


What should be next in lifelong posterior hypospadias: Conclusions from the 2023 ERN eUROGEN and EJP-RD networking meeting

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Abstract

Background: A congenital disease is for life. Posterior hypospadias, the severe form of hypospadias with a penoscrotal, scrotal, or perineal meatus, is a challenging condition with a major impact on lifelong quality of life.

Aim: Our network meeting is aimed to identify what is currently missing in the lifelong treatment of posterior hypospadias, to improve care, quality of life, and awareness for these patients.

Methods: The network meeting “Lifelong Posterior Hypospadias” in Utrecht, The Netherlands was granted by the European Joint Programme on Rare Diseases–Networking Support Scheme. There was a combination of interactive sessions (hackathons) and lectures. This paper can be regarded as the last phase of the hackathon.

Results: Surgery for hypospadias remains challenging and complications may occur until adulthood. Posterior hypospadias affects sexual function, fertility, and hormonal status. Transitional care from childhood into adulthood is currently insufficiently established. Patients should be more involved in defining desired treatment approach and outcome measures. For optimal outcome evaluation standardization of data collection and registration at European level is necessary. Tissue engineering may provide a solution to the shortage of healthy tissue in posterior hypospadias. For optimal results, cooperation between basic researchers from different centers, as well as involving clinicians and patients is necessary.

Conclusions: To improve outcomes for patients with posterior hypospadias, patient voices should be included and lifelong care by dedicated healthcare

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professionals guaranteed. Other requirements are joining forces at European level in uniform registration of outcome data and cooperation in basic research.

KEYWORDS

hypospadias, lifelong, posterior hypospadias, PROM, transition care

1 | INTRODUCTION

Hypospadias is a common congenital disorder in which the urethra ends more proximal and the meatus lies on the ventral side of the penis, in the scrotum or even perineal.¹ Furthermore, the prepuce is abnormally shaped, and a ventral curvature of the penis can be present. Hypospadias can be classified according to the location of the meatus: in the more common mild form, the meatus can be found on the distal part of the penis. The most severe form is called posterior (or proximal) hypospadias, in which the meatus is in a penoscrotal-, scrotal-, or perineal position. This is a rare disease classified as ORPHA 95706: Nonsyndromic posterior hypospadias. Treatment of this form of hypospadias is very challenging, with a persistent high prevalence of complications, such as urethral fistulas, diverticulas, strictures, and recurvature of the penis.² Complications can occur lifelong: early after surgery, during puberty due to fast growth, and in adulthood. Furthermore, despite initial successful surgical treatment, posterior hypospadias can lead to cosmetic dissatisfaction and functional complaints including spraying of the urinary stream, inability to urinate in a standing position, and pain during intercourse due to curvature later in life.^{3–6} We still do not fully understand how the transplanted tissue, used for urethral reconstruction in early childhood, behaves under the influence of hormonal changes during puberty, and how this may affect long-term outcomes and patient satisfaction. Therefore, transition of care into adulthood and lifelong care are important. Most patients are treated by pediatric urologists at an early age and followed into puberty. However, there are few adult urologists experienced in evaluating and treating adults with (severe) hypospadias.

In September 2023, a eUROGEN European Reference Network (ERN) networking meeting was held. The aim of the meeting was to bring experts from various backgrounds together, to identify what is needed to improve the care in patients with posterior hypospadias. The following topics were discussed: What are the challenges of surgery in patients with hypospadias? How should success be defined, from surgeon's and

patient's perspective? Why does treatment of posterior hypospadias fail and what future techniques and tools could be of help to improve lifelong outcomes? Should we pay more attention to sexual satisfaction and other aspects of quality of life? How can follow-up be improved? In this manuscript, we formulate the strategies and research questions which were identified at the meeting with the goal to further improve the care for boys and men with posterior hypospadias.

2 | METHODS

2.1 | Meeting

The network meeting “Lifelong Posterior Hypospadias” on September 8 and 9, 2023 in Utrecht, The Netherlands was granted by the European Joint Programme on Rare Diseases (EJP RD)–Networking Support Scheme (NSS). The meeting was advertised on LinkedIn, the website of European associations of target audience (European Association for Urology, European Society for Paediatric Urology, and the National Organizations for Urology) and on the eUROGEN website. Participants (15) were clinicians (pediatric urology, adult urology) and researchers (one scientist in molecular cell biology/tissue engineering (TE) and one in Health Humanities). Patients were invited but were not able to participate in person. They were consulted before the meeting on their views on current disease management (personal experience), the definition of success and on what could or should be prioritized to improve care, quality of life, and follow-up.

