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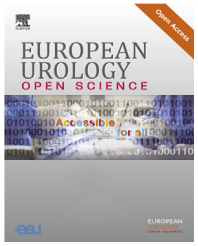

European Association of Urology

Education

Intravesical Injection of Bulking Agents: Validation of the Ghent University Hospital Porcine Teaching Model

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Abstract

Background and objective: Intravesical injection of bulking agents is an endoscopic treatment for vesicoureteral reflux (VUR) in children. The success of the procedure depends on the surgical technique; yet, few validated simulators exist for training. This study aimed to assess the face and content validity of a porcine bladder model for training in endoscopic VUR correction.

Methods: The Ghent University Hospital endoscopic reflux correction simulator, an ex vivo porcine bladder, was developed. Dextranomer/hyaluronic acid (Dx/HA) was used for bilateral subureteric injection. Participants from the 2022 European Society for Paediatric Urology Congress in Belgium completed a questionnaire evaluating the model's realism (face validity) and training effectiveness (content validity). Differences between experts and nonexperts were analyzed using the Mann-Whitney *U* test ($p \leq 0.05$).

Key findings and limitations: A total of 39 participants (12 experts and 27 nonexperts) evaluated the model, including urologists (53.8%), surgical trainees (35.9%), and pediatric surgeons (12.8%). The simulator showed high face validity, with a median Likert score of 5/5. The experts rated the realism significantly higher than the nonexperts ($p = 0.011$). The experts also rated content validity highly (median Likert score 5/5). Both groups agreed that the model should be included in training curricula for residents (92.3%), fellows (82%), and novice surgeons (59%).

Conclusions and clinical implications: The Ghent University Hospital porcine bladder model closely mimics a human bladder and is considered valuable for teaching

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the Dx/HA procedure. Further studies should examine whether this leads to clinically meaningful improvements in skill performance.

Patient summary: A high fidelity simulator is developed and validated in this study to improve surgical skills in endoscopic correction of vesicoureteral reflux, thereby improving patient outcomes.

1. Introduction

Vesicoureteral reflux (VUR) is one of the most common urologic anomalies affecting children, with an incidence of approximately 1% in the general pediatric population and up to 30–50% among children with a history of urinary tract infection [1]. Over recent decades, endoscopic injection of bulking agents has emerged as an effective alternative to long-term antibiotic prophylaxis and open surgical intervention for the management of VUR. During this minimally invasive procedure, a bulking agent is injected below the ureteric orifice to elevate the distal ureter and lengthen the submucosal tunnel. When the injection is performed correctly, it narrows the ureteral lumen and improves coaptation, thereby reducing reflux [2]. A meta-analysis involving 5527 patients and 8101 renal units reported an overall success rate of 85% following one or more injections [3]. However, success rates are lower in patients with duplicated systems, neuropathic bladders, or high-grade reflux [3,4]. Besides patient-related factors, outcomes are also highly operator dependent [4–6]. Endoscopic correction of VUR is a precise procedure that requires injection of 1–3 ml of dextranomer/hyaluronic acid (Dx/HA) into a small, delicate area of tissue using a fine needle put in the correct axis and angle. Given the limited margin for error and the minimal opportunity for intraoperative correction, surgical technique is paramount. Dalkiliç et al [7] demonstrated that a minimum of 20–35 endoscopic subureteric injections are required to achieve acceptable success rates, underscoring the steep learning curve for this procedure. Training with adequate feedback is essential for skill acquisition and refinement, but remains challenging. The traditional Halstedian method of "see one, do one, teach one" is increasingly regarded as outdated [8]. Historically, training programs have consisted of didactics, instructional videos, operating theatre assistance, and direct surgical performance. However, these methods are now being supplemented with hands-on dry and wet lab training, as well as simulation-based education. These training tools offer a controlled, pressure-free environment where trainees can refine their surgical skills repetitively without imposing any risk to patients [9–11]. Despite these advantages, the link between simulator-based training and improved surgical performance requires structured validation. Validity is defined as "the property of being true, correct, and in conformity with reality" [12]. For pediatric endoscopic urologic procedures, the face and content validity of ex vivo training models has seldom been evaluated systematically. The primary aim of this study was to validate the Ghent University Hospital model for training in endoscopic VUR correction. Specifically, this study assessed the model's realism (face validity) and its utility for skill acquisition (content validity). If validated, the teaching model could become an integral component of competency-based training curricula, ultimately improving patient safety.

