

# Operationalization of “urethral calibration protocol” to develop skills among caregivers and nursing personnel dealing with children undergoing urethroplasty

Sweety Lohchab (✉ [s.lohchab865@gmail.com](mailto:s.lohchab865@gmail.com))

All India Institute of Medical Sciences

Rupinder Kaur

Post Graduate Institute of Medical Education and Research

Sukhwinder Kaur

Post Graduate Institute of Medical Education and Research

J.K. Mahajan

Post Graduate Institute of Medical Education and Research

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## Research Article

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# Abstract

Hypospadias is considered as second most common birth defect in children with 1 in every 250 male births worldwide and 1 in every 150 boys in India. Urethroplasty is only mode of hypospadias repair which is associated with wide range of complications like urethrocutaneous fistula, meatal stenosis, narrow urethra. Rising incidence of these complications demands judicious postoperative care and urethral calibration.

**Objective:** To develop and operationalize protocol on urethral calibration for children undergone urethroplasty among caregivers and nursing personnel.

**Method:** An operational study was conducted on caregivers and nursing personnel at pediatric surgery OPD. Total of 40 study subjects i.e. 32 caregivers and 8 nursing personnel included by total enumeration sampling. Study was conducted in three phases. In 1<sup>st</sup> phase, current practices of urethral calibration were assessed. 10 observations were taken to identify lacunae regarding procedure. Protocol on urethral calibration was developed by extensive literature review, expert opinions using Delphi technique. In 2<sup>nd</sup> phase, training sessions were conducted using lecture cum discussion, demonstration and return demonstrations, booklets and posters. In 3<sup>rd</sup> phase, assessment of effectiveness of urethral calibration was done by evaluating occurrence of complications related to urethroplasty.

**Results:** Significant ( $p < 0.001$ ) increase in mean performance score of urethral calibration of caregivers and nursing personnel was achieved up to  $22.75 \pm 1.10$  and  $23.50 \pm 0.92$  after four and three subsequent return demonstrations respectively.

**Conclusion:** Protocol on urethral calibration is effective in developing skills among caregivers and nursing personnel related to procedure and improving surgical outcome of urethroplasty among children.

## Introduction

Every congenital birth defect demands correction with pediatric surgical procedures. According to Global Report on Birth Defects given by March of Dimes (MOD), worldwide 7.9 million births occur annually with serious birth defects and 94% of these births occur in the developing countries.<sup>[1]</sup> Prevalence of birth defects in India varies from 61 to 69.9/1000 live births.<sup>[2]</sup> Hypospadias is considered as the second most common birth defect in children accounting for more than 100,000 cases every year.<sup>[3]</sup> Worldwide incidence of hypospadias is approximately 1 in every 250 male births and in India one in every 150 boys are born with hypospadias; not uncommon at all.<sup>[4]</sup> It can predispose affected child to infection, obstruction, stasis, sexual dysfunction, impaired fertility and psychosocial issues.<sup>[5]</sup>

Urethroplasty is the only mode of treatment for the repair of hypospadias. The complications and unfavourable results of surgery are so high that urethroplasty and complications used synonymously.<sup>[6]</sup> The reported incidence of complications of urethroplasty range from 6 to 30% varying with the severity

of the hypospadias. Urethrocutaneous fistula is the most common complication of hypospadias repair (21%) followed by meatal stenosis (14%) and narrow urethra (14%).<sup>[7]</sup> Repair of these complications creates burden of secondary surgeries on health care system, physicians, nursing personnel, caregivers and children. These issues can be dealt by various methods like meticulous preoperative planning, judicious postoperative care and adopting proper preventive measures.<sup>[8]</sup> Also with advancement of medical development in field of pediatric surgery, actual trend is towards earlier intervention with ever-shorter hospitalization to reduce incidence of postoperative complications.

Urethral calibration is one of the preventive and curative method of treatment of meatal stenosis and other surgery related complications. It has a positive impact on dimensions of neo-urethra created via urethroplasty. Involvement of parents has positive impact in reducing postoperative complications by making urethral calibration more adaptable and less unpleasant to the child.<sup>[9]</sup> Apart from parents, nursing personnel has accountability in several dimensions of care provided during preoperative and postoperative period. A proficient nurse can better communicate with the parents regarding importance of urethral calibration and need of skill while doing calibration.<sup>[10]</sup> Both nursing management and parent's contribution in care can promote standardized care in turn reducing hospitalization and so, less suffering. So, need of the hour is to train both caregivers and nursing personnel for urethral calibration to reduce postoperative complications of hypospadias.

## **Objective**

To develop skills among caregivers and nursing personnel regarding urethral calibration in neo-urethral opening in children undergone urethroplasty.

## **Methods**

This study was carried out in Pediatric Surgery OPD, APC, PGIMER, Chandigarh. Caregivers of children who had undergone urethroplasty for first time and nursing personnel were included in study by total enumeration sampling technique, whereas those who had undergone multi-staged urethroplasty were excluded. Two observational checklists were prepared to assess the current practices and skills of caregivers and nursing personnel while doing urethral calibration respectively.