2.2 | Teaching methods

There was a combination of interactive sessions and lectures. The interactive sessions were set up as a hackathon.^{7,8} In short, the group was mixed and divided into smaller groups to make optimal use of the diverse skillsets of the participants. Each group consisted of at least one pediatric urologist, one adult urologist, and one

researcher. The topic for the hackathon was “What is currently missing in the lifelong treatment of posterior hypospadias, to improve care, quality of life, and awareness for these patients?.” Three rounds were held. The first round consisted of a nonhierarchical inventory of what the participants thought was important and relevant. The next round was a make-and-try-out phase where we imagined all is possible. Lastly, each group reported the outcome. While hackathons often last 24 h or more, we were limited in time. We spend 3 h on the hackathon, although this paper can be seen as part of the wrap up phase (fourth round).

3 | RESULTS

3.1 | What are the challenges in surgery for posterior hypospadias?

Surgery for hypospadias and especially posterior hypospadias comes with a high number of complications, both early and (very) late. Several factors playing into the challenges in posterior hypospadias surgery were discussed: the absence of corpus spongiosum (CS), lichen sclerosus (LS), testosterone, and age at surgery.

Typical for hypospadias is the absence of the (distal part of) the CS. The CS is important for the structural and functional integrity of the male urethra.⁹ It is thought that the CS will protect the grafted urethra from damage during sexual activity.¹⁰ This lack of support may play an important role in healing problems after surgical correction of hypospadias and may account for (very) late complications.

There is a potential association between LS and hypospadias. LS is a chronic inflammatory dermatological condition of unknown etiology. The prevalence of LS is estimated to be 0.04%–0.06% in the pediatric population (aged 0–20 years), and 0.1%–0.6% in adults.¹¹ There seems to be a relationship between LS and an increased risk of postoperative complications in hypospadias repair.¹⁰ This needs further investigation. It may be crucial to diagnose and manage LS appropriately to ensure the best surgical outcomes in posterior hypospadias repair.

Another factor is testosterone, as it impacts various penile tissues like skin, dartos, and cavernosal bodies. A deficiency in testosterone during fetal development can contribute to malformations and above-mentioned complications.¹² Therefore, the involvement of an endocrinologist in hypospadias care might be beneficial, especially if there is a suspicion of hormonal imbalances or other endocrine-related anomalies.

The optimal age for surgery remains a debated topic. Operating at a younger age, between 6 and 18 months, might mean better healing. Moreover, earlier repairs might present a psychological advantage, offering a more normalized appearance during formative years. Therefore, 6–18 months of age is the advised timing of surgery in the European guidelines.¹ Reasons to delay the surgery might be comorbidity or the wish of parents to leave the decision for surgery to the patient himself at an older age. There are also concerns about how surgical interventions at young age might affect future development of the penis given the significant anatomical changes during puberty period.¹³ Scar formation postsurgery may interfere with the synchronized development of the penis during puberty, leading to discrepancies between cavernosal bodies, skin, and the urethra, which in turn may induce complications or dissatisfaction with appearance or sexual function.

However, delay of surgery until older age may also cause emotional and psychological challenges and even various degrees of sexual dysfunction. Potential psychological trauma may arise if there's a stark difference in cosmesis during the sensitive phase of childhood and adolescence. This highlights the importance of involving a psychiatrist or psychologist and ensuring a smooth transition to adult care, especially in cases of posterior hypospadias.¹⁴

3.2 | Rethinking success in hypospadias treatment

Posterior hypospadias is a congenital and therefore lifelong condition. This implies that initial success does not guarantee a life without complications, which can occur even years after intervention. Furthermore, there is a gap between surgical success and the holistic well-being of hypospadias patients.

Key challenges in assessing long-term hypospadias treatment success include two major impediments.

First, there is a lack of comprehensive data. Due to treatment by a pediatric urologist and the potential occurrence of complications deep in adulthood, there is scarcity of comprehensive, long-term follow-up data. Lack of follow-up beyond transition is a major issue. Also, coding in for example Orphanet, is currently confusing: some codes are not specific enough and included other forms of hypospadias as well.

Second, there is a need for patient-centric assessment. There is a lack of validated questionnaires that encompass surgical outcomes as well as psycho-sexual aspects such as body image and self-esteem.

To address these challenges, we need a prospective lifelong follow-up study that recognizes hypospadias as an ongoing condition evolving throughout the patient's various life stages. Validated patient related outcome measures (PROMs) need to be developed in collaboration with patients, psychologists, and sexologists to also capture emotional and psychological development. The Delphi process can help find consensus to develop such a PROM.¹⁵ As posterior hypospadias is a congenital and lifelong condition, not only the patients themselves need to be involved, but at younger age also their parents. This poses an additional but crucial challenge, as the perspective over the disease will change over its course (from parents to patients) and early awareness thereof is essential.

