPS-CASS	British Association of Paediatric Surgeons Congenital Anomaly Surveillance System
CE	Conformité Européenne
CIC	clean intermittent catheterisation
CISC	clean intermittent self-catheterisation
DIDMOAD	diabetes insipidus, diabetes mellitus, optic atrophy, deafness
EAG	Expert Advisory Group
EAU	European Association of Urology
EU	European Union
EUROCAT	European Platform on Rare Disease Registration
HIQA	Health Information and Quality Authority
HRQoL	health-related quality of life
HSE	Health Service Executive
HTA	health technology assessment
IFU	instructions for use
MDR	Medical Device Regulation
PICOS	population, intervention, comparator, outcome, study type
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PUV	posterior urethral valve
PVR	post-void residual (urine volume)
SMA	spinal muscular atrophy
SWiM	Synthesis Without Meta-analysis
TRIP	Turning Research Into Practice (medical database)
UTI	urinary tract infection
WHO	World Health Organization

Glossary of terms

Anorectal malformations	A group of congenital conditions in which the anus and rectum do not develop or connect normally, often causing bowel and sometimes bladder problems.
Bias	In general, any factor that distorts the true nature of an event or observation. In clinical investigations, a bias is any systematic factor other than the intervention of interest that affects the magnitude of (that is, tends to increase or decrease) an observed difference in the outcomes of a treatment group and a control group.
Bladder cycling	Technique involving regular filling and draining of the bladder to increase bladder capacity.
Catheter	A thin, flexible tube which is inserted into the body to move fluids in or out, for example, to empty the bladder.
Comparator	The technology to which an intervention is compared.
Congenital	Something (for example, a medical condition), which is present at or before birth.
Continent (medical context)	The ability to control the bladder and or bowels.
Effectiveness	The benefit (for example, to health outcomes) of using a technology for a particular problem under general or routine conditions.
Encrustation	Deposits of mineral crystals on the surface and inside of implants inside the body.
Febrile	Having a fever.
Gastrostomy	A medical procedure whereby a small surgical opening is made in the abdomen, through the skin directly into the stomach, in order to deliver liquid food, water, fluids or medicines.
Health technology	Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organisational systems used in healthcare.
Health technology assessment (HTA)	Health technology assessment (HTA): the systematic evaluation of properties, effects, and or impacts of healthcare technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in healthcare.

	HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.
Heterogeneity (adjective: heterogeneous)	Variability or differences in the estimates of effects among studies.
Lithiasis	Stones in the body, for example in the urinary system, often known as 'kidney stones'.
Lower urinary tract	Bladder and urethra.
Mean (arithmetic mean)	The average value, calculated by summing all the observations and dividing by the number of observations.
Median	The middle value in a ranked group of observations. This can be a better estimate of the average value if there are extreme outlying values that may skew the arithmetic mean.
MEDLINE	An electronic database produced by the United States National Library of Medicine.
Mitrofanoff procedure	A major surgical procedure that creates a continent catheterisable channel from the skin to the bladder, most commonly using the appendix, in a procedure called appendicovesicostomy. The channel is implanted into the bladder with an anti-reflux mechanism to achieve continence, and is brought out to the skin, typically at the umbilicus or lower abdominal wall. The channel allows clean intermittent catheterisation while maintaining continence between catheterisations.
Native urethra	The natural, original tube in the body that carries urine from the bladder to the outside.
Neurogenic bladder	Where the nerves which control the urinary bladder and sphincter (a ring of muscle that opens and closes to control the flow of urine) are damaged.
Off-label use (of a medical device)	The use of a medical device outside of the manufacturer's intended purpose or instructions for use.
Outcomes	Components of a patients' clinical and functional status after an intervention has been applied.
Overgranulation	Excessive growth of bright red, friable, and jelly-like tissue that extends above the surface of a healing wound, often caused by infection, friction, or excessive moisture.
Percutaneous (procedure)	Insertion through the skin.

Perioperative	What happens before, during and after a surgical procedure.
Posterior urethral valves	A congenital condition where tissue blocks the urethra in boys, causing problems emptying the bladder.
Prune belly syndrome	A rare condition which causes abnormalities in the urinary tract.
Quality of life	A multi-dimensional measure comprising the physical and mental health perceptions of a patient in terms of health status, health risks, functional status, social support, and socioeconomic status.
Quality of evidence	Degree to which bias has been prevented through the design and conduct of research from which evidence is derived.
Sensate urethra	Someone who has intact nerves meaning they have sensation in the urethra.
Spina bifida	A congenital condition where the spine and spinal cord do not form properly in the womb. Spina bifida can range from being mild to causing serious disabilities, including problems with the bowel and bladder.
Stoma	An artificial opening made into a hollow organ, for example, the bladder.
Systematic review	A form of structured literature review that addresses a question that is formulated to be answered by analysis of evidence, and involves objective means of searching the literature, applying predetermined inclusion and exclusion criteria to this literature, critically appraising the relevant literature, and extraction and synthesis of data from the evidence base to formulate findings.
Upper urinary tract	The kidneys and ureters.
Ureter	The tubes carrying urine from each kidney down to the bladder.
Urethra	The tube that carries urine out of the body.
Urinary bladder	A hollow, muscular sac which stores urine.
Urinary retention	Inability to fully empty the bladder.
Vesicostomy	A vesicostomy is a surgically-created opening in the bladder.
Vesicostomy button	A silicone device which is surgically inserted in the lower abdomen and used to empty the bladder.

Yang-Monti conduit	Surgical technique used to create a continent catheterisable urinary diversion, primarily when the appendix is unavailable or unsuitable for a Mitrofanoff procedure. It involves reconfiguring a short segment of vascularised ileum (part of the small intestine) to create a narrow channel.

1 Introduction

1.1 Background to the request

Problems with storing urine and emptying the bladder can arise in children with particular health conditions. These include neurogenic bladder (where the nerves which control the urinary bladder and sphincter are damaged, for example due to spina bifida), posterior urethral valves (a congenital condition where tissue blocks the male urethra), prune belly syndrome (a rare condition which causes abnormalities in the urinary tract), and postoperative or temporary urinary retention (inability to fully empty the bladder).[1-3] If not managed promptly, children may develop urinary tract infections and damage to the upper urinary tract, including chronic kidney disease.[4, 5] Management options for urine storage and bladder emptying problems vary, depending on factors such as the severity of the condition, patient or caregiver's preferences and whether an option is feasible and safe due to an individual patient's anatomy.[6]

The main goals of bladder emptying are to:

- maintain low bladder pressure to prevent damage to the upper urinary tract
- minimise infections of the urinary tract
- prevent pain and discomfort
- manage urine leakage.[7]

The use of a vesicostomy button was proposed over 20 years ago, as early as 1996 as an alternative surgical management strategy for some children with urine storage and bladder emptying problems.[8] A vesicostomy is a surgically-created opening (known as a stoma) in the bladder. The vesicostomy button consists of a silicone device which uses a retained feeding tube (a soft tube usually placed in the stomach to allow for feeding), known as a gastrostomy button. The tube component of the vesicostomy button is placed into the vesicostomy to allow intermittent emptying of the bladder, without the need for a traditional catheter and catheter bag.[9, 10]

Initial scoping of the literature indicated that there are at least two devices currently being used in this way: the 'MiniONE®' (Applied Medical Technologies)[11] and the 'MIC-KEY®' (Avanos Medical).[12] Both of these devices are made from medical-grade silicone and are CE marked for the purposes of gastrostomy feeding (feeding through a surgical opening from the abdominal wall directly into the stomach), but not for urine storage and bladder emptying. CE marking is a declaration by a manufacturer that a product meets all of the relevant European Union requirements, for example, health, safety and environmental requirements. However, the use of

these devices in urine storage and bladder drainage is outside the manufacturers' intended purpose and instructions for use at present.[13-15]

Following a request from the Minister for Health, HIQA agreed to undertake a rapid Health Technology Assessment (HTA) of the use of vesicostomy buttons in children. This rapid HTA aims to identify and summarise the international evidence on the safety, effectiveness, and outcomes associated with the 'off-label' use of gastrostomy buttons as vesicostomy buttons in children. 'Off-label', in this context, refers to the use of medical devices outside the manufacturer's intended purpose or instructions for use.

1.2 Terms of reference

The terms of reference for the rapid HTA, agreed with the Department of Health, were to:

- describe common clinical indications for the use of vesicostomy buttons in children
- provide a description of the technology (vesicostomy buttons) to include a brief overview of the role of medical devices used for a clinical indication outside of their instructions for use, engagement with the relevant manufacturers and distributors and, where available, a brief overview of the guidance for the use of vesicostomy buttons internationally
- describe the clinical effectiveness and safety of vesicostomy buttons, including, where available, a comparison with the potential benefits and harms associated with the alternative management options (for example, traditional suprapubic catheters)
- provide advice to the Minister for Health, based on the evidence identified in this assessment.

1.3 Overall approach

Following an initial scoping of the available evidence, the terms of reference of this rapid HTA were agreed between HIQA and the Department of Health. HIQA appointed an Evaluation Team to carry out the assessment. HIQA convened an Expert Advisory Group (EAG) comprising representation from relevant stakeholders including: clinicians with specialist expertise in paediatrics and paediatric urology; the Health Products Regulatory Authority; experts in medical devices; an advocacy

group for people living with spina bifida and hydrocephalus and their carers and a patient safety organisation.

The role of the EAG is to inform and guide the process, provide expert advice and information, and to provide access to data where appropriate. A full list of the membership of the EAG is available in the acknowledgements section of this report. The Terms of Reference of the EAG are to:

- Contribute to the provision of high-quality research and considered advice by HIQA to the Minister for Health.
- Contribute to the work of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues, outside of group meetings as requested.
- Provide advice to HIQA regarding the scope of the report.
- Support the Evaluation Team during the process by providing expert opinion and access to pertinent data, as appropriate.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to HIQA's development of its approach to evidence synthesis by participating in an evaluation of the process on the conclusion of the project.
- Notify the project lead if a nominee can no longer participate or contribute to the process as non-participation may require alternative EAG membership to be sought.

The draft chapters on the description of the technology, epidemiology and burden of disease, and clinical effectiveness and safety were circulated to the EAG for discussion at the EAG meeting. Following the incorporation of feedback, a revised draft of the completed report, including the advice to the Minister for Health, was circulated for review by the EAG and amended, as appropriate. Following its approval by HIQA's Executive Management Team, the completed assessment was submitted to the Minister for Health as advice and published on the HIQA website.

2 Description of the technology

Key Points

- Urine storage and bladder emptying problems in children can be managed conservatively (for example with medicines) or via other non-surgical or surgical management options, depending on factors such as age, anatomy, bladder function and individual preference.
- Non-surgical management options include clean intermittent urinary catheterisation and indwelling urethral catheters.
    - Clean intermittent catheterisation (CIC) is the repeated insertion and removal of a small, flexible catheter several times daily to empty the bladder. It is the preferred long-term method when feasible, preserving bladder function and reducing infection risk.
    - Indwelling urethral catheters provide continuous drainage. Their use in children is generally limited to short-term perioperative (before, during or after an operation) management due to higher risk of infection and complications.
- Surgical management options are used in children when urethral catheterisation is not feasible, is poorly tolerated or would result in significant morbidity.
    - Suprapubic catheters are inserted percutaneously into the bladder via the abdominal wall, bypassing the urethra. They are typically used in cases of a sensate urethra, urethral injury or obstruction, or following complex bladder surgery, but carry procedural risks such as bleeding and bowel injury.
    - Vesicostomy refers to the surgical creation of a tract from the skin to the bladder (usually in the lower abdomen) to allow for bladder drainage or catheterisation. It may be performed as a temporary urinary diversion or as part of long-term bladder management and can be open or closed (using a vesicostomy button device).
    - Mitrofanoff continent urinary diversion is a major surgical procedure that creates a channel from the skin to the bladder which enables intermittent catheterisation while maintaining continence. It is considered for children who require long-term CIC but cannot use the urethra.
- Vesicostomy button devices are low-profile, medical-grade silicone devices (same material is used widely in urinary catheters) inserted through the abdominal wall into the bladder to create a channel, allowing for intermittent

urine drainage without the need for a long external catheter and a catheter bag. They are primarily used as a temporary solution in children who cannot reliably perform CIC, serving as a bridge to future definitive bladder management or reconstructive surgery.

- The vesicostomy button is a modified version of the gastrostomy button, originally designed for enteral feeding, that has been repurposed for urinary use. First described for bladder emptying in 1996, it has since gained wider adoption in paediatric urology. Two CE marked devices are currently in use, the MiniONE® (Applied Medical Technologies) and MIC-KEY® (Avanos Medical); in both cases they are being used 'off-label' for this indication. The manufacturers and distributor of these devices were offered the opportunity to provide a factual accuracy check and to share their perspectives on the use of their device as a vesicostomy button in children. They reiterated that the use of these devices in this manner is 'off-label'.
- Compared to a 'standard' catheter, which has longer tubing and a catheter bag on the outside of the body, the vesicostomy button is small and can easily be hidden under clothes and allows children to participate more comfortably in everyday activities, including sports and swimming.
- While the use of the button device in this manner is considered 'off-label', it is not contraindicated. The devices are manufactured from medical-grade silicone, a biocompatible material that is widely used in urinary catheters and other devices designed for the urinary tract, reflecting material compatibility across gastrointestinal and urinary applications.
- Clinicians within certain paediatric specialities often rely on the use of medical devices outside the manufacturer's intended purpose or instructions for use ('off-label') due to the relative scarcity of approved paediatric options. While the Medical Device Regulation 2017/745 obliges manufacturers to monitor systematic off-label use, the available data are typically low quality. Generating the robust clinical evidence needed to formally expand indications is often impractical in rare paediatric conditions, limiting evidence-based conclusions on safety and effectiveness.
- Any 'off-label' use of medical devices merits consideration of controlled risk management processes, clear governance structures and fully informed consent in accordance with legislation and the best available evidence. Patient and carer information leaflets should provide accessible information to support safe and effective care and a clear explanation of what 'off-label' means in this context.

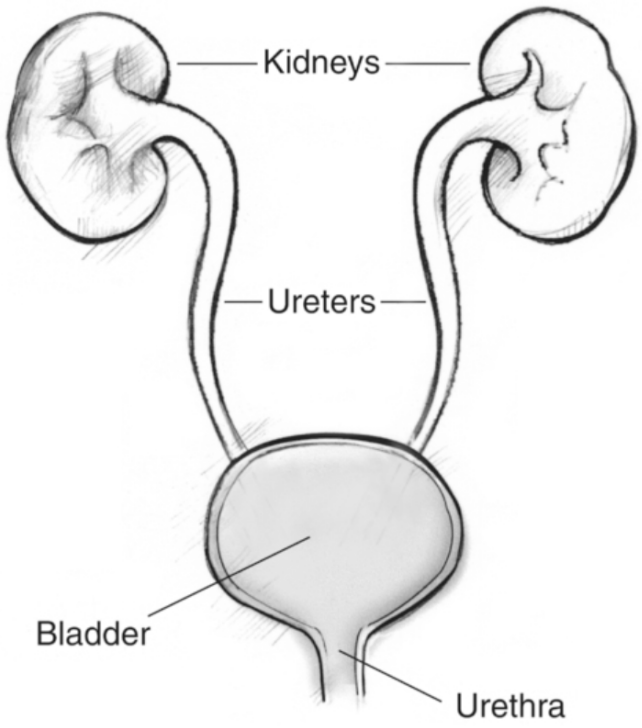
- Four clinical guidelines from German, Canadian, European and International organisations, plus one expert consensus statement, were identified that specifically mentioned the use of vesicostomy buttons in children. Each of these note that vesicostomy buttons may be used as a management option for patients with urine storage and bladder emptying problems.

2.1 Introduction

The purpose of this section is to describe the use of vesicostomy buttons for urine storage and bladder drainage in children. This section also briefly outlines selected alternative non-surgical and surgical management options. However, it should be noted that children with urine storage and bladder emptying problems may also receive other treatments as part of a comprehensive management pathway. Medicines, including anticholinergic agents, are widely used to optimise bladder storage and emptying and may be employed prior to, alongside, or in place of more invasive interventions.[16] Anticholinergic agents block a chemical that signals the body to relax and, for example, to pass urine.[17]

The urinary system (also known as the urinary tract) includes the kidneys, ureters, bladder and urethra.[18] The kidneys and ureters are known as the 'upper urinary tract', while the bladder and urethra are called the 'lower urinary tract'.[18] The kidneys filter waste products and extra fluid from the blood to produce urine, which then drains through the ureters into the bladder. The bladder is a muscular sac that expands as it fills with urine. At the outlet of the bladder is a sphincter, a ring of muscle that opens and closes to control the flow of urine. As the bladder fills, it sends signals through nerves to the brain to indicate fullness. Under normal circumstances, the bladder empties when nerve signals coordinate contraction of the bladder muscle with relaxation of the sphincter, allowing urine to drain fully and remain at low pressure, helping to protect the kidneys. When the nerve signals that control bladder filling and emptying are disrupted by congenital or acquired neurological conditions, this is referred to as neurogenic bladder.[19] Figure 1 provides a simple illustration of the urinary tract.