2. Patients and methods

2.1. Participants

In this study, participants were recruited voluntarily from delegates attending the annual European Society for Paediatric Urology Congress on June 9, 2022, in Ghent, Belgium. Delegates represented institutions from across the globe. Participants were categorized based on their self-reported experience with the Deflux procedure (total number of cases performed) into three groups: novices, intermediates, and experts. The novice group included individuals with no prior experience in Deflux surgery. The intermediate group consisted of those who had performed one to 50 procedures, while the expert group included participants with experience exceeding 50 procedures. For analysis purposes, both novices and intermediates were classified as nonexperts. This study was conducted in compliance with the general terms and conditions of the Ethics Committee of University Hospital of Ghent (B6702022000196).

2.2. Protocol

Each delegate received an introductory explanation of the study's purpose before proceeding to theoretical warm-up instructions given by the local faculty (E.V.D., M.W., and J. V.D.J.). This was followed by a brief video demonstration of the procedure. Participants were then given several minutes to familiarize themselves with the Ghent University Hospital model. The task involved performing a cystoscopy and bilateral injection of the nonanimal stabilized Dx/HA bulking agent (Deflux) just below both the ureteral orifices in a single porcine bladder. For the injection technique, the STING method originally described by Puri and O'Donnell [13] was utilized. Participants were allocated 20 min to complete the procedure. Throughout the technical training sessions, proctors from both local (E.V.L., C.J., and A.F.S.) and international (R.S. and M.P.) faculties were available to provide one-to-one guidance. Upon completion of the procedure, participants were asked to fill out a comprehensive questionnaire to collect demographic data and provide feedback on the simulator (Supplementary material). The questionnaire was divided into two sections: the first col-

lected demographics and prior cystoscopy experience, while the second contained 19 simulation-related metrics. Metrics 1–6 evaluated face validity, metrics 7–10 assessed learning content, and metrics 11–19 focused on the simulator's overall value as a training tool. Participants rated their level of agreement with each statement using a 5-point Likert scale, where a score of 5 represented strong agreement or a highly acceptable assessment, and a score of 0 corresponded to total disagreement or unacceptability.

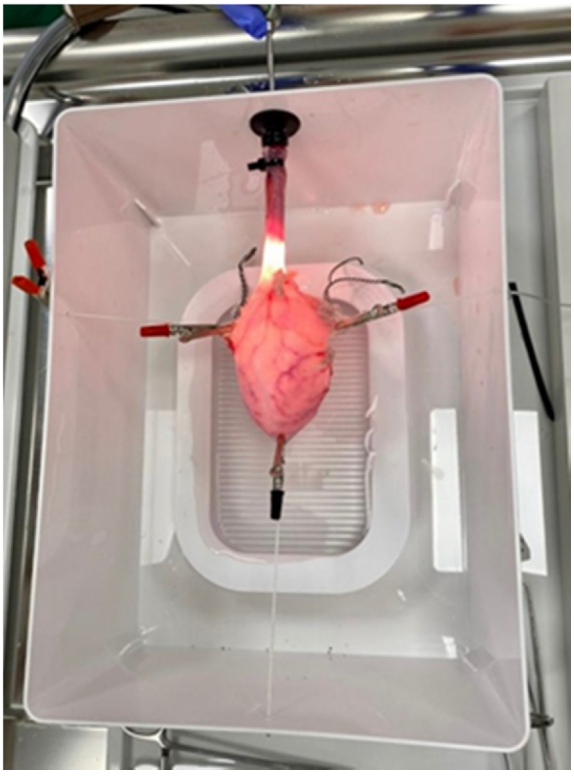

Fig. 1 – Porcine bladder mounted in a plastic box.