In combination with long-term follow-up and PROMs, there is also a need for data unification. By unifying European databases, we can access more extensive patient cohorts for robust and statistically powerful assessments of what success actually is in hypospadias care.

Lastly, defining success is an ongoing process. We therefore support regular communication between experts in the field and patients. This is vital to facilitate the exchange of knowledge, experience, and essential questions, via the virtual platforms by the ERN-eUROGEN or other multidisciplinary meetings. In this way we can provide more effective patient-centric care, ultimately improving outcomes for individuals living with hypospadias.

3.3 | The patient's voice

In most of current studies on hypospadias, outcome is defined as complications, redo surgery, curvature, and cosmesis as perceived by the surgeon. Questionnaires such as hypospadias objective penile evaluation score¹⁶ and pediatric penile perception score¹⁷ try to measure outcomes that are more patient centered. Nevertheless, we feel that current assessment tools lack the patient perspective, but also pay insufficient attention to sexual outcome and long-term satisfaction/success.

We invited some of our patients to attend the meeting to share their experiences and views on how to improve care. Despite our efforts no patient was willing to participate live. Potential reasons may be embarrassment, language barrier, or lack of financial compensation for their time.¹⁸

Sinclair et al.¹⁹ suggested three steps to attain or improve patient involvement: first, find research aware patients (RAP). In this study, potential participants were screened to ensure they were in good psychological health to participate in the study. Then, together with the

RAP, research questions were compiled. Second, prioritize these questions with input of other patients via an online survey. Sinclair et al. used closed Facebook groups for optimal security, and a private Twitter account, now X. Step three is to agree in common grounds on what background information should be asked for and to make a top 10 of most relevant questions. The authors in this study found that social media, online forums, and meeting in person were ranked the most preferable methods for communication with support groups networks and charities. This strategy to engage patients in research is the most common one according to several reviews,^{18,20,21} even in children.²² Using social media therefore is a promising route for engagement with the diverse hypospadias communities

3.4 | Is tissue the issue?

Regenerative medicine aims to address unmet medical needs by combining our body's own repair abilities with innovative engineering. TE is promising in case there is not enough autologous tissue for reconstructive surgery.²³ Despite early enthusiasm in application for complicated urethral reconstruction in boys,^{24,25} TE is far from a clinical reality. Hypospadias repair can only reconstruct urethral lumen, but posterior hypospadias is usually accompanied by CS defects. The CS is normally acting as vascular and mechanical protection of the urethra.

Therefore, TE should focus more on generating a vascular bed as a substitute to the CS to support the urethra.²⁶ Essential for successful TE is the study of native tissue first. The healthy urethra consists of multiple tissue layers, with distinct functions.²⁷ Preliminary data (manuscript in preparation) showed that in the urethral plate of hypospadias, no bundles of elastin fibers and less smooth muscle tissue were detected compared to healthy urethra. This may result in an increased stiffness of the tissue, which is in line with previous research.²⁸ Elastin fibers in the CS develop in utero around the time when voiding first occurs.²⁹ It is also hypothesized that the biomechanical stimulation during (fetal) micturition is an extrinsic factor that influences all components of the urethra. This is an indication that not only the right cells are important in TE, but also exposure to function (flow, stretch, urine composition) may be needed to fully develop a suitable TE graft for reconstruction surgery.

To advance TE from the bench to clinical reality, we need the following steps: first, we need to focus on the vascular bed, rather than on the epithelial tube. Second, the tissue needs to be multilayered with a certain elasticity. Third, the tissue needs to be matured by function. TE is

more than cells on scaffolds, as tried in the early days of this technology. With emerging technologies, it is time to combine TE with biofabrication and additive manufacturing^{30,31} to generate grafts in bioreactors. Only then can functional tissue be created, which can be used to substitute or augment the congenitally lacking tissue in posterior hypospadias. As opposed to transplanted tissue, TE tissue may hypothetically also follow a more synchronous development through puberty with the other genital structures and could therefore potentially be less prone to late complications.

3.5 | Sexual development and satisfaction

There is a lack of long-term follow-up regarding the sexual satisfaction of patients with a history of hypospadias surgery. Given that being sexually happy contributes to general satisfaction,³² it is preponderant not only to study the sexual function of hypospadias patients but also to evaluate their sexual satisfaction.