Figure 1: Simplified illustration of the urinary tract



Source: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health[20]

To facilitate understanding, a brief description of selected non-surgical and surgical management options for urine storage and bladder emptying problems is provided in Sections 2.2 and 2.3. Section 2.4 details the technical characteristics of two known gastrostomy buttons used as vesicostomy buttons for bladder drainage (that is, the MiniOne® and the MIC-KEY®) and the logistical considerations associated with their use. Regulatory considerations relevant to the use of vesicostomy buttons are outlined in Section 2.5. The use of vesicostomy buttons internationally, as identified from clinical guidelines, is summarised in Section 2.6.

Non-surgical management options for urine storage and bladder emptying problems include catheterisation via the native urethra. Intermittent catheterisation is generally used for medium- to long-term bladder management, whereas indwelling catheterisation is typically used on a short-term basis. Surgical management options include suprapubic catheterisation and surgical urinary diversion procedures, which involve the creation of alternative access routes or channels to the bladder through surgical procedures.[21, 22]

Surgical management options are typically reserved for children requiring a long-term solution for urine storage and bladder emptying problems or when less invasive options are not feasible. Ultimately, the choice of technique depends on the clinical diagnosis, anatomical considerations, and the child's capacity for self-management.[12] There are advantages and limitations associated with each

management option, including the preference of the child and or caregiver.[23] Table 1 below provides an overview of the main purported benefits and considerations for these management options, which are explained further in the below sections.

Table 1: Overview of the considerations for different bladder drainage techniques in children

Technique	Purpose	Main purported benefits	Considerations	Patient Characteristics/ Indication
Non-surgical management options				
Clean intermittent catheterisation (CIC)	Periodic bladder drainage via urethra or stoma; generally used for long-term management	Minimally invasive; low infection rate; promotes independence; minimal interference with day-to-day activity	Requires manual dexterity or caregiver support; adherence is essential; risk of urethral trauma	Children/adolescents able to perform CIC or with assistance from trained caregivers
Indwelling catheterisation	Continuous bladder drainage via urethra; used for short-term/ temporary periods	Useful for perioperative or acute retention; minimally invasive technique	Higher risk of infection & complications; patient discomfort; not suitable for long-term use	Short-term hospital/ acute management, perioperative patients
Surgical management options				
Suprapubic catheterisation	Continuous drainage through percutaneous tract; can be for temporary- or long-term use	Useful when urethral access not possible; avoids urethral trauma	Stoma care required; risk of infection over time; moderately invasive technique; patient comfort affected by external tubing	Children/ adolescents with urethral trauma or obstruction
Open vesicostomy	Continuous drainage via abdominal stoma; for temporary- or medium-term management	Protects upper urinary tract; reversible	Incontinent urinary diversion; stoma care required; risk of infection; patient discomfort & inconvenience; moderately invasive	Children (including infants) with poor urine storage and bladder emptying, recurrent UTIs, failed CIC

Technique	Purpose	Main purported benefits	Considerations	Patient Characteristics/ Indication
Closed vesicostomy with button device	Catheterisable drainage via abdominal stoma; typically used as a temporary measure	Protects upper urinary tract; intermittent or continuous drainage; discreet low profile; better comfort and quality of life relative to incontinent options, facilitates continence development/ toilet training	Stoma care required; risk of infection; possible leakage; moderately invasive	Children (including infants) with poor urine storage and bladder emptying, recurrent UTIs, failed CIC
Mitrofanoff continent catheterisable channel	Continent catheterisable urinary diversion via surgical stoma; intended for long-term management	Improved bladder management, preservation of upper tract function, improved independence without indwelling catheters	Invasive procedure with surgical risks; potential for stomal complications (stricture, leak, infection, or mucosal prolapse); requires regular catheterisation	Children/adolescents requiring long-term CIC who cannot access the urethra

Key: CIC – clean intermittent catheterisation; UTI – urinary tract infection

Adapted from Canadian Urological Association/Pediatric Urologists of Canada guideline[24]

2.2 Non-surgical management options

Non-surgical management options include intermittent urinary catheterisation and indwelling urethral catheters. Urethral catheterisation involves placing a flexible tube through the native urethra into the bladder for urine drainage or diagnostic purposes. Catheters may be inserted intermittently (that is, inserted then removed each time the bladder requires emptying), or indwelling (that is, left in place, either short-term or long-term).[25]

Intermittent urinary catheterisation, also known as clean intermittent catheterisation (CIC), is the repeated insertion and removal of a small, flexible catheter several times daily to empty the bladder.[26] CIC is the preferred long-term bladder drainage

strategy, when feasible, for children with incomplete bladder emptying or neurogenic bladder. It is recommended early to protect upper tracts in many congenital neurogenic bladder protocols, and practice guidelines favour intermittent catheterisation over indwelling devices where possible, to reduce the risk of infection and other complications.[16, 27, 28] Compared with indwelling catheters, CIC reduces the risk of catheter-associated urinary tract infections and other long-term complications, while preserving bladder physiology.[29-31] However, the technique does require patient dexterity or caregiver assistance, and repeated urethral catheter insertion can potentially cause urethral trauma.[12] In addition, adherence to the catheterisation schedule can be challenging and the procedure may have a psychological impact on some children or may not be the preferred option for the child and or their caregivers.[10, 32, 33]

Indwelling urethral catheters (often termed Foley catheters) provide continuous bladder drainage via a retention balloon and a closed collection system.[34] Their use in children is generally limited to short-term perioperative management, acute urinary retention, or situations requiring precise urine output monitoring.[35] Indwelling catheters require regular assessment of ongoing need, catheter site inspection, and monitoring of urine output and signs of infection.[36] Although indwelling catheters offer reliable continuous bladder drainage, they carry increased risk of urinary tract infections, urethral trauma, bladder spasms, catheter encrustation, and patient discomfort.[25] Therefore prolonged use of indwelling catheters is generally avoided if CIC is a practical option.

Overall, CIC is the least invasive and preferred long-term management option for urine storage and bladder emptying problems in children.[33, 37] However, in cases where CIC is not possible due to anatomical or functional barriers, alternative methods must be used.[11, 37, 38]

2.3 Surgical management options

Surgical management options are typically considered in children for whom native urethral catheterisation is not feasible, is poorly tolerated, or would result in significant morbidity. These procedures create either non-continent stomas (allowing continuous drainage) or continent catheterisable channels (enabling intermittent catheterisation while maintaining continence between catheterisations).[21, 22, 27, 39]

Suprapubic catheter

A suprapubic catheter is a tube inserted percutaneously directly into the bladder through a small incision in the lower abdominal wall, usually while a patient is under general anaesthesia, secured externally and used for continuous bladder drainage.[40] Suprapubic catheters bypass the urethra and are an alternative when

native urethral catheterisation is not possible or contraindicated. They are typically used in cases of a sensate urethra, urethral injury or obstruction, or following complex bladder surgery, but carry procedural risks such as bleeding and bowel injury.[41] Other limitations include the risk of site infection and the need for a planned catheter exchange schedule.[40]

Vesicostomy

Vesicostomy refers to the surgical creation of a tract from the skin to the bladder (usually in the lower abdomen) to allow for bladder drainage or catheterisation, usually while a patient is under general anaesthetic. It may be performed as a temporary urinary diversion or as part of long-term bladder management.[21] Vesicostomy provides reliable bladder decompression while bypassing the native urethra, making it suitable for children with urethral anomalies, trauma, or severe neurogenic dysfunction.[33]

The most common vesicostomy procedure in children was originally described by Blocksom in the 1960s and modified by Duckett.[42] It is most commonly used as a temporary diversion in infants and young children with neurogenic bladder or posterior urethral valves, particularly when intermittent catheterisation is not practical.[43] Vesicostomy offers bladder drainage which protects the upper urinary tract, and is generally performed until a more permanent solution, such as a Mitrofanoff channel,[44] can be arranged.[45] When no longer required, the vesicostomy can typically be closed with minimal intervention, allowing the child to progress to definitive bladder management.[38] A vesicostomy can be open (where the urine freely flows into a nappy or incontinence product) or closed (where a vesicostomy button device is inserted at the stoma and the bladder is intermittently drained). The main advantage of the closed versus the open vesicostomy is the improved social acceptability, because the device offers a continent management option as well as being low-profile and discrete.[38]

Mitrofanoff urinary diversion

Mitrofanoff continent urinary diversion is a major surgical procedure that creates a continent catheterisable channel from the skin to the bladder, most commonly using the appendix, in a procedure called appendicovesicostomy.[21, 46] The channel is implanted into the bladder with an anti-reflux mechanism to achieve continence, and is brought out to the skin, typically at the umbilicus or lower abdominal wall. The channel allows clean intermittent catheterisation while maintaining continence between catheterisations.[21] This procedure, which is carried out under general anaesthesia, is usually considered for children who require long-term CIC but cannot use the urethra due to anatomical complexity, severe neurogenic bladder, or previous reconstructive surgery. While it can improve quality of life and continence,

the Mitrofanoff channel requires lifelong catheterisation and carries risks of complications such as bowel obstruction, stoma leakage, bleeding, stenosis (the narrowing or blockage of the Mitrofanoff channel), and the possibility of further surgery if problems occur.[12]

2.4 Vesicostomy button devices (closed vesicostomy)

Vesicostomy button devices, also known as cystostomy button devices, are minimally invasive solutions that offer a hybrid approach between catheter-based bladder drainage and surgical urinary diversion techniques. The vesicostomy button is a low-profile catheter that passes from outside into the bladder via a surgically-created stoma (opening) through the abdominal wall. This allows for intermittent drainage, without the need for a long external catheter.[38] This device is primarily employed as a temporary measure in children who cannot reliably perform CIC, serving as a bridge to future management options, including more definitive reconstructive procedures or continence surgery.[38] However, in selected cases such as children with cerebral palsy or with associated co-morbidities, the vesicostomy button can be considered as a long term solution.

The vesicostomy button device is a modified version of the gastrostomy button; it was first described for bladder emptying in 1996[8] and subsequently adopted more widely in paediatric urology, apparently in the off-label setting.[11, 38] Originally designed for enteral feeding (feeding into the stomach), these low-profile devices have been repurposed for urinary use.[10] The devices are manufactured from medical-grade silicone, a biocompatible material that is widely used in urinary catheters and other devices designed for the urinary tract, reflecting material compatibility across gastrointestinal and urinary applications.[25] They feature a short, soft stem that sits flush with the skin, an internal balloon or retention bolster for secure placement, and a capped port that remains closed between use.[47] The low-profile design allows the external bolster to lie flat against the skin surface, creating a discreet profile that can be easily concealed under clothing. Urine is drained from the bladder by connecting an adapter and 'extension set'.[15] The one-way valve and safety plug allow the button to remain closed between drainage episodes, preventing leakage while allowing easy intermittent use.

Vesicostomy button devices are sized according to two parameters, the catheter diameter measured in French (Fr) units[1], and the stem length, corresponding to the distance between the skin surface and bladder lumen through the abdominal wall.(49) In paediatric vesicostomy practice, buttons of size 12 to 18 Fr are most commonly used, though devices are available in sizes ranging from 12 to 24 Fr.(10, 37, 38, 50) The stem length (usually 0.8 to 5.0 cm) corresponds to the thickness of the abdominal wall from skin surface to bladder mucosa. Measurement is typically performed intraoperatively using a button measuring device or sizing tool ('off-label' in this context) supplied by the manufacturer.(14, 47) Accurate measurement is important to ensure that the retention balloon or bolster sits securely within the bladder while the external button lies flush with the skin.

In paediatric practice, commonly used vesicostomy button devices include the MiniONE® (Applied Medical Technologies) and MIC-KEY® (Avanos Medical). Both devices are CE marked for the purposes of enteral feeding, therefore, in both cases they are being used 'off-label' for the purpose of bladder emptying. While they are being used 'off-label' for this indication, use in the bladder or vesicostomy setting is not specifically listed as a contraindication for either device. The devices are typically supplied as part of kits that include necessary extension sets and adapters for feeding and drainage.(14, 47) Earlier clinical series reported the use of Bard gastrostomy button devices,(8) however these are older devices that have been superseded by MiniONE® and MIC-KEY® devices.(12, 37, 38)

The MiniONE® family of low-profile devices (Applied Medical Technology, AMT) includes balloon-retained, non-balloon, and capsule non-balloon variants, available for children and adults. The MiniONE® Balloon Button utilises an internal retention balloon with an apple-shaped configuration to secure the device within the tract. The balloon can be inflated or deflated for insertion or removal. The MiniONE® Non-Balloon and Capsule Non-Balloon devices employ a mushroom-shaped internal retention bolster to maintain position within the tract.(47)

Both the MiniOne® and MIC-KEY® devices are available on the market as part of 'kits' for feeding in the gastrostomy setting (Table 2), but the complete kits are also

[1] Fr (French) refers to the Charrière scale, which is a historic unit used for measuring the outer diameter of medical instruments or catheters. 1Fr=1/3 millimetre. 48. Mansaki D. Urology Textbook, Surgical Management: Bladder Catheter: [Available from: https://www.urology-textbook.com/bladder-catheter.html.

used to achieve urine storage and bladder drainage when used off-label in the vesicostomy setting.

Table 2: Overview of button device kits

Component	MiniONE® Balloon Button Kit Specification	MIC-KEY® Gastrostomy Tube Kit Specification
Low-profile button/tube	Apple-shaped internal balloon, soft, medical grade silicone. Available in 12-24 Fr size with various stem lengths (0.8-10.0 cm).	Medical grade silicone, internal retention balloon. Available in various Fr sizes with adjustable stem lengths.
Bolus extension set	Yes (straight connector; Legacy or ENFit®)	Yes (2-inch Blue Cath Tip, SECUR-LOK® straight connector, clamp)
Continuous/ Y-port extension set	Yes (right-angle connector; Legacy or ENFit®)	Yes (12-inch extension set, SECUR-LOK® right angle connector, 2-port "Y" clamp)
Balloon syringe	Yes (5 ml/10ml balloon syringe depending on device size)	Yes (6 ml Luer-slip syringe)
Bolus feeding syringe	Yes (35 ml catheter tip syringe)	Yes (35 ml tip syringe)
Water-soluble lubricant	Yes	Yes
Gauze pads	Yes	Yes
Patient information/resources	Yes (instructions, care guide but not for the vesicostomy setting)	Yes (instructions, care guide but not for the vesicostomy setting)
Clinical indications, per instructions for use	Gastrostomy feeding	Gastrostomy feeding

2.4.1 Button placement

Vesicostomy button devices can be inserted using three possible techniques: open surgical placement, endoscopic or percutaneous insertion, or placement into an established tract.[11, 38, 51] The choice of technique is influenced by patient anatomy, previous surgery, bladder compliance, subcutaneous tissue thickness, and surgeon preference.[12] Surgical techniques have evolved over time, with refinements such as the routine use of purse-string sutures and bladder anchoring now incorporated to

improve device stability and reduce peristomal leakage, compared with earlier approaches.[11, 52] Perioperative antibiotic prophylaxis is typically administered regardless of technique, and device sizing is guided by tract-length measurement.[38]

The open technique represents the traditional method for primary button placement.[52] However, for suitably selected patients, the endoscopic or percutaneous approach is less invasive and may reduce recovery times. Endoscopic insertion of a vesicostomy button was first described by Haider and Subramaniam in 2008, who reported cystoscopy-guided percutaneous placement for bladder drainage in children.[52] Both the open technique and the endoscopic or percutaneous approach are carried out while the child is under general anaesthesia. The endoscopic or percutaneous approach is particularly suited to patients with thin abdominal walls, previous abdominal incisions, or when an open field is contraindicated.

In children with a pre-existing vesicostomy or suprapubic tract, button placement can be achieved by tract dilation followed by direct device insertion.[11, 38] Placement into established tracts allows occlusion and controlled assessment of bladder function, but some predictable leakage is common, particularly in recently formed or wide tracts.[11, 38]

2.4.2 Button aftercare and closure

Immediately post-operatively, the button is left on continuous drainage for 24 to 48 hours to allow tract maturation (that is, to ensure the path created by the tube becomes stable and functional) and reduce leakage.[10, 11] An intermittent drainage routine is subsequently established, using the device's extension tubing for bladder emptying at prescribed intervals.

Parents or carers receive education on routine device aftercare to support safe use and minimise complications. Training typically includes instructions on hand hygiene, correct connection and disconnection of drainage sets, and routine cleaning of the button device and surrounding skin in accordance with local clinical protocols.[10, 11] Daily care includes gentle cleansing of the peristomal skin (the area around the opening), regular inspection for erythema (redness), leakage, or granulation tissue (when new tissue and small blood vessels form around the base of a wound; this may prevent normal healing), and secure capping of the device between catheterisations.[15]

It is recommended that balloon volume is checked to maintain the recommended fill pressure and ensure secure positioning. The parent or carer is given guidance on how to recognise signs and symptoms of infection or blockage and advised on when and how to seek medical help if these occur, for example should the device be dislodged.[15] Device replacement intervals vary but typically occur every three

months, or earlier if there are signs of malfunction, leakage, or infection. Device replacement may be performed at home by trained parents or caregivers, often following a proficiency assessment to ensure safe handling, or in a clinic setting by a specialist nurse if closer monitoring or intervention is required.[15] In children, periodic reassessment of tract length and upsizing of button dimensions may be required to accommodate growth.