2.3. Simulator

The simulator featured a dissected ex vivo porcine bladder mounted in a plastic box (Fig. 1). These bladders were harvested from a local slaughterhouse following strict protocols, then vacuum sealed and frozen for storage. The bladder model included a bladder with an attached urethra and two ureters, both ligated with sutures. An opening was created at the base of the box to externalize the urethra. A pediatric cystoscope, (9.5 Fr; Karl Storz, Tuttlingen, Germany) including irrigation, light, and a digital camera, was used for the procedure. The injection was carried out using a Deflux metal needle and a single-use disposable syringe containing the bulking agent Dx/HA (Deflux injectable gel).

2.4. Outcome

The hypothesis was that the simulator would demonstrate both good face and good content validity. Face validity refers to the degree of resemblance between a concept instrument (simulator) and the real organ (pediatric bladder). Content validity relates to how effectively the simulator's training content represents the skills and knowledge required for performing endoscopic Dx/HA injections. Face validity is judged by any type of user, while content validity is based on experts' opinions only. Data were collected prospectively and analyzed using the statistical software package SPSS 29.0 (SPSS Inc. Chicago, IL, USA). Results were reported as median and range for each statement, stratified by experience. Differences in ratings between experts and nonexperts were analyzed using the Mann-Whitney *U* test, with a p value of $\leq$0.05 considered statistically significant. A post hoc analysis was performed comparing the expert and nonexpert groups to assess group differences using the Mann-Whitney *U* test.

3. Results

3.1. Participants' demographics

A total of 39 participants were included in this study. Of them, 25 were male (64.1%), 13 were female (33.3%), and

Table 1 – Participant demographics and Dx/HA experience

	Novice	Intermediate	Expert	Total
Participants, *n* (%)	11 (28.2)	16 (41)	12 (30.8)	39 (100)
Position, *n* (%)				
Medical student	2	0	0	2 (5.1)
Resident/trainee	3	3	1	7 (17.9)
Fellow	1	1	1	3 (7.8)
Urologic surgeon	5	8	8	21 (53.8)
Pediatric surgeon	0	3	2	5 (12.8)
Other	0	1	0	1 (2.6)
Age (yr), median (range)	32 (24–42)	36.5 (29–44)	51 (28–80)	37 (24–80)
Gender, *n* (%)				
Male	4	9	12	25 (64.1)
Female	7	6	0	13 (33.3)
X	0	1	0	1 (2.6)
Hospital type, *n* (%)				
Academic	7	12	10	29 (74.4)
Nonacademic	3	4	2	9 (23.1)
Public	9	14	10	33 (84.6)
Private	1	2	2	5 (12.8)
Missing	1	0	0	1 (2.6)

Dx/HA = dextranomer/hyaluronic acid.

one was identified as X-gender (2.6%). The majority of participants were certified urologists (53.8%), followed by pediatric surgeons (12.8%) and residents (17.9%). Twelve participants (30.8%) reported having performed >50 Dx/HA procedures, classifying them as the expert group. The median age of the expert group was 51 (range 28–80) yr. Additional demographic details are presented in Table 1.

3.2. Face validity

All participants completed the questionnaire. Overall, the simulator was rated as highly realistic (face validity), with a median Likert score of 5/5. Trainees' subjective scores (median) for separate metrics are presented in Fig. 2. Among the evaluated aspects, visual feedback and preoperative setup were perceived as most realistic, as, respectively, 82% and 72% of the group scored 5/5.

When face validity assessment was stratified by level of experience, experts rated the cystoscopic experience and overall realism of the simulator significantly higher than nonexperts (p = 0.009 and p = 0.011, respectively), as detailed in Table 2.

3.3. Content validity

When expert surgeons were asked whether the porcine model effectively simulates the real Dx/HA procedure (content validity), they strongly agreed, assigning a median Likert score of 5/5. The model's efficacy in simulating key aspects, such as eye-hand coordination, depth perception, successful resolution of VUR, and reproducibility, was also rated with a median Likert score of 5/5 (Fig. 3).