It is important to consider the link between body image, genital satisfaction, and sexual satisfaction. Poor genital self-image causes shame and negative self-belief which leads to a false perception of inability to perform sexually. This will then make genitally dissatisfied people more avoidant of peers and of sexual or intimate contacts and consequently reduce their sexual activity.^{33–35}

Ruppen et al. showed³⁶ that the position and shape of the meatus is considered as the least important aspect of penile appearance by women when asked what a good-looking penis is. Moreover, laypersons unacquainted with hypospadias rate distal hypospadias similarly as non-affected circumcised penises.³⁷ In line with many authors, that raises the question of the necessity to treat distal hypospadias during childhood in the absence of voiding or sexual dysfunction.

On the other hand, previous studies revealed that patients with posterior hypospadias were more at risk to present lower genital satisfaction. Furthermore, having undergone multiple surgeries is a risk factor for genital dissatisfaction.³⁸ Andersson et al. reported³⁹ that patients with posterior hypospadias were globally sexually satisfied (although meatal position was rarely distal glandular) but needed more support in that field.

We definitely need more studies with larger groups to evaluate the sexual satisfaction, particular in men with posterior hypospadias. We should propose an age-adjusted follow-up starting around adolescence with the help of other professionals (psychologist, sexologist) and develop and use questionnaires to assess body image, genital satisfaction, sexual function, and sexual satisfaction.

3.6 | Lifelong follow-up

Long-term outcomes on micturition symptoms, sexuality, and satisfaction with cosmesis of the penis show that patients with hypospadias are slightly less satisfied than controls of the same age.⁴⁰ Patients with posterior hypospadias, more often have impaired fertility and a higher risk of hypogonadism.⁴¹ For complications corrected in adulthood after childhood hypospadias surgery, symptoms were most often already present during childhood. However, 5% of complications occur during puberty and 15% at postpubertal age.⁴² A worrisome high number of 1.3%–20% of patients with hypospadias develop urethral stricture disease at some point.⁴³ Patients corrected for hypospadias and with associated urethral strictures have been reported to have stricture recurrence in about half of the cases after 5–10 years.^{44,45} Patients with posterior hypospadias more often have surgical complications.⁴⁶

The knowledge that also at adult age, hypospadias may have impact on health issues and quality of life warrants lifelong care for these patients. Lifelong urology, or congenitology, is increasingly recognized as an important area of expertise.⁴⁷ The transition from pediatric to adult care may still be a hurdle that is not easy to overcome. Transitional clinics are being established little by little, but the main focus of these clinics is on spinal dysraphism and bladder exstrophy. Transition has to be initiated by the pediatric caretaker and may be hindered by reluctance to transfer the patient to the adult counterpart.⁴⁸ There may also be immaturity or a reluctance to acknowledge a problem potentially requiring further surgery in adolescents and young adults delaying referral to adult care.⁴² The adult caretaker, on his/her turn, may lack specific knowledge of congenital conditions and may not be familiar with typical adolescent behavior and associated problems with treatment compliance. Reconstructive urologists seem the most appropriate to take over the lifelong care of posterior hypospadias patients.⁴⁹ However, specific training in the treatment of congenital conditions and lifelong urology is recommended. Cross-border discussions, even after adolescence, between pediatric urologists and reconstructive urologists may also be of benefit in selected cases.^{47,50}

4 | CONCLUSIONS

During this network meeting, we identified our targets for further research and development. We need to look beyond surgical techniques to improve care for posterior hypospadias. Our primary aim is to ensure lifelong follow-up for our patients. In collaboration with the ERN eUROGEN, we plan to establish patient registries for

posterior hypospadias patients. This initiative will facilitate long-term follow-up of treatment outcomes into adolescence and adulthood, allowing us to better understand the evolution of treatments over time. A critical aspect of this initiative is standardization of data collection and registration, for instance by improving PROMs and correct coding in for example, Orphanet. Therefore, it's essential to connect with the patients to ensure we are addressing the priorities of our most important stakeholder. We have shared some ideas to start this process.

In a parallel approach, basic science can help in creating a vascular embedding for the neourethra using TE, a process which may take years to achieve. Also, the role of LS in complications needs to be explored.

This meeting marked the initial step toward establishing an international network. We will continue with virtual meetings to implement the strategies we discussed and satellite meetings during the meetings of the EAU and ESPU. We envision the network to be dynamic and, as such, we welcome additional participants for this import endeavor.

AUTHOR CONTRIBUTIONS

Michel Wyndaele, Laetitia de Kort, and Petra de Graaf: Conceptualization. **All authors:** Contribution of parts of manuscript. **Rianne Lammers and Petra de Graaf:** Editing of the manuscript. **Teresa O. Ekerhult, Mikołaj Frankiewicz, and Petra de Graaf:** Funding. **Petra de Graaf:** Corresponding author.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Our manuscript does not contain data that falls under this statement.

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