When a vesicostomy button is no longer required due to improved bladder function (including spontaneous voiding or successful transition to CIC), or progression to definitive surgical management, the device can be removed. In some cases, the vesicostomy tract may close spontaneously after removal.[10] Alternatively, elective closure can be performed, or the tract may be closed at the time of other reconstructive surgery, such as Mitrofanoff formation.[10]

2.5 Regulatory aspects of vesicostomy buttons

The MiniOne® and MIC-KEY® gastrostomy devices can form part of a 'kit' composed of several medical devices ranging from Class I low risk devices to class IIb invasive devices.[13, 14] The 'class' refers to the risk classifications of medical devices ranging from class I to class III devices under the European Union (EU) Medical Device Regulation (MDR) 2017/745,[53] with Class I representing the lowest risk.[54] The risk class of a device will determine its performance and safety requirements, as well as its route to market.

The instructions for use and marketing material associated with the MiniOne® and MIC-KEY® gastrostomy buttons indicate that they are intended to be used in both adults and children, within their specified intended purpose as a gastrostomy button.

Within certain paediatric specialities, clinicians often rely on the use of medical devices outside the manufacturer's intended purpose or instructions for use.[53] This is sometimes referred to as 'off-label' use.[55, 56] The need to use a device 'off-label' is often due to the relative scarcity of devices that are specifically CE-marked for that purpose in paediatric populations.[57, 58] However, the prevalence of 'off-label' use is not well characterised.[59] An additional challenge associated with the use of medical devices in children is the risk of withdrawal from the market of devices intended for rare conditions. This may be due to a range of reasons including the time and costs associated with the increased regulatory requirements arising from the MDR 2017/745.[53]

In general, MDR 2017/745 does not regulate the use (or 'off-label' use) of a device by a healthcare professional.[60] However, the MDR requires manufacturers to identify systematic misuse or 'off-label' use of devices with a view to verifying that the intended purpose of the device is correct.[56, 61] However, these data are

collected through post-market clinical follow up and are typically considered to represent low-quality levels of evidence and equivalent to that of case studies. The lack of sufficient-quality data arising from 'off-label' use outside of controlled protocols ultimately limits the ability to draw evidence-based conclusions about the effectiveness and safety of these devices. Expanding the manufacturer's original intended purpose to include additional clinical indications may instead necessitate costly clinical investigations (research studies) in order to verify their safety and effectiveness. This is a challenge particularly in rare conditions of unmet medical need, where clinical investigations may not be feasible for a number of reasons, including the limited availability of eligible participants.[62, 63]

Furthermore, the Medical Device Coordination Group, an expert advisory body established under the EU's Medical Device Regulation, acknowledges that in some circumstances the off-label use of a device might be well established and accepted by the clinical community as standard clinical practice that offers clinical benefit above available alternatives. In such cases, there may be a lack of equipoise (a lack of genuine uncertainty about the benefit of a treatment) meaning it may not be appropriate or necessary to carry out such a clinical investigation (trial). The Medical Device Coordination Group acknowledges that, in some circumstances, clinical data from 'off-label' use may be considered acceptable to support the expansion of a device's intended purpose.[64] However, cost and effort may be prohibitive factors to manufacturers pursuing clinical evaluation and notified body assessment[2] in order to expand the use of devices, particularly when the instances of 'off-label' use are low or limited to a select number of patients.[63]

The manufacturers and distributor of these devices were offered the opportunity to provide a factual accuracy check and to share their perspectives on the use of their device as a vesicostomy button in children.

Avanos Medical have noted in correspondences with HIQA that the use of their MIC-KEY® devices for vesicostomy or bladder drainage represents use outside the device's intended purpose and instructions for use. They noted that MIC-KEY®

[2] For certain classes of devices, manufactures are required to obtain a CE certificate from a notified body prior to CE marking their devices and placing them on the market. The notified body assessment generally assesses the conformity of the products to the applicable EU requirements. CE marking is a declaration by a manufacturer that a product meets all of the relevant European Union requirements, for example, health, safety and environmental requirements.

devices have not been evaluated for bladder drainage, vesicostomy performance, or urinary system exposure.

Technopath have noted in correspondence with HIQA that they do not market the MiniOne® device as a vesicostomy button.

HIQA also contacted Applied Medical Technologies requesting a factual accuracy check and to provide their perspective on the use of the MiniONE® device as a vesicostomy button. However, no formal response has been received by HIQA.

HIQA also requested any available post-marketing safety information related to the use of these devices in the 'off-label' setting that may have been reported to Avanos Medical, Applied Medical Technologies and Technopath. Only one complaint was noted by Avanos Medical which stated that during a vesicostomy procedure a dye was injected for visualisation, and the urinary tract took on a blueish hue. The manufacturer stated that the button apparatus was not the cause of the issue, but was used during the event, and no patient harm was reported. Applied Medical Technologies did not provide a response to this query.

2.6 International practice

A search of the grey literature (as described in Section 4.2 and Appendix A) identified a limited number of records which specifically mentioned the use of vesicostomy buttons in children. These comprised four clinical guidelines and one expert consensus statement. Two of the clinical guidelines were published by German[16] and Canadian[24] organisations respectively, while the other two clinical guidelines were from European[65] and international organisations.[66] The expert consensus statement was published on behalf of a group of international experts from France, Italy, the Netherlands, Spain and UK.[67] Each of these five documents note that vesicostomy buttons may be used as a management option for patients with urine storage and bladder emptying problems. A brief commentary was also provided on the complications typically associated with the use of vesicostomy buttons, with the four clinical guidelines all drawing on the same study by Mosiello et al.[12], which reported an overall complication rate of up to 34% over a mean follow-up of 37 months, most commonly urinary tract infections (UTIs). However, no clear criteria were provided regarding which groups of patients are likely to benefit from the use of vesicostomy buttons.

3 Epidemiology and burden of the disease

Key Points

- A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. However, these conditions are generally rare or uncommon. This chapter describes the epidemiology and burden of disease, focusing on three key paediatric conditions that commonly lead to these bladder problems requiring surgical urinary diversion: neurogenic bladder (predominantly due to congenital or acquired neurologic disorders), anorectal malformations and posterior urethral valves.
- Children with these bladder problems are at an increased risk of complications including recurrent urinary tract infections, urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage. For a subset of these patients, surgical urinary intervention is required to prevent significant long-term clinical consequences.
- 'Neurogenic bladder' refers to a disruption in normal bladder, bladder neck, or urinary sphincter function that arises from any disorder of the nervous system. Neurogenic bladder in children is most commonly caused by congenital neural tube defects, particularly spinal dysraphism, including spina bifida, with myelomeningocele representing the most severe and clinically significant form.
- Children with neurogenic bladder often present with urgency, incontinence, or difficulty voiding. Long-term management focuses on protecting kidney function, improving continence where possible, and supporting independence.
- In Ireland, neural tube defects occur at rate of 10-11 per 10,000 of total births, of which spina bifida is the most common form. According to a report published in 2014, approximately 40 new cases of spina bifida are identified annually in Ireland, and a high proportion of affected children (around 80-90%) experience bladder problems.
- Anorectal malformations are rare congenital conditions, with a birth prevalence of approximately one in 2,500 to 5,000 live births in Europe and include a wide spectrum of severity. Although anorectal malformations are uncommon, they are clinically significant and are frequently associated with lower urinary tract dysfunction, including neurogenic bladder in around 25% of cases. Despite their low prevalence, anorectal malformations carry a substantial long-term disease burden with many children requiring ongoing bladder management.
- Posterior urethral valves are a rare congenital condition occurring exclusively in boys, with an estimated incidence in the UK and Ireland of one in 4,000 to 5,000 live male births. Posterior urethral valves are the most common cause of

congenital lower urinary tract obstruction in boys. This often leads to lifelong complications, including bladder dysfunction, which requires intervention in up to 40% of cases, and progressive renal impairment, with around one third of affected boys developing end-stage renal disease.

- From 2018 to 2026, a total of 26 vesicostomy buttons were placed in patients at Children's Health Ireland (CHI) hospitals. This means that between two and four vesicostomy buttons have been placed each year for the past six years for a variety of indications. The clinical indication for placement of vesicostomy buttons varied but was consistent with the clinical indications described in the case series reported in Chapter Four.

3.1 Introduction

A wide variety of complex clinical conditions can result in problems with urine storage and bladder emptying in children. In this section, the epidemiology and burden of disease will be described with a focus on three key paediatric conditions that commonly lead to urine storage and bladder emptying problems requiring surgical urinary diversion: neurogenic bladder (predominantly due to congenital or acquired neurologic disorders), anorectal malformations and posterior urethral valves.[24, 68, 69] These conditions represent major congenital and developmental causes of complex bladder emptying problems in childhood and account for a substantial proportion of patients considered for vesicostomy button placement.

3.2 Neurogenic bladder

Neurogenic lower urinary tract dysfunction, commonly termed neurogenic bladder, refers to a disruption in normal bladder, bladder neck, or urinary sphincter function that arises from any disorder of the nervous system.[24] Neurogenic bladder in children most commonly results from congenital defects of the neural tube (a tube-like structure which forms during the early development of the embryo), collectively termed spinal dysraphism.[24] Spinal dysraphism is an umbrella term for a wide spectrum of congenital neural tube defects resulting from incomplete closure of the spinal column and overlying tissues during early foetal development. Spina bifida is one of the most common forms of spinal dysraphism and includes several subtypes (spina bifida occulta, meningocele, and myelomeningocele).[7] Myelomeningocele represents the most severe and clinically significant type of spina bifida, in which the spinal cord, nerves, and meninges protrude through an opening in the spine.

Overall spinal dysraphism is the predominant cause of neurogenic bladder in children, with open forms such as myelomeningocele making up the large majority of cases, closed or "occult" spinal defects accounting for a smaller share, and other neurological conditions (including sacral agenesis, spinal cord injury, cerebral palsy, and tumours or prior spinal surgery), together responsible for a small minority.[7, 70]

Children with neurogenic bladder are at increased risk of recurrent urinary tract infections (UTIs), urinary incontinence and increasing dilatation of the ureters and renal pelvis, leading to progressive kidney damage.[24] Symptoms occur during both the storage and voiding phases of urination. These include urgency, frequency and incontinence during storage; and hesitancy, incomplete emptying, retention, or overflow during voiding; all of which can heighten infection risk and long-term bladder or kidney harm. Long-term management therefore focuses on preserving renal function, achieving urinary continence, and maximising independence, as appropriate.[71] The European Association of Urology guidelines recognise vesicostomy as a management option for neurogenic bladder when clean intermittent catheterisation (CIC) is not feasible (weak recommendation, expert opinion). In carefully selected cases, vesicostomy buttons may be used within this management framework.[16, 28]

Recent data indicate that congenital neural tube defects occur at an estimated global average of approximately 20 per 10,000 births.[72] In Europe, large registry studies reported a prevalence of around nine neural tube defects per 10,000 total births between 1991 and 2011, [73] while more recent surveillance in England indicates rates of approximately 12-13 per 10,000 total births between 2010 and 2019.[73] In Canada the estimated prevalence is lower at around 4-5 per 10,000 total births.[24]

In Ireland, neural tube defects occur at rate of 10-11 per 10,000 of total births,[74] of which spina bifida is the most common form.[75] According to a report published in 2014, approximately 40 new cases are identified annually in Ireland, with over 500 affected children aged 0-18 years requiring lifelong multidisciplinary care.[75] The report included survey data from 139 children aged 0-18 years, representing approximately 25-30% of the estimated national population of children with spina bifida. Of these, 84% of children needed interventions for bladder and bowel support, rising to 93% among school-aged children (that is, children over five years). Among the 84% who required intervention, 20% used prophylactic antibiotics, 38% performed CIC and 6% had undergone bladder or bowel surgery. Additionally, 59% used incontinence products. According to the report, the high prevalence of incontinence can have a significant impact on the child and family in terms of dependence and psychological wellbeing. Early urological assessment, ongoing surveillance and timely bladder management interventions are recommended to protect renal function and support continence.[75]

3.3 Anorectal malformations

In the European Union, rare diseases are defined as conditions that affect fewer than one in 2,000 people; as such, anorectal malformations fall within this category.[76] Anorectal malformations are congenital conditions in which the rectum, anal canal, and surrounding sphincter muscles do not develop or connect to the skin

in the usual way, sometimes ending blindly or opening via fistulae into the urinary or genital tract.[68] Cloacal malformations represent the most complex end of this spectrum in girls, where the rectum, vagina, and urethra share a single common channel. These conditions are rare but clinically significant causes of lower urinary tract dysfunction in childhood and are frequently associated with neurogenic bladder or outlet obstruction requiring specialised bladder drainage strategies.[77] Children with anorectal malformations can present with a broad range of urological abnormalities, with prevalence generally increasing with the severity of the malformation. Urological management is therefore important for children with anorectal malformations, as chronic kidney disease and end-stage renal disease are the main contributors to reduced life expectancy in this population.[77]

Registry data collected by the European Anorectal Malformation Network (ARM-NET) consortium indicate that anorectal malformations have a birth prevalence of around one in 2,500 to 5,000 live births.[68, 77] Within this spectrum, cloacal malformations occur in approximately one in 50,000 births and account for about 10% of all anorectal malformation cases.[78] In the UK and Ireland, contemporary incidence estimates are derived from the British Association of Paediatric Surgeons Congenital Anomaly Surveillance System (BAPS-CASS), which collects clinician-reported case ascertainment of rare surgical conditions in participating paediatric surgical units. Recent estimates from a 2024 report using BAPS-CASS data (2015-2016), indicate an incidence of around one in 5,000 live births in the UK and Ireland, which is comparable with European estimates.[68] For cloacal anomalies and complex urogenital malformations, UK and Irish numbers are very small each year, which is also consistent with the low prevalence reported in European series.

Despite their low birth prevalence, anorectal and urogenital malformations carry a substantial long-term disease burden.[77] Data from ARM-Net centres document frequent hospitalisations in the first years of life, high rates of surgery for complications such as strictures or prolapse, and a persistent need for bowel management programmes, bladder drainage strategies, and continence support.[77] From a bladder-management perspective, these anomalies create a spectrum of lower-urinary tract dysfunction ranging from mild sphincter impairment to severe neurogenic bladder and outlet obstruction. It is estimated that approximately 25% of children with anorectal malformations develop bladder problems consistent with neurogenic bladder, particularly those with complex malformations or associated spinal/sacral anomalies, requiring active bladder management (such as CIC or surgical urinary diversion).[79] The European Association of Urology guidelines recognise the increased risk of neurogenic bladder in children with anorectal malformations and recommend urodynamic assessment, noting vesicostomy as a management option under neurogenic bladder guidance.[16, 28] Long-term follow-up studies emphasise that bladder issues often persist into adolescence and adulthood,

necessitating ongoing surveillance and multidisciplinary care to minimise urinary incontinence, recurrent UTIs, and progressive kidney damage.[80]

3.4 Posterior urethral valves

Posterior urethral valves (PUV) are congenital obstructing folds in the posterior urethra that occur exclusively in boys. Posterior urethral valves are classified as a rare disease, with international series reporting an incidence of approximately one in 8,000 live born males, although rates vary by region and by ascertainment method.[81] In the UK and Ireland, data from the British Association of Paediatric Surgeons Congenital Anomaly Surveillance System (BAPS CASS) indicate an incidence of approximately one in 4,000–5,000 live male births.[82] Posterior urethral valves are the most common cause of congenital lower urinary tract obstruction in boys and can impose a significant lifelong disease burden. Most boys with posterior urethral valves develop some form of bladder dysfunction, with up to 40% requiring intervention such as anticholinergics or CIC to facilitate bladder management.[69] The condition can lead to varying degrees of lower urinary tract obstruction, which can result in high-pressure voiding, recurrent UTIs, bladder dysfunction, and progressive renal impairment, ranging from mild renal scarring to end stage kidney disease. It is estimated that one-third of boys born with posterior urethral valves will progress to end-stage renal disease and require dialysis or renal transplant.[69]

The choice of treatment is influenced by multiple factors and can vary depending on healthcare setting. The primary aim is to relieve pressure on the bladder and kidneys. Valve ablation is the standard initial treatment, aimed at relieving obstruction, typically performed endoscopically once the child is of sufficient size and clinical suitability.[83] The European Association of Urology guidelines recommend temporary urinary diversion, most commonly vesicostomy, in infants who are too small for safe endoscopic surgery, in those whom valve ablation is not effective, or when renal function and bladder pressures do not improve satisfactorily after endoscopic treatment.[84] Bladder problems and kidney disease can persist after treatment, highlighting the importance of long-term follow-up care to support long-term health.[85]

3.5 Estimated vesicostomy button case volume

Estimating the number of vesicostomy button cases is challenging because evidence is largely limited to small, single-centre case series, with no national or population-level data to define how commonly these devices are used. While overall case volume is difficult to quantify, centre-level activity can be approximated from published case series that report consecutive patients over defined time periods. Four of the case series provide such data.[12, 27, 37, 86] Varik et al. reported 29 children managed with a vesicostomy button over a 15-year period at a single institution in

London, UK.[37] Mosiello et al.[12] and Galati et al.[27] reported 35 children over 16 years, and 33 children over four years, respectively, from institutions in Rome, Italy. Martin-Crespo Izquierdo et al. reported that 13 children were managed with vesicostomy buttons over 10 years at an institution in Toledo, Spain.[86] The observed differences likely reflect variations in centre size, referral practices, and reporting methods, rather than underlying differences in disease incidence.