3.4. Overall

At the end of the questionnaire, general statements regarding the simulator's usefulness for trainees were evaluated. Both experts and nonexperts agreed that the model should be incorporated into the training curriculum for residents (92.3% of participants), fellows (82%), and novice surgeons (59%), but not for medical students (15.4%).

3.5. Power analysis

For a power of 80% and a significance level (α) of 0.05, using the Mann-Whitney U test to compare expert versus nonex-

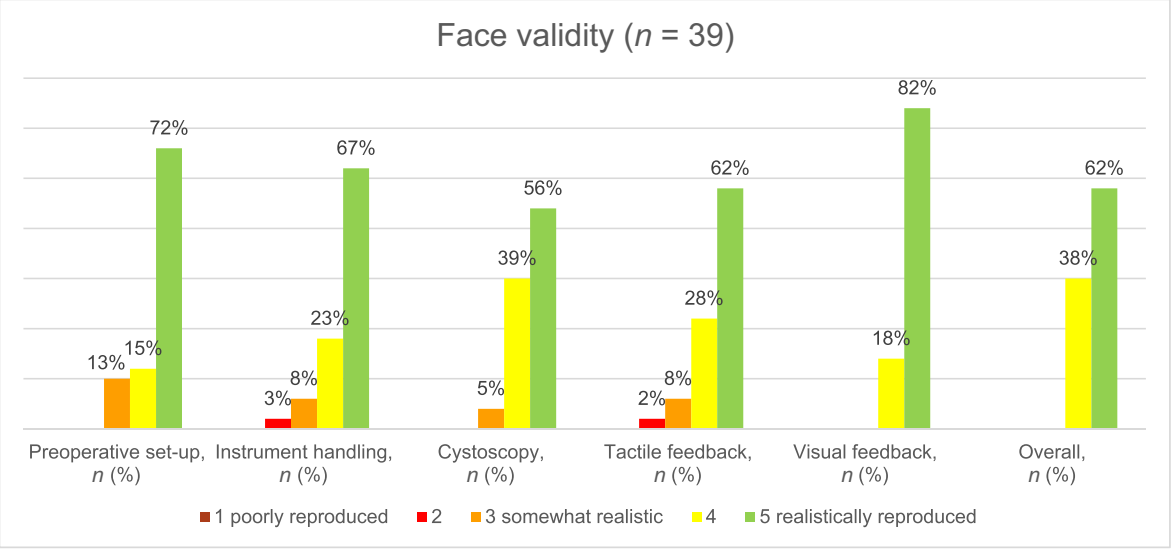

Fig. 2 – Face validity assessment in the overall group.

Table 2 – Subgroup analysis (expert vs nonexpert) of face validity assessment

Face validity statement	Median score (range)			p value [a]
	Expert (n = 12)	Nonexpert (n = 27)	Overall (n = 39)	
Preoperative setup	5 (4–5)	5 (3–5)	5 (3–5)	0.059
Instrument handling and ergonomics	5 (3–5)	5 (2–5)	5 (2–5)	0.475
Cystoscopy experience	5 (3–5)	4 (3–5)	5 (3–5)	0.009
Tissue handling and tactile feedback	5 (4–5)	5 (2–5)	5 (2–5)	0.052
Visual feedback	5 (4–5)	5 (4–5)	4 (4–5)	0.303
Overall realism	5 (4–5)	4 (4–5)	5 (4–5)	0.011

[a] As measured by the Mann-Whitney U test.