From 2018 to 2026 a total of 26 vesicostomy buttons were placed in patients at Children's Health Ireland (CHI) hospitals, of which two have transitioned to adult services. This means that between two and four vesicostomy buttons have been placed each year for the past six years for a variety of indications. As of February 2026, 22 vesicostomy buttons are still *in situ*. The clinical indication for placement of vesicostomy buttons varied but were consistent with the clinical indications described in the case series reported in Chapter Four.

4 Clinical effectiveness and safety

Key Points

- A systematic review was conducted for this chapter. The overall evidence base was very limited and comprised: 15 publications from 14 case series involving 244 patients who had undergone button vesicostomy.
- Three case series were considered to be low quality, seven intermediate quality and four high quality. All case series were uncontrolled and none compared the use of vesicostomy buttons with alternative bladder management interventions.
- Eleven out of the 14 studies reported the sex of participants; of the 193 participants in these studies, 131 (68%) were male. The age of participants varied widely across the studies, ranging from newborn infants to age 19, with a median age of five years.
- Eight studies reported the use of the MIC-KEY® device within nine publications, two reported the use of the MiniONE® device and one reported use of a Bard device. Four studies did not specify the brand of device used, and one study used both MIC-KEY® and MiniONE® devices.
- Reporting of patient characteristics, diagnoses, indications and prior bladder management was heterogeneous, inconsistent, and often incomplete.
    - Common underlying diagnoses included spinal dysraphism (including spina bifida), posterior urethral valves, neurogenic bladder (not otherwise specified), and anorectal malformations.
    - Indications for vesicostomy buttons included poor bladder emptying, bladder assessment, management following previously attempted interventions which may have failed, and temporary diversion to allow time before definitive treatment.
- Button removal rates varied widely (0% to 100%) and may reflect whether the device was intended as a temporary or permanent management option and that the follow-up time varied between studies. Reasons for button removal included patients moving to urethral continence or subsequent treatments such as learning or complying with clean intermittent catheterisation (CIC) and clean intermittent self-catheterisation (CISC), surgical interventions such as Mitrofanoff diversion, bladder augmentation, bladder reconstruction, renal transplant and artificial urinary sphincter implantation.
- Reports on bladder function outcomes following vesicostomy button placement were heterogeneous in terms of outcome selection, measurement and reporting. Six case series reported generally positive perceived outcomes

related to bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. However, in the absence of comparator groups, no firm conclusions can be drawn regarding the relative effectiveness of vesicostomy buttons versus other bladder management strategies.

- Fourteen studies reported on the presence or absence of urinary tract infections (UTIs). The proportion of patients experiencing UTIs ranged from 0-54%. Five studies reported no UTIs with a range of follow-up times between six months and 10 years. Five studies reported on the incidence of symptomatic or febrile UTIs, ranging from 15-31%. In four studies, UTIs ranged between 21-54% but the authors didn't specify if they were symptomatic. In four studies where the incidence of UTIs were reported before and after vesicostomy button placement, more than half of the patients who had a UTI after button placement had a history of UTIs prior to button placement.
- The rate of infection at the site of the vesicostomy button ranged from 0-14% of patients over a wide range of follow up periods. Overgranulation (excessive growth of tissue around the button insertion site) was reported in 13% and 24% of patients in two case series. One patient from a relatively large case series (n=35) had button-related skin ulceration requiring revision (correction of complications and or adjustment of the device), and removal of the device.
- Twelve case series reported on vesicostomy button leakage, with reported leakage rates of 0-28% across follow-up periods ranging from two months to 13 years. The reporting on this outcome was not standardised; however, seven case series reported a proportion of these leaks as 'major' or 'significant'.
- Device- or procedure-related complications were inconsistently reported. Where reported, events included mechanical malfunction, encrustation, blockage, dislodgement, retention of the device in the bladder neck, unplanned exchange or revision, difficulties with the drainage tubing, and lithiasis (formation of stones within the bladder due to the presence of the device). Four case series reported no device failures; six reported at least one device- or procedure-related issue.
- Patient or parent satisfaction was reported in nine case series. Only one study conducted a formal quality-of-life comparison between a subset of patients receiving a vesicostomy button and another sample of patients performing CIC; no statistically significant difference in any quality-of-life domains or overall mean score (69.8 versus 72.3, p=0.65) was observed, although the questionnaire used had been substantially modified from its validated form and due to the low participant number, the study likely did not have the statistical

power to detect a difference. The remaining studies reported generally positive satisfaction but did not use formal assessment methods.

- Given the limitations of this evidence base it is not possible to draw definitive conclusions regarding the clinical effectiveness of vesicostomy button use in children relative to other management options. However, no serious safety concerns were noted, patient and carer satisfaction appeared to be positive overall, and vesicostomy buttons appeared to be well tolerated. In these patients, damage to the urinary system may be avoided, while potentially preserving future management options. They provide a continent alternative to a open vesicostomy for select children and may have additional benefits, for example, allowing children to participate in activities, such as sports and swimming.

4.1 Introduction

The aim of this section is to describe the clinical effectiveness and safety of vesicostomy buttons in children, relative to the available alternatives, as assessed using systematic review methodology.

4.2 Methods

The full details on the methods used for this report are described in the accompanying protocol. The following provides a summary of the methodology. This review considered the following question:

- What is the clinical effectiveness and safety of the use of vesicostomy buttons in children?

Table 3 outlines the Population, Intervention, Comparator, Outcomes, Study Design (PICOS), as well as details of the eligible records and languages.

Table 3: Population, intervention, comparator, outcomes, study design (PICOS)

Population	Newborns or children who need bladder drainage due to poor urine storage and bladder emptying.
Intervention	Bladder drainage using a gastrostomy button, also known as a vesicostomy or cystostomy button.
Comparator	Any or none.
Outcome	Any clinical effectiveness, safety or humanistic outcomes. Examples include: ▪ clinical effectiveness: proportion of patients with adequate voiding, adequate urine storage, rate of UTI, and rate of lithiasis. ▪ safety: complication rate, incontinence rate, reversal rate ▪ humanistic: acceptability, quality of life, satisfaction.
Study design	Included: ▪ HTAs, systematic reviews, clinical guidelines, narrative reviews, RCTs, non-randomised controlled trials, cohort studies, case-control studies, cross-sectional studies, case series, case reports. Excluded: ▪ Editorials, correspondence, opinion pieces.
Languages	Only articles for which an adequate English translation can be obtained will be included.

Key: HTA – health technology assessment; RCT - randomised controlled trial; UTI – Urinary tract infection

4.2.1 Search strategy

Electronic searches were last conducted on 20 October 2025 in MEDLINE (EBSCOhost), Embase (Elsevier), CINAHL (EBSCOhost) and Web of Science. In

addition, a search was conducted using the Cochrane Controlled Register of Trials (CENTRAL) via the Cochrane Library, Clinicaltrials.gov and the International Clinical Trials Registry Platform (ICTRP) to identify ongoing and completed clinical trials and research studies. A manual search of the *Journal of Pediatric Urology*, *Urology* and the *Journal of Urology* was also carried out. The search strategy for the MEDLINE (EBSCOhost) search is outlined in Appendix A. Complete documentation of all search strategies for this assessment can be found on the Zenodo open repository: https://doi.org/10.5281/zenodo.18875842.

A grey literature search was also performed (see Appendix A), including a search of the International Network of Agencies for Health Technology Assessment, Guidelines International Network, Guideline Central, UpToDate.com and the Turning Research Into Practice (TRIP) database. Up to the first 50 results for each search on each website were reviewed.

Reference lists from the included records were searched for potentially relevant citations. Forward-citation searching of included studies up to 4 November 2025 was undertaken using the citationchaser package https://estech.shinyapps.io/citationchaser/. No language or date restrictions were applied to the eligibility criteria or the search strategy. DeepL Pro Translate professional software was used to obtain translations of non-English language documents.[87]

4.2.2 Record selection

Returned citations from the collective search were added to EndNote for reference management. Following the removal of duplicates, the records were imported to Covidence for screening. Two reviewers independently conducted title and abstract screening followed by full-text screening of citations against the pre-defined eligibility criteria set out in Table 3. Any disagreements were resolved through discussion. Reasons for exclusion following full-text review were documented and summarised in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Figure 2).[88]

4.2.3 Data extraction and synthesis

Data extraction was performed by one reviewer using a pre-piloted standardised data extraction template in Microsoft Excel and checked by a second reviewer. Any disagreements were resolved through discussion. Where appropriate, authors were contacted to clarify missing or unclear information.

A narrative synthesis was conducted in accordance with the Synthesis Without Meta-analysis (SWiM) guidelines and reported in line with the PRISMA guidelines– see Zenodo open repository: https://doi.org/10.5281/zenodo.18875842 .[89] No meta-analysis was attempted as heterogeneity was known to be high *a priori*, and all data

came from case series. Results were synthesised according to their outcomes by summarising estimates of clinical effectiveness and safety. Outcomes were tabulated where appropriate, and the frequency of various diagnoses and general conditions were plotted using packages from the tidyverse in R Studio Version 4.3.2.[90] A high-level narrative summary of ongoing trials and research studies identified from the search of the trial registries was also generated.

4.2.4 Quality appraisal and certainty of evidence

Two reviewers independently assessed the methodological quality of included studies using the JBI Critical Appraisal Checklist for Case Series[91] with any disagreements resolved through discussion. The checklist was piloted first on a small number of included studies, and modifications made if needed, before standardising for the remaining studies. No assessment of the certainty of evidence was carried out, as it was known *a priori* that relying on evidence solely from case series would result in all outcomes being of very low certainty, and therefore the assessment would be of limited value.[92]

4.3 Results

4.3.1 Search Results

An overview of the article selection process is presented in the PRISMA flowchart (Figure 2). After deduplication of the database records, 264 records were screened by title and abstract, of which 34 were assessed at full text screening. Fourteen records met the inclusion criteria and were included in the review from the database and registry search.

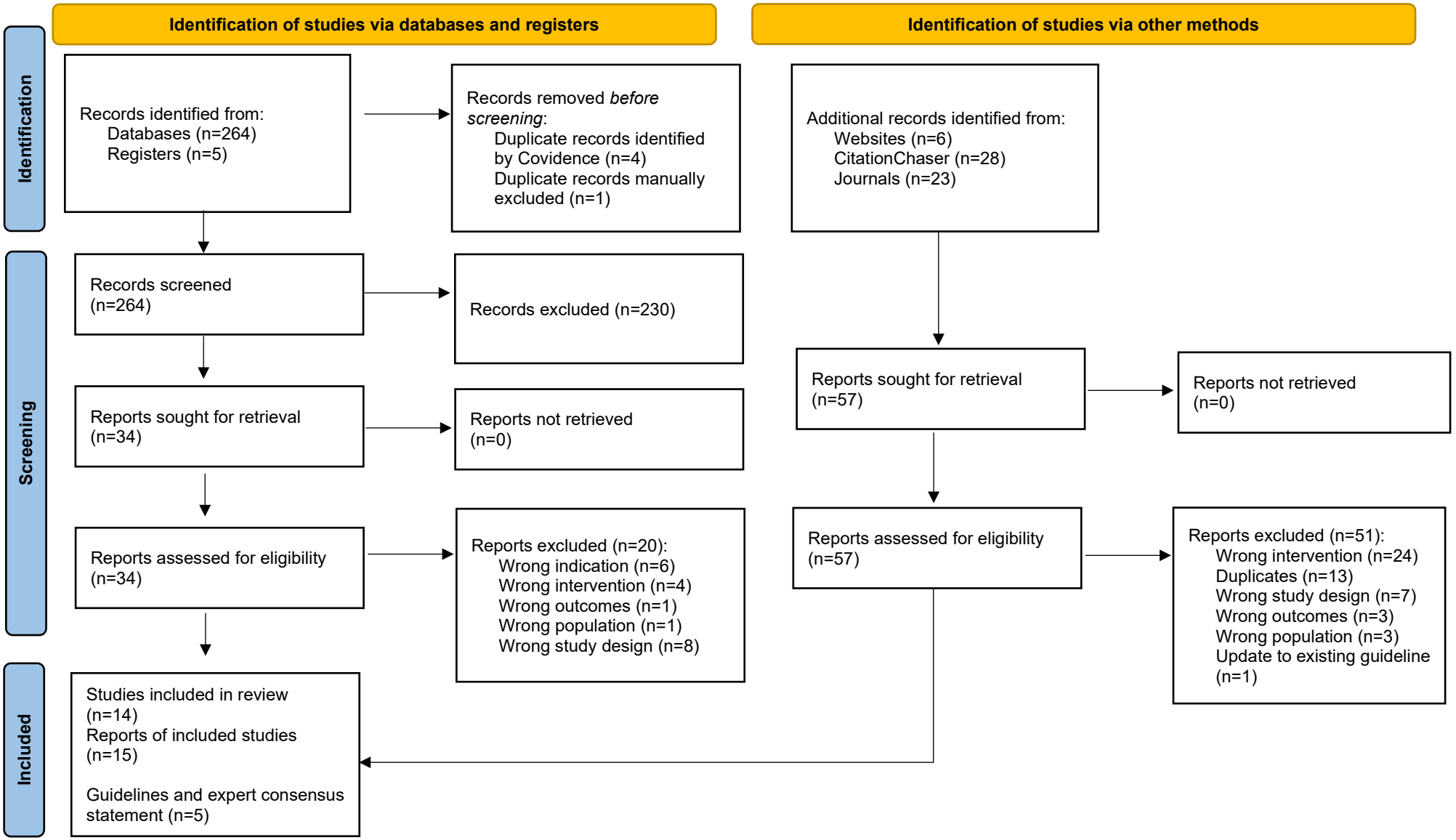
Database and registry searches were supplemented with additional identification methods. Grey literature searching and searches of three urology journals (see Section 4.3.1 and Appendix A) identified a further 23 records and six webpages. Forward and backward citation searching conducted using the citationchaser package yielded 72 and 80 records, respectively. Of these, 28 of these records from citationchaser were sought for retrieval. Only one relevant additional article was found by forward-citation searching; no relevant articles were found from backwards citation searching or by searching the three journals. Additionally, four relevant guidelines and one expert consensus statement were identified from grey literature searching for full text screening and subsequently included. The findings from these five documents are briefly described in Section 2.6.[16, 24, 65-67]

In total, 14 case series, reported within 15 publications, were identified, one of which described itself as a 'retrospective study'. However, for the purposes of this review, it was reclassified as a case series given the results were primarily descriptive and there was no comparison or control group.[27]

One case series published in 2010 was later published as an extended case series in 2012 and included data for all of the patients originally reported; both papers were therefore treated as records which provided information on the same case series.[50, 51]

Two case series were published by the same institution; however, these appeared to be separate non-overlapping cohorts that used different techniques for vesicostomy button placement.[33, 52]

Figure 2: PRISMA flow diagram of study selection process



4.3.2 Overview of results

Table 4 provides a summary of the characteristics of the included studies. The 15 publications included a total of 244 individuals and originated from the following countries: the United Kingdom (n=6),[10, 11, 33, 37, 52, 93] Italy (n=3),[12, 27, 94] the United States (n=2),[38, 86] France (n=2),[50, 51] the Netherlands (n=1)[95] and a combined case series from the United States and Argentina (n=1).[8] The age of participants varied widely across the included studies, ranging from newborn infants (one day old)[86] to adolescents aged 19 years[27, 50] with a median age of five years (calculated from the 11 studies which reported median age or individual ages). Seven studies included infants younger than 24 months,[10, 11, 27, 37, 38, 50, 51, 86] 13 included children aged 2-8 years,[8, 10-12, 27, 33, 37, 38, 50-52, 93-95] 11 included participants aged 9-13 years,[8, 10-12, 27, 37, 38, 50, 51, 93-95] and nine included adolescents aged 13-18 years.[10-12, 27, 37, 38, 50, 51, 93, 95] Two studies reported a median age (7.1 years in both studies) without providing any indication on the range or spread of ages.[33, 52]

The sex of the participants was reported in 11 of the 15 publications; of the 193 participants across all studies for whom sex was known, 131 (68%) were male.[12, 27, 33, 37, 38, 50, 52, 86, 94, 95] However, reporting of sex was incomplete in four studies,[10, 11, 38, 51] and three reports did not provide sex-stratified clinical details or outcomes.[10, 11, 51]

Regarding device type, eight studies reported the use of the MIC-KEY® device within nine publications,[10-12, 33, 38, 50-52, 95] two reported the use of the MiniONE® device[11, 37] and one reported use of a Bard device.[8] One study used both MIC-KEY® and MiniONE® devices.[11] Four studies did not specify the brand of device used.[27, 86, 93, 94]

Some description on button care protocols was included in seven studies,[10-12, 27, 33, 38, 52] and three further studies (reported in four publications) partly described this by specifying how long vesicostomy buttons remained in place before being changed.[8, 37, 50, 51] The time between button changes ranged from five to 12 weeks. In eight of the 14 case series, the duration that the button remained *in situ* was not reported.[12, 27, 33, 38, 50-52, 86, 93-95] Two further studies provided this information for only a subset of patients.[8, 27] Reported durations ranged from one to 38 months in one study and from one to 30 months in the other, allowing for periodic button adjustment or replacement in accordance with button care protocols.

Table 4: Summary of the characteristics of the included case series

Author, year Country	Sample size Sex	Age	Device	Duration *in situ*	Replacement protocol
Bradshaw, 2014[11] **UK**	n=30 Sex not reported	Median: 4 years Range: 4 days - 16 years	MIC-KEY® MiniOne® †	1 to 38 months (median = 11.0 months)	The first VB exchange took place with the urology nurse specialists as an outpatient 6 weeks after insertion. Subsequent exchanges were predominantly done by the family at home. As experience and knowledge developed with the VB, the interval for button exchanges was increased to 3-monthly owing to low infection rates.
Cobussen-Boekhorst, 2003[95] **The Netherlands**	n=9 Male: 7 Female: 2	Median: 4.8 years Range: 2-15 years	MIC-KEY®	NR	NR
Colliver, 2012[93] **UK**	n=4 Male: 4	Median: 9 years Range: 5-13 years	NR	NR	NR
de Badiola, 1996[8] **Argentina, USA**	n=3 Male: 1 Female: 2	Median: 3 years Range: 2-10 years	Bard	4 weeks for 1 patient 5 weeks for 1 patient NR for 1 patient	NR however no VBs in place longer than 5 weeks.
Galati, 2025[27] **Italy**	n=33 Male: 25 Female: 8	Median: 7.96 years Range: 0.1-19.4 years	NR	4 patients' duration = 2.6 +/- 1.3 years. NR for patients with VB in situ at end of study.	The first VB exchange was performed under anaesthesia in the hospital. Subsequent exchanges were carried out in the outpatient setting.

Author, year Country	Sample size Sex	Age	Device	Duration *in situ*	Replacement protocol
Haider, 2008[52] **UK**	n=12 Male: 8 Female: 4	Mean: 7.1 years	MIC-KEY®	NR	VBs changed in the outpatient setting.
Hitchcock, 2007[10] **UK**	n=21 Sex not reported	Median: 5 years Range: 4 days - 16 years	MIC-KEY®	Median duration of use=11 months (2-30 months). Buttons in situ until physiological voiding was established or definitive management performed. The button was expected to be temporary but in some cases 'acceptable and effective, and is in continuing use'.	First VB exchange took place as an outpatient 6 weeks later and subsequent exchanges were made by the family at home. The VBs were exchanged initially weekly, but later at 6-weekly intervals due to low infection rates.
Lacreuse, 2010[51]§ **France**	n=10§ Sex not reported	Mean: 5 years Range: 5 months - 19 years	MIC-KEY®	NR	VB changed every three months.

Author, year Country	Sample size Sex	Age	Device	Duration *in situ*	Replacement protocol
Lacreuse, 2012[50]§ **France**	n=21 Male: 13 Female: 8	Median: 4 years Range: 5 months - 19 years	MIC-KEY®	NR	VB changed every three months.
Martin-Crespo Izquierdo, 2017[86] **USA**	n=13 Male: 12 Female: 1	Median: 20 days Range: 14–60 days	Not clear	NR	NR
Milliken, 2007[33] **UK**	n=17 Male: 9 Female: 8	Mean: 7.1 years	MIC-KEY®	NR	VB changed every three months either on the ward or in the community by a urology nurse specialist.
Mosiello, 2017[12] **Italy**	n=35 Male: 19 Female: 16	Mean: 8.6 years ± 4.8 (SD) years	MIC-KEY®	NR	The first VB exchange took place in the hospital at least 2 months after insertion, with or without sedation depending on neurological status of the patients. Subsequent VB exchanges were performed every three months in the outpatient setting with caregivers trained in button replacement.
Nast, 2016[38] **USA**	n=13 7 males, 1 female in matched cohort (sex not reported for full case	Median: 3.8 years Range: 7 months - 18 years	MIC-KEY®	Reported average: around 2 years	VB changed every six to eight weeks, either in the outpatient clinic by nursing staff, or at home by caregivers.

Author, year Country	Sample size Sex	Age	Device	Duration *in situ*	Replacement protocol
	series of VB patients)				
Pellegrino, 2024[94] **Italy**	n=4‡ Male: 3 Female: 1	Median: 7.5 years Range: 4-8 years	Not clear	NR	NR
Varik, 2025[37] **UK**	n=29 Male: 23 Female: 6	Median: 3.5 years Range: 0.5-14.5 years	MiniOne®	Mean: 80 months Range: 20-188 months	Recommended that VB changed every 3 months.

Key: NR – not reported; SD – standard deviation; UK – United Kingdom; USA – United Statues of America; VB – vesicostomy button

†MIC-KEY® button was used more frequently (25 patients had MIC-KEY® at initial insertion), but the MiniONE® balloon button was also used (5 at initial insertion). Not clear which devices were used after initial insertion.

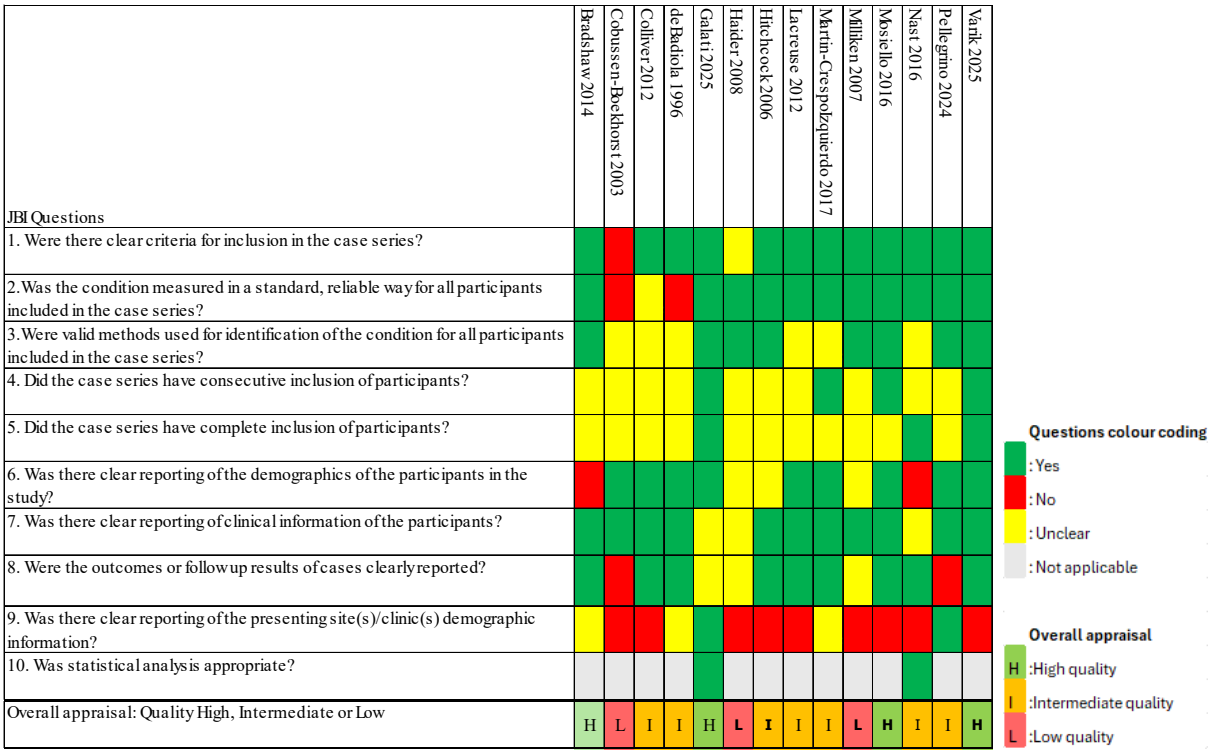
§All patients included in Lacreuse et al. 2010 are also included in Lacreuse et al. 2012.

‡6 patients in case series, only 4 had buttons placed.

4.3.3 Quality Appraisal

Figure 3 presents the quality appraisal of the included studies using the JBI Critical Appraisal Checklist for Case Series.[91] Of the 14 included studies, four were considered to be high quality,[11, 12, 27, 37] seven were intermediate quality,[8, 10, 38, 50, 86, 93, 94] and three were low quality.[33, 52, 95] Most of the studies did not clearly report if the participants were consecutive (10 out of 14 studies) or whether all of the eligible cases from their clinic were included (11 out of 14 studies). Very little or no information was provided about the presenting site or clinic in 12 out of the 14 studies and only two of the studies undertook statistical analysis.

Figure 3: Quality appraisal of included studies



4.3.4 Diagnoses, indications and previous treatment

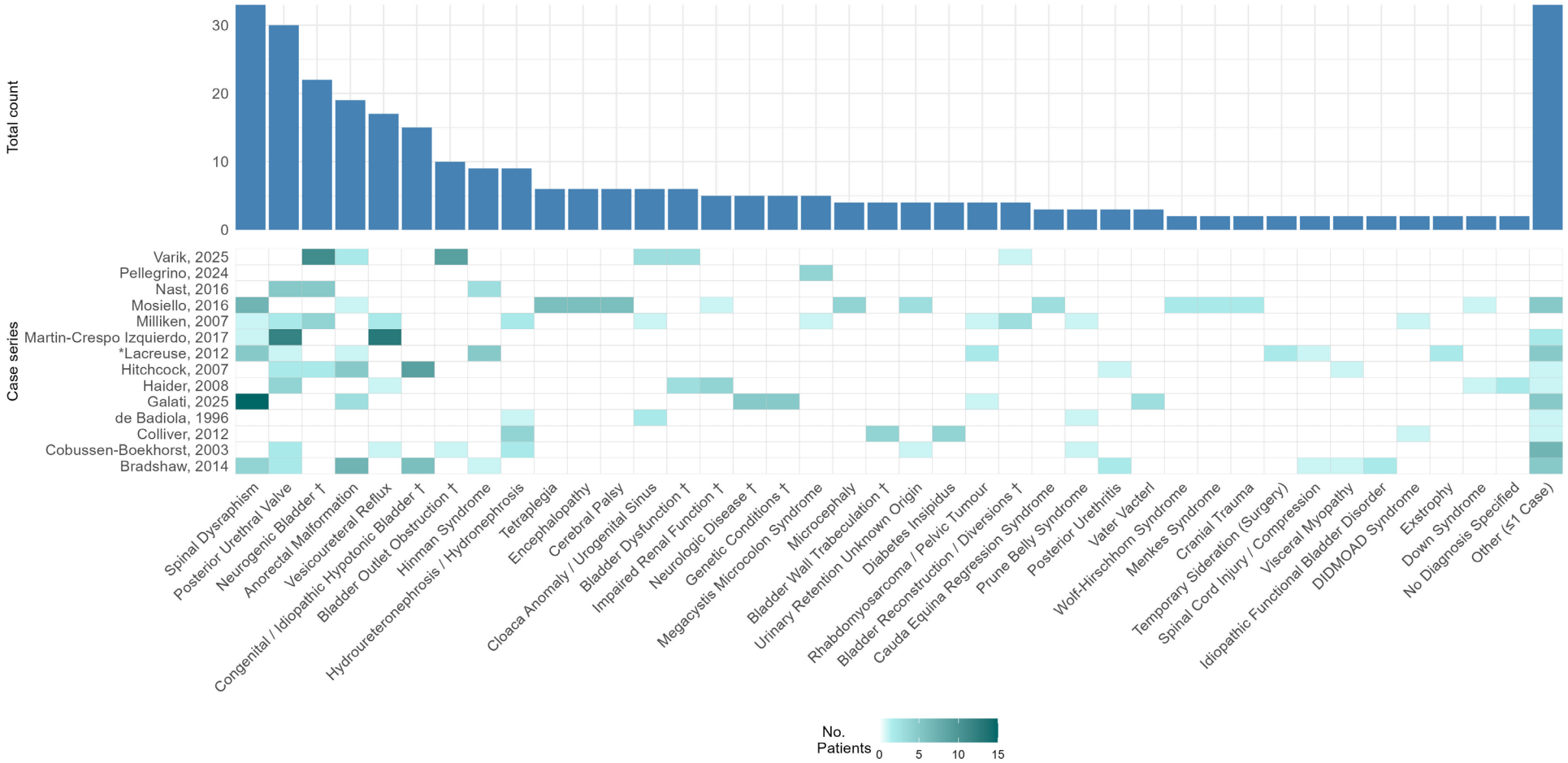
The 14 case series identified from this systematic review included patients who varied greatly in terms of their reported diagnoses or general clinical conditions, indications for insertion of the vesicostomy button, and prior procedures.

The most frequently specified clinical condition was spinal dysraphism which affected 33 patients in six case series.[11, 12, 33, 50, 51, 86] Five case series included a total of 17 children with spina bifida or myelomeningocele,[11, 12, 33, 50, 51] one included 15 children with spinal dysraphism not otherwise specified, and one included a single child with lipomeningocele.[27] Posterior urethral valves (PUV), a condition which only affects males, was the second most frequently specified condition affecting a total of 30 patients in eight case series.[10, 11, 33, 38, 50-52, 86, 95] Anorectal malformations were the third most common specified condition; 19 patients with this condition appeared in six case series.[10-12, 27, 37, 50] All other conditions are presented in a descending order of frequency in Figure 4.

Underlying diagnoses were poorly reported or reported for only a proportion of patients in eight case series.[10-12, 37, 38, 52, 86, 94] Many of the case series used general descriptions of the clinical condition in lieu of the underlying primary diagnosis. Examples of this included the following descriptions (number of studies detailed in parentheses): neurogenic bladder (n=5),[10, 12, 33, 37, 38] congenital or idiopathic hypotonic bladder (n=2),[10, 11] bladder dysfunction (n=2),[37, 52] postoperative bladder reconstruction or diversion (n=2),[33, 37] bladder outlet obstruction (n=2),[37, 95] postoperative pelvic surgery (n=1),[50] congenital abnormalities (n=1),[95] impaired renal function (n=1),[52] bladder wall trabeculation (n=1),[93] neurologic diseases (n=1)[27] or genetic diseases not otherwise specified (n=1).[27]

Figure 4 illustrates the frequency of reported diagnoses and conditions of patients receiving vesicostomy buttons across the 14 case series. Notably, some patients had two or more co-existing conditions, for example anorectal malformations and spina bifida, and therefore the total number of recorded diagnoses often exceeds the number of patients in a given case series. Several of the underlying primary diagnoses (for example, spinal dysraphism or posterior urethral valves) may be the cause of more general conditions such as 'neurogenic bladder' or 'bladder outlet obstruction'. However, where the underlying diagnosis was not specified, patients were categorised according to the general description of the clinical condition (for example, neurogenic bladder) in Figure 4. These diagnoses have been labelled as 'not otherwise specified' in Figure 4. Thirty-three diagnoses and conditions which only appeared once across the 14 case series were collapsed into the category 'Other' (≤1 Case). Full details on all of these diagnoses and conditions are available from Table A.5 in Appendix B.

Figure 4: Reported diagnoses and conditions of patients receiving vesicostomy buttons



Key: DIDMOAD – Diabetes Insipidus, Diabetes Mellitus, Optic Atrophy, Deafness; SMA – Spinal Muscular Atrophy; †– not otherwise specified
*Information on diagnoses in Lacreuse 2012 supplemented with information from Lacreuse 2010.
Note: where the underlying diagnosis was not specified, patients were categorised according to the general description of the clinical condition (for example, neurogenic bladder). Diagnoses and conditions which appeared only once across the case series were grouped under 'Other'.

A specific indication or rationale for the vesicostomy button was stated in 13 case series. These included:

- **Poor bladder emptying:**
  - generally poor bladder emptying or dysfunction not otherwise described[12, 33, 86]
  - bladder emptying which could not be achieved via the urethra with clean intermittent catheterisation (CIC) or clean intermittent self catheterisation (CISC),[10, 11, 27, 37, 38, 51] sometimes due to a sensate urethra (that is, someone who has intact nerves meaning they have sensation in the urethra)[94]
  - poor bladder emptying with recurrent infections[52]
  - complete urethral obstruction[52, 86]
  - management of the effects on the upper urinary tract in terms of dilation and infection[52, 86]
  - presence of renal failure or declining renal function associated or not associated with urinary sepsis[37, 86]
  - as a diversion in a patient with ichthyosis (severe perineal skin involvement).[37]
- **Bladder assessment:**
  - which could include prior to or after another intervention such as surgery[11, 50]
  - for assessment of bladder function over a longer period of time[95]
  - for assessment prior to vesicostomy closure.[8, 11, 50, 52]
- **Subsequent management following previous interventions:**
  - failure with Mitrofanoff[51], Yang-Monti conduit,[33] or another bladder drainage technique (not specified)[50]
  - Mitrofanoff stomas 'considered unsuitable'[33]
  - patient preference over Mitrofanoff[33] or CIC[94]
  - CISC not possible and surgery refused[33]
  - to improve quality of life in patients initially treated with CISC[33]
  - issues arising after previous vesicostomy closure.[33]
- **Temporary management:**
  - until CISC or CIC regime established[11], or patient satisfied with CIC[11] or CISC[33] regime
  - as bladder recovery was deemed possible[11]
  - to facilitate bladder cycling or bladder training[33, 37]
  - following pelvic surgery[50]
  - temporary drainage in patients waiting for continent or incontinent urinary diversion.[12]

In one case series of patients with diabetes (n=4) the indication was not explicit, however in all patients CIC was not an option because of sensate urethras.[93]

Twelve of the 14 case series reported the use of prior procedures, some of which were used to manage urine storage and bladder emptying problems.[8, 10-12, 27, 33, 37, 38, 50, 86, 94, 95] Multiple prior procedures were reported in nine of these 12 case series, and some patients had more than one intervention with respect to bladder management prior to the insertion of a vesicostomy button. The most common prior procedure was either self- or assisted urethral catheterisation (n=7)[11, 12, 27, 33, 50, 51, 94, 95] and previous vesicostomy (n=7)[8, 10, 11, 33, 38, 50, 94] followed by suprapubic catheterisation (n=6).[10-12, 27, 33, 37] Other procedures included Mitrofanoff procedures,[50, 51] ileocystoplasty,[33] ileostomy,[33] bladder neck reconstruction,[33] endoscopic laser resection,[86] cloacal anomaly reconstruction,[8] and nephrostomy.[12] Patients from the series by Pelligrino et al. (n=6) underwent gastrostomies, jejunostomies, and ileostomies although it was unclear whether these procedures occurred before or after button placement. Such gastrointestinal procedures, although not part of bladder management, may affect urinary output or bladder outcomes and limit the generalisability of results.