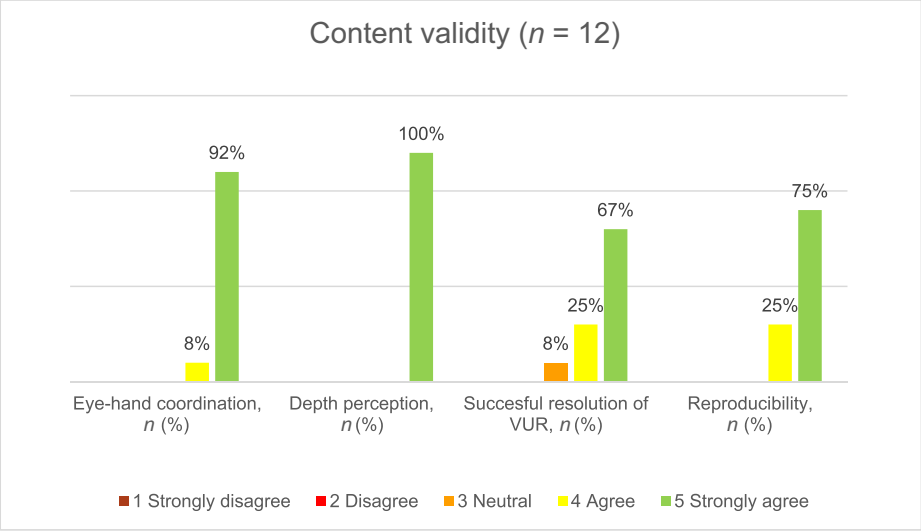

Fig. 3 – Content validity assessment in the expert group. VUR = vesicoureteral reflux.

pert groups, a post hoc power analysis indicated that approximately 40–50 participants per group would be required to achieve sufficient power.

4. Discussion

In this study, we demonstrated that the Ghent University Hospital porcine bladder model shows an overall high value as a training modality for endoscopic VUR treatment in children.

4.1. Simulation-based education

As Aristotle said, "We are what we repeatedly do. Excellence, then, is not an act, but a habit," emphasizing that training is the cornerstone of achievement. When applied to urologists, this means that comprehensive training is essential to master safe and effective surgery. The evolving surgical landscape has moved away from the traditional Haldestian apprenticeship-based model due to practical, legal, and ethical considerations. Regulatory constraints have significantly reduced the working hours of hospital doctors, which impaired the development of consistent trainer-trainee relationships and limited opportunities for novice surgeons to gain hands-on experience in the operating room. The field of medical technology is moving fast, creating steep learning curves for surgeons to achieve proficiency in surgical procedures. Increased emphasis on patient safety, coupled with rising patient expectations, has further intensified the demands on health care providers' competencies.

In response to these challenges, there is an ongoing search for effective skill acquisition methods outside the immediate clinical environment. Simulation-based education offers a competency-based approach to develop both technical and nontechnical skills in a controlled, patient-safe setting. It provides trainees with greater confidence, fostering competencies that help prevent or address procedural complications. Errors can be made, learned from, and reflected upon without causing harm to any patient [9–11,14]. Programs such as the European Basic Laparoscopic Urological Skills (E-BLUS) course reflect the widespread recognition of simulation's value in urologic training [15].

In endourology, simulators have emerged in various forms, including virtual reality (VR) trainers, three-dimensional (3D) printed models, and ex vivo models [9,11]. One popular device is the UroMentor (UM; Simbionix, Cleveland, OH, USA), a computerized platform that creates high-fidelity animations of the bladder, ureter, and kidney, combined with an intelligent tutoring system. Trainees using the UM demonstrated significantly faster procedure times (511 ± 67 vs 111 ± 10 s, $p < 0.001$), fewer iatrogenic injuries (12 ± 2 vs 5 ± 1, $p < 0.001$), and better overall performance (1.3 ± 0.2 vs 3.9 ± 0.2 points, $p < 0.001$) than first-time operators [16]. Owing to the $85 000 cost per UM, several study groups have investigated methods to optimize its usage. Persoon et al [17] reported that trainees showed greater surgical confidence and perceived higher value in the UM after first practicing on a low-cost, simple model made from a glass food container.