4.3.5 Reported outcomes

The choice and reporting of outcomes included in the 14 case series varied considerably. Sections 4.3.6 to 4.3.12 provide a narrative summary of these reported outcomes; in brief they include removal of the vesicostomy button, improvement in bladder function, urinary tract infections, infection at the site of the vesicostomy button and tissue reactions, device or procedure failure and patient or carer satisfaction. A summary of the outcomes reported in each case study is provided in Table 5 below.

Table 5: Table of outcomes

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
Bradshaw, 2014[11] **n=30**	Suprapubic catheter: n=6 Vesicostomy: n=3	Max 13 years	Median:11 months (range: 1-38 months)	Button well tolerated; no early removals; families requested to keep button; perceived improved flexibility; overall very well tolerated*	Overgranulation (n=4) Wound infection (n=4)	8	Transient leaks (n=4) Significant leaks (n=3)	Due to blockage (n=1), no reports of stones or encrustation
Cobussen-Boekhorst, 2003[95] **n=9**	Transurethral catheter followed by suprapubic catheter: n=1	Mean: 8 months (range: 2-28 months)	NR	NR	NR	2	Leakage requiring VB replacement (n=1)	NR
Colliver, 2012[93] **n=4**	None	NR	Unclear	NR	NR	1	NR	NR
de Badiola, 1996[8] **n=3**	Vesicostomy: n=3 Cloacal anomaly reconstruction: n=2	6-22 months	4-5 weeks	"Patient tolerance was excellent"*; no complications related to urine exposure; no added technical difficulty at closure	NR	None	None	No encrustation, lithiasis or stones

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
Galati , 2025[27] **n=33**	Suprapubic catheter: n=6 Failed CIC: n=33	Mean: 2.1 ± 1.4 years	Mean: 2.6 +/- 1.28 years (4 patients) NR for other patients	Satisfied with at-home management: n=31*; remaining 2 transitioned to CIC	NR	5	Leakage at exit site: n=2 resolved with resizing	NR
Haider, 2008[52] **n=12**	NR	Mean: 11 months (range: 3-24 months). Data collected prospectively	NR	NR	None	None	None	Device or procedures failure NR No reports of lithiasis
Hitchcock, 2007[10] **n=21**	Suprapubic catheter: n=3 Vesicostomy: n=3	Median: 2.5 years (range: 0.75-8 years)	Median duration of use=11 months (2-30 months). Buttons were left in situ until physiological voiding was established or definitive management performed. The	Button drainage easy; management accepted by almost all patients*	Site infection/ erythema (not definitive) : n=3 Granulation: n=5	4	All those with previous open vesicostomy leaked: n=3, suprapubic tract leak: n=1, none in standardise	Button exchange failure: n=1, mild encrustation: n=1, no reports of lithiasis

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
			button was expected to be temporary but in some cases has proven acceptable and effective, and is in continuing use.				d button stoma: n=17	
Lacreuse, 2010[51] **n=10†**	Mitrofanoff failure: n=2 Voluminous pelvic tumour surgery: n=2 Failure of CIC: n=1	Mean:~ 1 year	NR	Reported that "patients and parents were satisfied"*	None	None	None	None
Lacreuse, 2012[50] **n=21**	Mitrofanoff diversion: n=2 CISC: n=3 CISC followed by Mitrofanoff: n=1 Vesicostomy: n=4 Bricker conduit: n=1 Assisted CIC: n=1	~2 years (range: 1-4 years)	NR	Satisfied: n=13 Dissatisfied: n=7 Removals (some rapid) due to dissatisfaction or complications: n=5	NR	4	Minor leak: n=4 Major leak: n=3	Lithiasis: n=1 Retention of device in neck of bladder: n=1

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
	Crede manoeuvre: n=1 No previous management: n=8							
Martin-Crespo Izquierdo, 2017[86] **n=13**	Endoscopic laser resection: n=2	Mean: 4.3 years (range: 2-10 years)	NR but average age at closure was 20 months (between 19-30 months)	NR	NR	None	None	None
Milliken, 2007[33] **n=17**	CISC: n=4 Vesicostomy: n=2 Ileocystoplasty & suprapubic catheter: n=1 Ileocystoplasty & Yang-Monti procedure: n=1 Bladder neck reconstruction: n=3 Ileostomy: n=1	Mean: 16 months (range: 2-40 months)	NR 3 removed 14 in situ at end of study	All patients felt QoL improved*	Wound infection: n=1	None	Significant leakage: n=4, 1 of which spontaneously resolved, 3 resolved with shorter button.	Device or procedures failure: NR No reports of lithiasis

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
Mosiello, 2017[12] **n=35**	CIC: n=16 Suprapubic cystostomy indwelling tube: n=15 Nephrostomy: n=1	Mean: 37 ± 19.7 months	Cystostomy button was closed after a mean time of 29 ± 13.49 months: n=6 Left in situ at time of reporting: n=22 Unclear: n=7	All current users satisfied; felt that button improved QoL*	Button side infection: n=1 Button-related skin ulceration requiring revision and removal; n=1	10	Leakage at site: n=2	Lithiasis: n=1
Nast, 2016[38] **n=13**	Vesicostomy: n=7	Mean: 24.7 months (range: 3-54 months)	Mean: ~2 years 10 patients still using VB at time of reporting.	Formal QoL comparison: VB score 69.8 vs CIC 72.3 (no significant difference, p=0.65)	Wound infection: n=1	7	Leaks (n=5) in patients with prior vesicostomy tracts, no leaks with endoscopic placement	Button malfunction: n=3 Dislodgement: n=1 Leakage needing revision: n=1 Tubing difficulty: n=1

Author, year Sample size	Procedures prior to VB	Follow-up	Duration in situ	Patient satisfaction	Local tissue reactions	UTIs after button placement	Leakage	Device or procedure failure or complications
Pellegrino, 2024[94] **n=6‡**	CIC: n=2 Vesicostomy: n=1	Median: 2 years (IQR 1-6.7 years) for all 6 patients in study	NR	NR	NR	None	NR	None
Varik, 2025[37] **n=29**	Suprapubic catheter: n=7 Vesicostomy: n=5	Median: 4.5 years (range: 1-7 years) post-closure	Mean: 80 months (range: 20-188 months)	NR	NR	9	Leakage: n=8 mostly resolved with balloon adjustment	Blockage from encrustation: n=2

Key: CIC – clean intermittent catheterisation; CISC – clean intermittent self catheterisation; NR – not reported; QoL – quality of life; UTI – urinary tract infection

*No formal QoL tool, survey or methods reported for assessment.

† Button malfunction was considered a complication if the patient was seen in the emergency department or clinic for significant leakage requiring button or tubing change before the planned initial change or for dislodged buttons.

‡ Only four had vesicostomy buttons, data only reported for the four patients unless otherwise specified.

4.3.6 Button removal and further management

Eight case series reported patients transitioning to a state of continence, alternative bladder management strategies, or pursuing subsequent related surgical interventions,[8, 10, 11, 27, 33, 37, 38, 86] while 10 noted that the vesicostomy button was still *in situ* for some or all children at the time of reporting.[10, 11, 27, 33, 37, 38, 52, 86, 93, 95]

In these 14 case series, vesicostomy buttons were intended as part of temporary or indefinite management. However, these intentions prior to button placement were rarely reported by the authors and were not explicit in the reporting of case series. Rates of removal of the vesicostomy buttons followed by closure of the vesicostomy opening ranged from 0-100% of children, with a wide breadth of management pathways post-button placement or removal.[8, 52, 93]

Mosiello et al. (n=35) was the largest case series which reported outcomes related to button removal and further management, and button removal was reported in six patients.[12] This was the only case series which reported button removal and vesicostomy closure (after removal) as a result of adverse events. Removal of the button was driven by recurrent urinary tract infections (UTI; defined as four or more UTI episodes in one year) in four patients, of which one patient had UTIs associated with site leakage. One vesicostomy button was removed because the patient experienced difficulty with bladder emptying and developed lithiasis, and one was removed as part of efforts to treat button-related skin ulceration. All of these patients had transitioned to CIC at the time of reporting. However, it was not clear if the change in management was part of the patient's planned care or was undertaken to address and manage UTIs. Three patients opted for Mitrofanoff diversion and one of these three patients underwent subsequent sacral neuromodulation treatment. The authors noted the buttons have an important role as a 'bridge to more definitive treatments' such as sacral neuromodulation treatment and the Mitrofanoff procedure.

Conversely, the 11 other case series reported changes in management or proportions of button removals as either a positive or neutral outcome, three of which were of a relatively similar size to Mosiello et al.[10, 11, 27, 33, 37, 38, 52, 86, 93, 95]

Galati et al. (n=33) reported that four patients eventually had their buttons removed for non-adverse event related reasons including: due to implantation of a sacral neuromodulator in two patients; clinical improvement in one patient; and the fashioning of a continent diversion in another patient.[27] However, they did not report on transition of management for the other 29 patients or the current status of their vesicostomy buttons.[27] Bradshaw et al. (n=30) reported that 23 patients had their buttons removed, of which 10 children subsequently achieved adequate voiding after button removal, although two of these remained incontinent.[11] Eight children successfully learned CIC, and four progressed to definitive surgery with Mitrofanoff

formation. The final patient whose button was removed had their button initially inserted to assess bladder functioning prior to vesicostomy closure. However, they experienced a significant leak, and the assessment was unsuccessful. At the time of reporting, seven patients still had their button *in situ*, however the authors reported they were 'extremely well tolerated'.

Varik et al. (n=29) reported that 15 patients had their vesicostomy buttons removed. Of these 15 patients, button removal was possible due to an improvement in bladder dysfunction in nine patients; eight of these patients had their vesicostomies closed while one patient was awaiting closure at the time of reporting. All nine children who had their vesicostomy buttons removed due to an improvement in bladder dysfunction were able to pass urine via the urethra with good emptying at follow-up. The remaining six patients progressed to Mitrofanoff diversion, and five of these six also underwent bladder augmentation.[37]

Eight relatively smaller case series also indicated a breadth of management pathways following button insertion.[10, 33, 38, 52, 86, 93, 95] Hitchcock et al. (n=21) reported improved bladder function sufficient to permit button removal in eight children.[10] Four other patients transitioned to CIC with urethral emptying, four underwent subsequent Mitrofanoff, one transitioned to open vesicostomy, and one transitioned to continuous drainage via suprapubic catheter and three were still using the button at the time of reporting. Of the four who underwent subsequent Mitrofanoff diversion, one also proceeded to have bladder augmentation, and another had an artificial urinary sphincter implanted. In Milliken et al.'s case series (n=17) three children appeared to transition to other forms of management including CISC in two patients; however, the reporting on this was unclear. The remaining 14 patients had the button *in situ* at the time of reporting.[33]

Martin-Crespo Izquierdo et al. (n=13) stated that vesicostomy closure was indicated after a urodynamic study demonstrated bladder stability; that is, normal detrusor function, in the absence of involuntary detrusor contractions, and in the presence of adequate bladder capacity and accommodation.[86] It was unclear whether all patients underwent vesicostomy closure, however 11 patients did undergo simultaneous urinary tract reconstruction and vesicostomy closure. Nast et al. (n=13) noted that 10 children, at the time of reporting, were still using the button, while two had the button removed and were voiding spontaneously and one transitioned back to a open vesicostomy.[38] One of the three patients who had their button removed had outgrown the maximum tube length (5cm) of the vesicostomy button. One patient used the button for bladder cycling prior to a successful transplantation. Haider et al. (n=12) reported all buttons remained *in situ* and were working satisfactorily at the end of their study, however two children were awaiting an undiversion procedure (a surgical procedure whereby the flow of urine, which had previously been diverted, is restored), two were awaiting bladder reconstruction

procedures, and one child had a renal transplant with the button remaining in situ.[52] The remaining children (n=7) were being followed up with no decision made in relation to their long-term management at the time of reporting.

Cobussen-Boekhorst et al. (n=9) noted vesicostomy closure was evaluated, proposed or considered in all patients. After evaluation the vesicostomy was closed surgically in seven children but postponed in two; one due to leakage alongside the button attributed to high bladder pressure during a urodynamic study, and the other at the request of the parents due to persistent low volume (30-50ml, no post-void residual, PVR) and a UTI. However, it is not clear whether any of these patients underwent vesicostomy closure.[95] After inserting the vesicostomy button and prior to evaluating for closure, one patient with PUV underwent a control cysto-urethroscopy with resection of scar tissue, one patient with prune belly syndrome underwent a period of physiotherapy and practiced bowel exercises, one patient with several congenital abnormalities underwent stepwise dilation of the urethra using increasing diameter of balloon catheter for two weeks. Colliver et al. (n=4) reported vesicostomy buttons remained *in situ* for all four patients at the time of reporting, with no indication of any immediate or foreseen removal.[93] de Badiola et al. (n=3) documented vesicostomy closure in all three cases with patients achieving continence, and in one of these cases the patient also underwent subsequent bilateral ureteral reimplantation and continent Mitrofanoff diversion.[8]

Standardised stomas showed a stronger tendency for spontaneous closure than open vesicostomies. Hitchcock et al. (n=21) reported 13 of the 17 standardised button stomas were closed at the end of treatment, seven of which closed spontaneously, four were closed during definitive surgery, and two required operative closure after 11 and 12 months' use.[10] Of the two buttons in suprapubic catheter tracts removed, one closed spontaneously and the other was closed during Mitrofanoff formation. In two cases, open vesicostomies were electively closed without a prior trial of spontaneous closure.

Overall, button removal and vesicostomy closure possibly enabled transition to continence and urethral voiding, CIC, CISC, Mitrofanoff or other bladder management strategies. However, where the button remained *in situ* it did not necessarily indicate a failure in management or a poor outcome.

4.3.7 Improvements in bladder function

Reports on bladder function following vesicostomy button placement were heterogeneous in terms of outcome selection, measurement and reporting. Six case series documented at least one outcome related to improvements in bladder emptying, capacity, compliance or intravesical pressures.[8, 37, 38, 86, 93, 95] However, the lack of standardised outcomes limited the ability to synthesise findings.

Four case series reported on outcomes related to bladder emptying, all of which generally indicated effective or improved bladder emptying.[8, 37, 93, 95] Favourable bladder emptying was described by Varik et al. (n=29) who reported improvement in bladder dysfunction in nine patients.[37] The authors described 'good emptying' and urethral voiding preserved at long-term follow-up (median 4.5 years), with PVR <10% of bladder volume. They also noted that three patients showed clear improvements in bladder dynamics and upper tract dilatation, and were able to void spontaneously after button removal, following spinal cord untethering. Similarly, Cobussen-Boekhorst et al. (n=9) reported mean voided volumes of 100mL (range 30–180mL) and low PVR (measured by parents or patients) in all children, which indicated effective bladder emptying.[95] However, pre-treatment voided volumes and PVRs were not reported. Similarly, de Badiola et al. (n=3) documented increases in bladder capacity at safe filling pressures (<30cm water), reaching 230–320mL with acceptable compliance in two patients.[8] In the third patient these measures were not reported, however cystometrography (measurement of bladder pressure, capacity, and function) showed normal bladder capacity and compliance for their age. Bladder function remained unchanged following vesicostomy closure in all cases with no upper tract deterioration. Colliver et al. (n=4) reported symptomatic relief of incontinence in all patients. Comfortable daytime voiding, improvements in hydronephrosis (swelling of the kidney due to lack of proper drainage) and no significant rise in bladder pressure during filling were reported in three patients.[93]

Effects on upper urinary tracts were reported by three studies.[37, 38, 86] Nast et al. (n=13) was the only case series that reported creatinine measurements and imaging outcomes for 10 and 12 patients respectively.[38] Creatinine was measured before and one month after button placement; remaining stable in all 10 patients (maximum change = 0.12 mg/dL). Ten renal ultrasounds confirmed the absence of hydronephrosis or stable to improved hydronephrosis post-button placement. The other two patients had nuclear medicine scans confirming equal and stable functioning bilaterally. These observations were supported by Martin-Crespo Izquierdo et al. (n=13) who reported bladder stabilisation and resolution of high intravesical pressure in all patients, with adequate decompression of the upper urinary tract.[86] Varik et al. reported (n=29) no patients developed end-stage renal disease.[37]

Cobussen-Boekhorst et al. (n=9) reported at the end of their case series that three children were fully toilet-trained and continent, while four remained in nappies but continued to empty their bladders effectively, indicating preserved functional voiding.[95] Of those who remained in nappies, it is not clear whether they were still too young to have progressed to toilet-training, as the age at final follow-up was not reported.

4.3.8 Urinary tract infections

Fourteen studies reported on the presence or absence of UTIs, as outlined in Table 6.[8, 10-12, 27, 33, 37, 38, 50-52, 86, 93-95] The time period over which UTIs were observed, the presence of fever or other symptoms and the location of the UTI were less consistently reported.

Five studies reported no UTIs following button placement with a range of follow-up times between six months and 10 years.[8, 33, 52, 86, 94] One of these studies reported no UTIs before button placement (Martin-Crespo Izquierdo et al., n=13; follow-up: 2-10 years)[86]; one study reported one patient with a UTI prior to button placement (Milliken et al., n=17; follow-up: 2-40 months)[33]; another study reported two patients with pyelonephritis prior to button placement (de Badiola et al., n=3; button *in situ* for 4-5 weeks, follow-up: 6-22 months)[8];. Pellegrino et al. (n=4), reported UTIs as 'common' in three patients before button cystostomy, but they were no longer observed after adequate bladder emptying management; the insertion of the vesicostomy buttons formed part of this bladder emptying management,[94] and Haider et al. (n=12; follow-up: 3- 24 months)[52] didn't clearly report whether patients had UTIs prior to button placement.

Five studies reported on the incidence of symptomatic (showing signs or symptoms of disease or illness) or febrile (showing signs of a fever) UTIs specifically.[10, 27, 37, 50, 95] In Cobussen-Boekhorst et al., (n=9), two children developed a symptomatic UTI (follow-up: 2-28 months). In both cases, the parents removed the button as instructed and the children were started on antibiotic treatment.[95] Hitchcock et al. (n=21), reported symptomatic UTIs occurring in four patients, with buttons in use between two and 30 months with follow-up of between 0.75 and 8 years. One of these patients required admission and treatment with intravenous antibiotics. Three out of the four patients with UTIs had multiple UTIs prior to button placement.[10] Galati et al., (n=33) reported five febrile UTIs during follow-up (mean follow-up time 2.11+/-1.44 years). Two of these patients had recurrent infections prior to button placement and one developed a UTI during intensive care admission for aspiration pneumonia and permanent transurethral catheter placement. Lacreuse et al., (n=21) reported four patients who developed a UTI over a follow-up period between one and four years. Two of these were lower UTIs and two were upper UTIs. Upper UTIs, major peristomal leakage or patient dissatisfaction were all considered to be a procedure failure in this study.[50] Eight failures were reported in this study. Varik et al. (n=29) reported that colonisation (where bacteria is present in a urine sample but the patient doesn't have any symptoms) was common, and that nine children had a symptomatic UTI requiring antibiotic treatment (eight were admitted and received intravenous antibiotics) and a mid-course change in button (button *in situ:* 20-188 months and follow-up: 1-7 years).[37]

In four studies, UTIs were reported but the authors didn't specify if they were symptomatic or not. In a small study (n=4), Colliver et al. reported one patient initially developed a recurrent UTI infection after button placement, but this resolved after management with bladder washouts (a procedure to rinse out a patient's bladder using a salt-water solution).[93] Mosiello et al. (n=35), reported that 10 patients had UTIs (mean follow-up: 37+/-19.7 months). Four of these patients had their button removed due to >4 UTI episodes in a year as well as site leakage.[12] Bradshaw et al. (n=30), reported eight patients with UTIs following button placement (button *in situ* for 1 to 38 months, maximum length of follow-up: 13 years).[11] Seven patients had ongoing recurrent UTIs prior to button placement, six of these patients continued to experience recurrent UTIs following button placement, while UTIs resolved in one patient. Two of the eight patients had no previous history of UTIs and were treated with antibiotics and an exchange of the button. None of these patients required permanent removal of the button. Nast et al.(n=13) reported seven children with UTIs after button placement. However, only three children had new UTIs 30 days after button placement while four children who had recurrent UTIs continued to have infections after button placement (follow-up: 3-54 months).[38]

Management of UTIs wasn't consistently reported in the studies. However, in four studies, buttons were reported to be removed or changed as part of the management of UTIs,[11, 12, 37, 95] while other studies reported using intravenous antibiotics after hospital admission,[10, 11] antibiotic treatment (route of administration or location where administered not specified),[27, 95] or bladder washouts[93] to manage UTIs.

Across all 14 studies, 244 patients received a vesicostomy button and 50 (20.5%) patients were reported to have a UTI at some point post-button placement. Four of the studies (97 patients)[10, 11, 27, 37, 38] reported the number of patients with UTIs post button placement (n=24), and the number of these patients with a history of UTIs prior to button placement (n=15), with more than half of the reported UTIs occurring in patients with a history of UTIs.

Table 6: Overview of urinary tract infections (UTIs) in the included studies

Study	N of patients	Length of follow up Duration *in situ*	N of UTIs after button placement	N of new UTIs	Number of patients with UTIs before placement	Number of patients with UTIs before and after placement	Management of infection
Bradshaw, 2014[11]	30	Max 13 years Median: 11 months (range: 1-38 months)	8	2	7	6	Hospital admission, antibiotics and exchange of button.
Cobussen-Boekhorst, 2003[95]	9	Mean: 8 months (range: 2–28 months) NR	2	2	1	NR	Button removed and antibiotic treatment given.
Colliver, 2012[93]	4	NR Unclear	1	NR	NR	NR	Management with washouts (a procedure to rinse out a patient's bladder using a salt-water solution)
de Badiola, 1996[8]	3	6–22 months, data collected on UTIs 4 weeks after button placement 4-5 weeks	None*	None	2 cases of pyelonephritis	None	NR

Study	N of patients	Length of follow up Duration *in situ*	N of UTIs after button placement	N of new UTIs	Number of patients with UTIs before placement	Number of patients with UTIs before and after placement	Management of infection
Galati, 2025[27]	33	Mean: 2.1 +/- 1.4 years Mean: 2.6 +/- 1.28 years (4 patients). NR for other patients	5	3	2 (might be higher as authors state preoperative UTI rates were partially unavailable)	2	Antibiotics
Haider, 2008[52]	12	Mean: 11 months (range: 3–24 months) NR, all buttons remain in situ	None	None	Recurrent UTIs in PUV listed as indication for VB in at least 4 patients, unclear total number of recurrent UTIs.	None	NR
Hitchcock, 2007[10]	21	Median: 2.5 years (range: 0.75–8.0 years) Median: 11 months (range: 2-30 months)	4	1	6	3	One of the 4 patients required admission to hospital with IV antibiotics.
Lacreuse, 2012[50]	21	~2 years (range: 1–4 years) NR	4	NR	NR	NR	NR

Study	N of patients	Length of follow up Duration *in situ*	N of UTIs after button placement	N of new UTIs	Number of patients with UTIs before placement	Number of patients with UTIs before and after placement	Management of infection
Martin-Crespo Izquierdo, 2017[86]	13	Mean: 4.3 years (range: 2–10 years) NR	None	None	NR	None	NR
Milliken, 2007[33]	17	Mean: 16 months (range: 2–40 months) NR	None	None	1	None	NR
Mosiello, 2016[12]	35	Mean: 37+/- 19.7 months Mean: 29 +/- 13.5 months (6 patients), unclear for n=7, 22 left in situ at time of reporting	10	NR	NR	NR	4 of these patients had their button removed due to more than 4 UTI episodes in one year.
Nast, 2016[38]	13	Mean: 24.7 months (range: 3–54 months) Data on UTIs collected 12 months before and after VB placement Mean: ~ 2 years 10 patients still using VB at time of reporting	7	3	4	4	NR

Study	N of patients	Length of follow up Duration *in situ*	N of UTIs after button placement	N of new UTIs	Number of patients with UTIs before placement	Number of patients with UTIs before and after placement	Management of infection
Pelligrino, 2024[94]	4*	Median: 2 years (IQR 1-6.75), this includes all 6 patients in study NR	None	None	3	None	NR
Varik, 2025[37]	29	Median: 4.5 years (range: 1–7 years) Mean: 80 months (range: 20-188 months)	9	NR	Poor bladder emptying with recurrent UTI listed as indication for VB in 1 patient.	NR	Mid-course change in button plus treatment for infection. 8 required hospital admission and IV antibiotics.

Key: IV – intravenous; NR – not reported; UTI – urinary tract infection; VB – vesicostomy button

*4 out of 6 patients received button cystostomy.

4.3.9 Local infection and tissue reactions

Seven studies reported on local infections and tissue reactions at the site of the vesicostomy button.[10-12, 33, 38, 51, 52] The proportion of patients experiencing a local infection ranged from 0% to 14% of patients over follow-up periods, which varied from three months to 13 years.

Lacreuse et al. (n=10) found no such events after a mean follow-up of approximately one year.[51] However this outcome was not reported on in their later expanded cohort published in 2012 (n=21).[50] Similarly, Haider et al. (n=12) reported no local infections after a mean follow-up of 11 months (range: 3-24 months).[52]

In the largest of the seven case series, Mosiello et al. (n=35), one patient had an infection at the side of their vesicostomy button after a mean follow-up of 37 months (standard deviation ±19.7 months).[12] Similarly, Milliken et al. (n=17) reported one patient developed a wound infection after a mean follow-up of 16 months (range: 2-40 months).[33] Nast et al. (n=13) also reported one patient who developed a wound infection after a mean follow-up of 25 months (range: 3-54 months).[33]

Bradshaw et al. (n=30) reported four children included in their series had wound infection. However, some of this cohort had a much longer follow-up period of 13 years, during which time an infection could occur.[11] Similarly, Hitchcock et al. (n=21) found three children included in their study had a definitive or suspected site infection after a median follow-up of 2.5 years (0.75-8 years).[10]

Other local tissue reactions were reported in three case series. Mosiello et al. (n=35) reported one case of button-related skin ulceration requiring revision and removal.[12] Overgranulation was reported in two further case series at the site of the vesicostomy button: this was reported in four and five of the patients included in Bradshaw et al. (n=30) and Hitchcock et al. (n=21), respectively.[10, 11]

4.3.10 Leakage

Twelve case series reported on leakage of the vesicostomy button,[8, 10-12, 27, 33, 37, 38, 50-52, 95] nine of which found that at least one patient had a leak at the site of the vesicostomy button at some point during their follow up.[10-12, 27, 33, 37, 38, 50, 95] The proportion of patients who experienced a leak ranged from 0-28% across follow-up periods spanning two months to 13 years. Seven case series reported 'major' or 'significant' leaks, or leaks which required additional management.[11, 12, 27, 33, 37, 50, 95] Management strategies included resizing, replacement, or adjustment of buttons. However, some leaks did appear to resolve spontaneously.

Two case series by Haider et al. (n=13),[52] and Martin Crespo Izquierdo et al. (n=13)[86] reported no leakage over a mean follow-up of 11 months and 4.3 years, respectively. Similarly, de Badiola et al. (n=3) reported no leakage with follow-up periods of at least 22 months, nine months and six months for their three study participants.[8]

Bradshaw et al. (n=30) found that three children had 'significant' leaks and four had 'transient' leaks.[11] Similarly, Lacreuse et al. (n=21) reported three 'major' leaks and three further 'minor' leaks in their series.[50] Neither of these studies described whether these events required intervention.

Five case series described rates of leakage and the need for subsequent management in greater detail.[27, 33, 37, 95] Milliken et al. (n=17) reported four significant leaks in their case series,[12] one resolving spontaneously and three managed by switching to a shorter button.[33] Galati et al. (n=33) reported two patients experienced a leak, which was resolved with resizing.[27] Cobussen-Boekhorst (n=9) reported that one patient included in their series had a leak which required replacement of the vesicostomy button.[95] Varik et al. (n=29) reported eight patients experienced leakage which 'mostly resolved' with balloon adjustment, though one required re-siting.[37] Mosiello et al. (n=35) noted that one patient experienced leakage which resulted in the removal of the button due to UTI associated with button site leakage after a mean follow up of 37 months.[12]

All studies which reported leakage included some patients with a history of previous vesicostomy or suprapubic catheter, however it was often not clear whether leakage was more common in those with these prior management interventions. One case series by Hitchcock et al. (n=21) specified that leakage only occurred in four patients; three placed through an open vesicostomy site, and one where a previously established suprapubic tract was used.[10] No leaks occurred in the 17 patients who had a standard button stoma. Similarly, Nast et al. reported seven patients in their series had a previous vesicostomy, five of which developed a leak.[38] However, there were no leaks in patients with endoscopic placement.

4.3.11 Device or procedure failures

Device- or procedure-related issues were reported inconsistently across the included case series, with many studies reporting no failures or not reporting this outcome explicitly. Where reported, failure events were heterogeneous and included mechanical malfunction, encrustation, blockage, dislodgement, retention of the device in the neck of the bladder, unplanned exchange or revision, and difficulties with the drainage tubing or lithiasis (formation of stones within the bladder due to the presence of the device).

Four case series reported no device failures during follow-up.[8, 33, 86, 94] de Badiola et al. (n=3) reported no encrustation or stone formation over follow-up periods of up to 22 months, but did not comment more widely on device or procedure issues.[8] Martin-Crespo Izquierdo et al. (n=13), Milliken et al. (n=17), and Pellegrino et al. (n=4) reported no device-related failures, and all had variable follow-up durations ranging from months to several years.[33, 86, 94]

Six case series did report device- or procedure-related issues. Encrustation was reported in two case series. Bradshaw (n=30) reported one case of a blockage due to device failure and Varik et al. (n=29) reported two cases of blockage due to encrustation. The length of time these buttons were *in-situ* was unclear.[11, 37]

Nast et al. (n=13) reported three cases of button malfunction within 30 days of placement which included dislodgement (n=1), leakage requiring revision (n=1), and tubing difficulty (n=1).[38] Mosiello et al. (n=35) reported one case of lithiasis and one case of button-related skin ulceration requiring revision and removal,[12] while Lacreuse et al. (n=21) reported one case of lithiasis and one case of device-related retention.[50] Hitchcock (n=21) reported one case of 'button exchange failure' and one case of mild encrustation.[10]

4.3.12 Patient and carer satisfaction

Patient or parent satisfaction was reported in nine of the 14 case series; however, only one study conducted a formal health-related quality-of-life (HRQoL) comparison. Nast et al. (n=13) modified a validated HRQoL questionnaire (Intermittent Self-Catheterisation-Questionnaire, ISC-Q) and administered it to eight patients or their family during a scheduled clinic visit. The reasons for excluding the other five patients receiving vesicostomies were not specified. This modified self-report survey evaluates four domains: ease of use, convenience, discreetness and psychological well-being. Patients receiving the vesicostomy button were matched to six patients who received CIC based on age and sex. No statistically significant difference was observed in any quality-of-life domains or overall mean score (69.8 versus 72.3, p=0.65). This case series likely lacked the statistical power to detect any potential differences, and this issue was compounded by the fact patients were not matched on a 1:1 basis, with only six controls for the eight patients that received a vesicostomy button. The statistical methods were not described, and it is unclear whether matching was accounted for in their analyses. Additionally, five ISC-Q items relating to the single nature of the urethral catheter were removed and remaining questions were amended to reference the MIC-KEY® device rather than urethral catheters, which may compromise applicability of the original questionnaire's validation.

The remaining eight studies referenced satisfaction briefly in results or discussion sections, without reporting formal methods such as questionnaires or interviews. Mosiello et al. (n=35) reported that "all current users" (n=22) were satisfied and noted patients believed that the button improved quality of life. Galati et al. (n=33) reported that 31 patients (94%) were satisfied with at-home management of the vesicostomy button, while the remaining two patients later transitioned to and accepted CIC.

Bradshaw et al. (n=30) reported that the buttons were well tolerated, with no early removals and families describing a perceived improvement in flexibility. Some families (n=7) requested to keep the buttons, however the rationale for this or alternative management being presented to patients was not explained. Hitchcock et al. (n=21) reported that management was accepted by "almost all patients", with one patient initially having difficulties but subsequently succeeding. The authors also state that button drainage was easy.

Lacreuse et al. (n=10) initially reported that "patients and parents were satisfied", however when later reporting on the expanded series (n=21) they noted that 13 patients were satisfied and five unsatisfied. The remaining three patients had their buttons rapidly removed due to complications; however, satisfaction was not explicitly reported in these patients. Milliken et al. (n=17) reported that all patients, "especially the older children, believed the button gave them an improved quality of life".