4.2. Validated training in Dx/HA procedure

Despite the availability of various endoscopy simulators, validated training tools for cystoscopic treatment of VUR remain scarce. In 2011, Bauschard and colleagues [18] introduced the cystoscopy and endoscopy virtual learning method, which utilized static and interactive visuals for training in the Dx/HA procedure, although it has not been adopted widely. Additionally, Escolino et al [19] developed a 3D bioprinted model for Dx/HA training. By using this Fish Tank Simulation Model, 50% of all experienced surgeons and 45.4% of all novices perceived the creation of the ureter mound as satisfactory, showing moderate content validity. While they promote its cost effectiveness due to the reusability, the model loses user friendliness due to the continuous need for manual water removal. Furthermore, few ex vivo bladder models have been developed. Grimsby

et al [20] introduced the first boar bladder model, although it lacked validated benchmarks. More recently, Soltani et al [5] presented a porcine bladder-based Dx/HA injection simulator. In this validation study, 11 fellows and residents underwent a 2-h supervised hands-on session on the model. Skill improvement was significant (56% first attempt vs 92% last attempt, $p = 0.008$), demonstrating concurrent validity. The model effectively differentiated surgical experience ($r = 0.90$, $p = 0.001$), indicating construct validity. Additionally, five experts confirmed content validity, finding the model realistically representative of the Dx/HA procedure (most common Likert score 4/5). To date, there is no other evidence offering validation of animal models for endoscopic VUR treatment.

4.3. Ghent University Hospital model

In our study, 39 participants from across the globe with varying surgical experience were included. They demonstrated the Ghent University Hospital porcine model as very comparable with the human bladder, proving its unique face validity. A subgroup analysis revealed that experts found the simulator to be significantly more realistic than nonexperts, which contrasts with the findings of Escolino et al's [19] study, where no difference between the two groups was observed, while Soltani et al [5] did not perform a subanalysis. Several other studies have highlighted significant differences in face validity ratings between experts and nonexperts. For example, Schreuder and colleagues [12] attributed these differences to the more refined knowledge of experts, which enables them to better appreciate the complexity and applicability of the simulator. In contrast, nonexperienced users may be overwhelmed by the complexity of the procedural task, leading to cognitive overload [11].

When determining the suitability of the simulator for training in the Dx/HA procedure, the Ghent model demonstrated high content validity. Most general studies rely solely on expert opinions to assess content validity, while others such as the studies of Escolino et al [19] and Schreuder et al [12] incorporated novices and intermediates as well. Their subgroup analyses revealed no significant differences between the scores of experts and nonexperts. However, it is important to acknowledge that categorizing participants as novices, intermediates, or experts is somewhat arbitrary. These classifications are based on cutoff points set by researchers, as there are no established guidelines defining these groups. For example, Soltani et al [5] defines an expert as someone with over 20 yr of experience, performing at least 15 Dx/HA procedures annually, while Escolino et al [19] considers surgeons who have completed 20 procedures overall as experts. Our definition is primarily based on the study by Dalkiliç et al [7], which demonstrated that high success rates are achieved after performing >40 Dx/HA procedures. Nonetheless, we recognize that these terms should be viewed as part of a continuum along the learning curve.

In our study, most participants agreed that the teaching model should be integrated into training programs, especially for advanced trainees. Interestingly, Soltani and colleagues [5] found that the greatest skill improvement occurred in participants who had completed their 4th year of pediatric urology rotation (construct validity; $r = 0.90$, $p = 0.001$), which could be a crucial consideration when designing training curricula.

4.4. Limitations

This study has several limitations. First, there is a potential sampling bias. As enrollment in the course was voluntary, participants may be early adopters of technology and may perceive simulation training as particularly beneficial, which could affect the generalizability of the findings. Second, a post hoc analysis showed that the study was underpowered, especially in the expert group. However, it is worth noting that there are only a limited number of studies on face and content validation, all of which have smaller sample sizes than this study. This supports the need for a larger trial involving participants with varying levels of experience. Additionally, our study was based on subjective Likert scores. Future research could benefit from the incorporation of objective metrics to evaluate the composite performance of the trainees. Ideally, feedback after a simulator session should be generated automatically. However, ensuring its accuracy, realism, and trustworthiness presents a challenge, necessitating proper validation. Moreover, up to this date, there is no validated metrics assessing the success (or failure) of an injection, both in vivo and ex vivo. This model is therefore as reliable as possible. In the study by Soltani et al [5], a single senior pediatric urologist was selected to evaluate these metrics. While this approach allowed for the assessment of the simulator's ability to differentiate levels of surgical experience (construct or discriminant validity), it introduced a potential bias due to subjectivity and lack of blinding. The need for a human-monitored evaluation makes the model time consuming. Nonetheless, the importance of constructive feedback through human supervision should not be underestimated [9]. Soltani and colleagues [5] compared the first attempt on the simulator with the last attempt after 2 h of training, thereby investigating concurrent validity. However, it should be acknowledged that there is currently no gold standard with which the simulator can be compared. To facilitate the widespread implementation of this model in training curricula, the next step would be to determine whether the improvements in skill performance observed during training translate into clinically meaningful outcomes in real-life scenarios (predictive validity).