4.3.13 Authors conclusion on effectiveness and safety

In the authors conclusions, six studies mention that button vesicostomy is 'safe'[11, 12, 37, 51, 52, 94] or has a relatively low rate of complications.[27] It is described as 'suitable',[11] 'successful',[95] 'effective',[10, 12, 27, 52, 94] 'useful'[8] or 'an improvement' [86, 93] in terms of bladder management in certain patient groups and is often described as an alternative when CIC is not possible or declined.[10-12, 37, 50, 94, 95] Many of the authors stated vesicostomy buttons were a 'temporary'[8, 10-12, 37, 95] or short-to-medium term solution[11] or emphasised the need for additional studies to evaluate its use long-term.[27, 52] Two studies suggested vesicostomy buttons could be considered for use short and long term in appropriately selected patients.[33, 37]

Lacreuse et al. included particular patient groups that the device could be considered for (such as in cases of CISC intolerance or after failure of another urinary diversion), but also stated that they were hesitant to recommend its use during infancy when the urinary tract seems to be a high-pressure, low capacity system with poor compliance.[50]

Although only one study formally assessed quality of life,[38] four studies commented in their conclusions that receiving a vesicostomy button has improved the quality of life of the patients.[12, 38, 52, 93]

5 Discussion

Following a request from the Minister for Health, the Health Information and Quality Authority (HIQA) agreed to undertake a rapid Health Technology Assessment (HTA) on the use of vesicostomy buttons in children. This rapid HTA report provides a description of the technology, a summary of the epidemiology and burden of the disease and a systematic review of the clinical effectiveness and safety of the use of vesicostomy buttons in children with urine storage and bladder emptying problems.

As described in Chapter 2, the vesicostomy button is a modified version of the gastrostomy button (which is made from medical-grade silicone), originally designed for enteral feeding, that has been repurposed for urinary use. It was first described for bladder emptying in 1996, and two devices are currently in use, the MiniONE® (Applied Medical Technologies) and MIC-KEY® (Avanos Medical). In both cases they are being used 'off-label' for this indication. Other management options for bladder emptying problems (aside from the use of the vesicostomy button) may include clean intermittent catheterisation (CIC), indwelling catheterisation, suprapubic catheterisation, open vesicostomy (that is vesicostomy without a button) and Mitrofanoff diversion.

As outlined in Chapter 3, there are three key congenital paediatric conditions which commonly lead to urine storage and bladder emptying problems: neurogenic bladder, anorectal malformations and posterior urethral valves. These conditions can lead to urinary problems including urgency, recurrent urinary tract infections (UTIs), incontinence, difficulties passing urine and if not treated promptly, can lead to damage to the kidneys, including chronic kidney disease.

5.1 Summary of the clinical effectiveness and safety evidence

The evidence base for the clinical effectiveness and safety of vesicostomy buttons in children, as identified by this systematic review, was very limited; this comprised 14 case series of varying reporting quality, and included a total of 244 patients. Four clinical guidelines and one expert consensus statement were also identified, each containing a very small amount of information related to the use of vesicostomy buttons in children. This low volume of literature, despite a broad set of inclusion criteria for the review with respect to study design, reflects the fact that the use of vesicostomy buttons is uncommon.

The 14 case series included in this review varied considerably in terms of the clinical characteristics of patients included and previous management for bladder emptying problems. Similarly, reporting of the clinical effectiveness of vesicostomy buttons differed notably between studies. Reported outcomes included the number of patients who: became toilet-trained; transitioned to other management options, for

example, CIC; or showed improvements in bladder stability, emptying or intravesical pressure. While the reports varied in terms of the numbers of patients who achieved a successful outcome, bearing in mind the variety in clinical characteristics of the included patients, six case series appeared to report generally positive outcomes related to bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence.

Various adverse events were reported by the included case series, including UTIs, local infections and tissue reactions, and leakage from the vesicostomy site. However, no serious safety concerns were noted. Patient or parent satisfaction was reported in nine case series, however only one study formally evaluated quality of life using a validated tool. Overall, the reported patient and parent satisfaction was positive and the vesicostomy buttons appeared to be generally well tolerated by patients.

5.2 Interpretation of the clinical effectiveness and safety evidence

With regard to comparing to the effectiveness of other interventions used for bladder emptying problems, it is not possible to draw definitive conclusions on the relative effectiveness of vesicostomy buttons based on the current evidence base. All of the effectiveness literature identified was non-comparative in nature, and despite the inclusion criteria for the review incorporating all clinical study designs, only 14 studies were identified. Further, clinical characteristics, previous interventions for management of bladder emptying, and reported outcomes varied considerably. It was not possible to attribute outcomes solely to the use of the vesicostomy button, and it is not clear whether the rates of beneficial or adverse outcomes would have been higher or lower in those who received an alternative intervention such as suprapubic catheterisation, open vesicostomy, CIC or Mitrofanoff diversion.

With regard to safety, this review did not identify any serious safety concerns raised in the literature since the initial reported use of vesicostomy buttons in 1996. The adverse events identified are also consistent with the risks and harms associated with some of the alternative management options for urine storage and bladder emptying problems, for example, the suprapubic catheter. It is also important to note that some adverse events, for example, UTIs, may be attributed to the patients' underlying clinical conditions, rather than being related to the use of the vesicostomy button.

The case series included in this systematic review demonstrated that vesicostomy buttons have been used for both short- and long-term bladder management; where the button remained *in situ* at the time of reporting it did not necessarily denote either a good or a poor outcome. The timing and selection of surgical interventions

for children with urine storage and bladder emptying problems is an important consideration, particularly given the irreversible nature of permanent procedures and the potential for bladder function to improve over time. In this context, vesicostomy buttons provide a continent, reversible option for urine storage and bladder emptying problems in some children in whom other management options are limited or not preferred by patients and carers. In this way, damage to the urinary system is avoided, while preserving future management options, including the potential for spontaneous voiding.[11, 37] Varik et al. reported the use of vesicostomy buttons as a safe second-line option in 29 children unable to perform CIC.[37] In their cohort, nine patients had the vesicostomy button removed after a median of 4.5 years, following resolution of an underlying condition, and achieved effective urethral voiding, while 14 required ongoing drainage and six progressed to Mitrofanoff diversion. Similarly, Bradshaw et al. noted that in their cohort of 30 patients, a vesicostomy button was used with the intention of providing a temporary solution, with 23 children having the vesicostomy button removed after a median duration of 11 months.[11] Of these 23 children, 10 regained adequate urethral voiding, eight successfully transitioned to CIC, and four underwent definitive Mitrofanoff diversion surgery; while it was determined one child should remain with a freely-draining open vesicostomy.

Separate to the studies identified within this review which examined use in children, a small number of studies reporting on the use of vesicostomy buttons in adults have also been published; each had a small sample size. A prospective pilot study published by Chong et al. evaluating 15 adults with indwelling suprapubic catheters who were converted to vesicostomy buttons found an improvement in catheter-related quality of life scores three months following the conversion procedure.[96] A pilot study published by Bennett et al. evaluated 19 adults with neurogenic bladder who had vesicostomy buttons inserted and completed a quality of life questionnaire at the end of each clinic visit (mean follow-up: 19 months; range: 11-51 months).[97] The authors reported that the vesicostomy button approach was safe and effective and of for all of the nine patients who completed the study, overall quality of life was improved.

Similarly, the findings of this systematic review indicate that vesicostomy buttons provide a continent alternative to open vesicostomy, offering positive patient and carer satisfaction in select children.[11, 38] Further, it is noteworthy that vesicostomy buttons represent a more discreet, low-profile management option and may enhance social comfort and confidence. For example, they allow children to participate in activities, such as sports and swimming, and enable them to wear regular underwear, which patients and carers may prefer over open vesicostomy.

5.3 Strengths and limitations of this rapid HTA

This rapid HTA has several strengths. The systematic search of the clinical effectiveness and safety of vesicostomy buttons was robust and comprehensive, and is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[89] An Expert Advisory Group (EAG) comprising key stakeholders, was convened to support the assessment. All chapters were updated following review by the EAG. Additionally, the technical characteristics of the MiniOne® and MIC-KEY® devices were submitted for review by the relevant manufacturers and distributor in Ireland to ensure that the devices were accurately described.

However, the limited evidence base underpinning the clinical effectiveness and safety of vesicostomy buttons in children restricted the ability to draw definitive conclusions about the clinical effectiveness and safety of vesicostomy buttons relative to alternative management options. The quality of effectiveness evidence identified was very low, comprising 14 studies, each with a small number of patients, all of which were non-comparative case series. The varied reporting of key characteristics and outcomes across the studies, further limited the ability to aggregate findings. While larger comparative studies would help to establish the effectiveness and safety of vesicostomy buttons relative to other management options, given the rarity of its use, such studies may not be feasible. By way of illustration, the largest case series identified in this review included all of the patients who had a vesicostomy button inserted over a six-year period in a single institution and still included only 35 patients.

As outlined in Section 2.6, four clinical guidelines, and one consensus statement relating to the use of vesicostomy buttons in children were also identified during this rapid HTA. While these reports indicated that vesicostomy buttons may be used as an alternative management option in children with urine storage and bladder emptying problems, no clear criteria were provided regarding which groups of patients are likely to benefit from them.

5.4 Use of medical devices outside of their instructions for use

This rapid HTA considered a medical device which is being used outside of the manufacturer's instructions for use; this is commonly known as 'off-label' use. At present, all vesicostomy button procedures require the use of devices outside of their manufacturer's instructions for use. The need for 'off-label' use of devices has a long history, and occurs commonly where alternatives are limited, particularly in medical specialties such as surgery and paediatrics.[98, 99] This is at least in part due

to the lack of commercially available alternatives for rare diseases or certain paediatric indications where devices are needed in low numbers.

In the surgical setting, for example, the first metal stents used to treat arterial stenosis were originally only approved for use in the biliary tree (in the abdomen) to relieve jaundice.[100] Similarly, Foley catheters, which are licensed for urinary use, can also be used 'off-label'; in some circumstances instead of gastrostomy or jejunostomy tubes for delivering nutrition and or enteral feeding or to administer enemas via a stoma.[101]

Advantages to this 'off-label' use include ready availability of the device being used 'off-label', lower cost and ease of insertion.[102] 'Off-label' use of devices may also allow clinicians to address patient needs for which there are no suitable available alternatives on the market. In the paediatric setting, a single-institution retrospective review of all routine interventional cardiology procedures over a three-year period (2005-2008) found that 63% of their 473 paediatric patients underwent procedures using approved medical devices, but for 'off-label' indications.[103] However, the available safety and effectiveness data is not sufficient to make meaningful conclusions, and this can increase safety risks to patients.[53, 62]

The case series and guidelines identified in this systematic review illustrate that the 'off-label' use of gastrostomy buttons in this setting (for their use as vesicostomy buttons) has an established history of use in specific sets of circumstances.[11, 37] Notwithstanding the findings of this systematic review, any 'off-label' use of medical devices merits consideration of controlled risk management processes, clear governance structures, and fully informed consent in accordance with legislation and the best available evidence. HIQA has previously issued recommendations at a national level to the Health Service Executive (HSE) and to Children's Health Ireland (CHI), following an independent review of governance at CHI in relation to the use of implantable medical devices.[104] The report noted that all healthcare services should consider its findings and recommendations and use them as learnings to formally review and where necessary improve their governance and oversight of the introduction and use of medical devices, including surgical implants. Consideration of these recommendations should also take into account the National Standards for Safer Better Healthcare. When medical devices are used 'off-label', it is important that patients or their caregivers are informed of this. During the scoping phase of this rapid HTA, a small number of patient and caregiver information leaflets were identified. One of these, from the UK, provides an example of how a clear explanation of 'off-label' use can be provided to patients and their caregivers, directly informing them that vesicostomy buttons are being used in this setting.[15] Members of the EAG representing Children's Health Ireland indicated that patient

and carer information leaflets are also used in their centres as part of the information-giving process.

5.5 Conclusion

This rapid HTA was conducted in response to a request from the Minister for Health seeking a review of the clinical effectiveness and safety of the use of vesicostomy buttons in children. The evidence identified in this systematic review is limited to 14 case series with small sample sizes. In addition, four clinical guidelines and one consensus statement relating to the use of vesicostomy buttons in children were identified, each of which provided very limited information. Given the limitations of this evidence base, it is not possible to draw definitive conclusions regarding the clinical effectiveness and safety of vesicostomy button use in children relative to alternative management options. However, no serious safety concerns were noted and generally positive outcomes are reported in relation to bladder emptying, effects on the upper urinary tract, and the use of incontinence products or progression to toileting and continence. Patient and carer satisfaction were positive overall, and vesicostomy buttons appeared to be well tolerated. Further, it is noteworthy that vesicostomy buttons represent a more discreet, low-profile management option and may enhance social comfort and confidence. For example, they allow children to participate in activities, such as sports and swimming, and enable them to wear regular underwear, which patients and carers may prefer over open vesicostomy.

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Temple Street: A statutory review conducted under Section 8 of the Health Act 2007 (as amended) 2025.

7 Appendix

Appendix A: Search strategies

Grey Literature search

Table A1 Organisations and links for grey literature search

Organisation type	Link to URL
Guideline Central	https://www.guidelinecentral.com/
Guidelines International Network international guideline library and registry of guidelines	https://g-i-n.net/international-guidelines-library
International HTA database	https://database.inahta.org/
MAGIC Evidence Ecosystem Foundation	https://app.magicapp.org/#/guidelines
Trip Database	https://www.tripdatabase.com/
UpToDate	https://www.uptodate.com/contents/search?search=guidelines

Database search strategies

Complete documentation of all search strategies for this project can be found on the Zenodo open repository: https://doi.org/10.5281/zenodo.18875842

Table A2 Example database search - MEDLINE

Database name	Date search was run
MEDLINE Complete via EBSCO	20 October 2025

#	Query	Limiters/Expanders	Last Run Via	Results
S4	S1 OR S2 OR S3	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	65
S3	XB (("mic key" OR mic-key OR mini OR minione OR mini-one) N3 (gastronomy OR button*)	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	47
S2	XB button* N1 gastrostomy AND XB (bladder OR urin*)	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	8
S1	XB (button* N1 (vesicostomy OR cystostomy))	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	17

Appendix B: Additional data

Table A3 Reported diagnoses and conditions of patients receiving vesicostomy buttons

Diagnosis or general condition not otherwise specified	Count
Anorectal malformation	21
AQP2 Gene Mutation	1
Bardet Biedl Syndrome	1
Beals Auriculo-Osteodysplasia Syndrome	1
Bilateral megaureter	1
Bilateral Obstructive Ureteroceles	2
Bladder dysfunction †	6
Bladder evacuation disorder	1
Bladder outlet obstruction †	10
Bladder reconstruction/diversions †	4
Bladder wall trabeculation †	4
Cauda Equina Regression Syndrome	3
Cerebral palsy	6
Cloaca anomaly/urogenital sinus	6
Congenital hypothyroidism	1
Congenital/Idiopathic Hypotonic Bladder †	15
Constipation & extreme toilet fear	1
Cranial trauma	2
Craniopagus Twin	1
Currarino Syndrome	1
Diabetes Insipidus	4
DIDMOAD Syndrome	2
Double Ectopic Ureteroceles	2
Down Syndrome	2

Duckett Syndrome	1
Encephalopathy	6
Exstrophy	4
Gangliosidosis II	1
Genetic conditions †	5
Hinman Syndrome	3
Hydrocephalus	1
Hydroureteronephrosis/hydronephrosis	9
Idiopathic functional bladder disorder	2
Impaired renal function †	5
Lipomeningocele	1
Mckusick Kaufman Syndrome	1
Megacystis	1
Megacystis Microcolon Syndrome	5
Meningitis	1
Menkes Syndrome	2
Microcephaly	4
Mowar-Wilson Syndrome	1
Multiple congenital abnormalities †	1
Myelum cyst	1
Neonatal Medullar Ischemia	2
Neuroblastoma	1
Neurofibromatosis	3
Neurogenic bladder †	22
Neurogenic bladder unknown origin	1
Neurologic disease †	5
No diagnosis specified	3
Non-Neurogenic Neurogenic Bladder	11

Osler-Weber-Rendu Syndrome	1
Pelvic-Ureteric Junction Stenosis	1
Polytrauma	1
Posterior Urethral Valve	15
Posterior Urethral Valve Syndrome	12
Posterior urethritis	3
Post-obstructive large utricle	1
Post-obstructive urethral hypoplasia	1
Prune Belly Syndrome	3
Renal agenesis	1
Rhabdomyosarcoma/pelvic tumour	6
Sacrococcygeal Agenesia	3
SMA Type 1	1
Spina Bifida (inc. Myelomeningocele)	24
Spinal cord injury/compression	3
Spinal Dysraphism	15
Temporary sideration (Surgery)	4
Tetraplegia	6
Traumatic urethral rupture	1
Urinary retention of unknown origin	4
Valve bladders †	5
VATER/VACTERL association	3
Vesicoureteral Reflux	17
Visceral myopathy	2
Wolf-Hirschhorn Syndrome	2

Key: DIDMOAD – Diabetes Insipidus, Diabetes Mellitus, Optic Atrophy, Deafness; SMA – Spinal Muscular Atrophy; †– not otherwise specified

Note: Information on diagnoses in Lacreuse 2012 supplemented with information from Lacreuse 2010. Where the underlying diagnosis was not specified, patients were categorised according to the general description of the clinical condition (for example, neurogenic bladder).

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