Although the porcine model is widely regarded as a high-fidelity surrogate for the human bladder, it exhibits some minor anatomical differences, such as a more medially displaced ureteral orifice and the absence of bleeding. However, when the specimen is filled with irrigation fluid, the tissue distends in a manner identical to that of human patients, providing the opportunity to practice various injection techniques such as subureteral transurethral injection (STING), hydrodistension implantation technique (HIT), and double HIT. The setup allows trainees to experience force feedback and accurately identify the target area for injection, while positioning their needle at the correct

angle and appropriate mucosal depth. In the slaughterhouse, it became apparent that not all porcine bladders were suitable for the procedure: the urethra had to be of adequate length, and the bladder needed to be intact without ruptures. This highlights a potential issue regarding the reproducibility of the model. Although animal models offer a valuable alternative to cadaveric bladders, which are associated with challenges such as high costs, limited availability, and issues related to handling and storage, the use of live animal models remains a controversial topic, making ex vivo animal models particularly useful for high-fidelity simulation training [20]. While ex vivo models are still costly compared with low-fidelity simulators such as plastic box trainers, these provide a more realistic training experience. Low-cost models may be particularly beneficial for novice trainees, allowing them to learn key steps of unfamiliar procedures, whereas ex vivo models could be reserved/justified for more advanced trainees [11]. Recently, advanced simulation modalities in endourologic training have emerged. VR trainers, such as UroMentor, and operable 3D printed models, such as the Fish Tank Simulation Model, present promising avenues for safe surgical training [16,19]. However, these are limited by high setup costs, low fidelity in replicating complex procedural tasks, and a lack of haptic feedback. Until the development of more sophisticated and affordable technologies is achieved, ex vivo trainers remain the most realistic simulators available in our training armamentarium.

4.5. Implications

This is one of the few studies to evaluate an ex vivo porcine bladder model as a training tool for the Dx/HA procedure in children, demonstrating unique face and content validity. Moreover, the number of participants in this study exceeds that of previous studies. Participants were recruited from institutions worldwide and included both pediatric and urologic surgeons, enhancing the generalizability of the findings. Incorporation of this hands-on training model into structured training programs could improve surgeons' proficiency and minimize the impact of the learning curve, ultimately ensuring the highest-quality care for pediatric urology patients. Future research should focus on developing comparative effectiveness studies including objective metrics and exploring the long-term impact on patient outcomes.

5. Conclusions

In conclusion, this study demonstrated the face and content validity of the Ghent University Hospital porcine bladder model. This high-fidelity simulator was considered a valuable training tool for the endoscopic treatment of VUR in children. Future research confirming predictive validity would further establish its relevance for clinical practice prior to its integration into structured training curricula.

Author contributions: Manon De Loof and Jolien Van der Jeugt had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Jamaer, Spinoit.
Acquisition of data: Jamaer, Spinoit, Van Der Jeugt.
Analysis and interpretation of data: De Loof, Jamaer, Spinoit, Van der Jeugt.
Drafting of the manuscript: De Loof, Jamaer, Spinoit, Van der Jeugt.
Critical revision of the manuscript for important intellectual content: Hoebeke, Peycelon, Spinoit, Van Laecke.
Statistical analysis: De Loof, Van der Jeugt.
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Other: None.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2025.06.001.

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