The study was conducted in three phases. In first phase the current practices regarding urethral calibration were assessed with an observational checklist where only the physicians were observed who performed urethral calibration. Total 10 physicians were observed by covert participatory observation. The observer was posted in research units from 8 am to 4 pm as a master student and this is how the physicians were unaware of her intention in the unit. Research protocol was submitted for consideration, comment, guidance and approval to Institute's ethics committee of PGIMER, Chandigarh and permission were taken from head of department of pediatric surgery. No amendment to the protocol was made without consideration and approved by the committee. Research process including data collection and methodology was done as per the protocol approved and the guidelines set by the ethics committee. The

informed consent was taken from study subjects at the beginning of phase 2. Informed consent from illiterate people were obtained via their legally authorized representatives.

Protocol on urethral calibration in hospital setting and in home setting was developed by extensive literature review and expert opinion. In second phase operationalization of the protocol on urethral calibration was done. The training sessions were conducted to train 32 caregivers and 8 nursing personnel regarding urethral calibration by lecture cum discussion using posters and demonstration and return demonstration. Procedure of urethral calibration was demonstrated to caregivers and nursing personnel on individual basis and group wise respectively. The return demonstrations were taken by employing detailed stepwise observational checklist till the study subjects were fully trained. Four and three observations were made from caregivers and nursing personnel respectively as after every incomplete training scores, again a demonstration was given to train them fully. Booklet was given for ready reference and posters on urethral calibration were displayed in pediatric surgery OPD to review the steps.

In third phase, caregivers were contacted telephonically and during regular follow-up in pediatric surgery OPD. They were interviewed related to development of any complication related to urethroplasty that came across during last three months. Effectiveness of urethral calibration was assessed by knowing occurrence of complications among children who had undergone urethroplasty. Data was analysed by using descriptive and inferential statistics with the help of SPSS.

## Results

The results showed that the study subjects i.e. caregivers (mothers and fathers) and nursing personnel were in the range (23-53) years with mean  $\pm$  SD of  $31.88 \pm 5.44$  years, (26-56) with mean  $\pm$  SD of  $34.56 \pm 5.71$  and 23-37 with mean  $\pm$  SD of  $27.63 \pm 5.12$  years respectively. 32 caregivers and 8 nursing personnel participated in the study. As per educational qualification, out of 32 caregivers 37.5% mothers were educated up to senior secondary and 43.8% fathers were graduate. 50% nursing personnel were having professional qualification of GNM course and remaining were graduate with B.Sc. Nursing degree. 37.5% nursing personnel had more than 5 years of experience in pediatric surgical care units.

Clinical profile of caregivers revealed that three fourth (81.3%) of mothers conceived the affected pregnancy between the age 21-30 years with mean  $\pm$  SD  $25.63 \pm 5.29$ . Two third of mothers (65.6%) had taken folic acid tablets after first month of conception. Out of 21 mothers, only 3 (9.4%) had started folic acid intake during first month, remaining 7 (21.9 %), 5 (15.6%) and 6 (18.8) had started folic acid intake during second month, third month and fourth month of affected pregnancy respectively. Family history of hypospadias was present in 8 patients (25%). (Table 1)

**Table 1 : Socio-demographic and Clinical profile of Caregivers**

(N=32)

Variable	n(%)
<b>Mother's age (Years )</b>	
21-30	13 (40.6)
31-40	<b>17 (53.1)</b>
>40	2 (6.2)
<b>Mother's age at conception(in years)</b>	
Less than 20	
21-30	4 (12.5)
More than 30	<b>26 (81.3)</b>
	2 (6.2)
<b>Folic acid intake during affected pregnancy</b>	
Yes	21 (65.6)
No	11 (34.4)
<b>Duration of folic acid intake</b>	
First month	3 (9.4)
Second month	7 (21.9)
Third month	5 (15.6)
Fourth month	6 (18.8)
<b>Father's age (Years)</b>	
21-30	7 (21.9)
31-40	<b>23 (71.9)</b>
>40	2 (6.2)
<b>Education of mother</b>	
Illiterate	1 (3.1)
Primary	1 (3.1)
Secondary	8 (25.0)
Senior Secondary	<b>12 (37.5)</b>
Graduate or above	10 (31.3)
<b>Education of Father</b>	
Secondary	10 ( 31.3)
Senior Secondary	8 (25.0)
Graduate or above	<b>14 ( 43.8 )</b>
<b>Family history of hypospadias</b>	
Maternal	3 (9.4)
Paternal	<b>5 (15.6)</b>

Mean  $\pm$  SD of age of Mothers in Years (Range )  $31.88 \pm 5.44$  (23-53)

Mean  $\pm$  SD of age of Fathers in Years (Range)  $34.56 \pm 5.71$  ( 26-56)

Mean  $\pm$  SD age of Mother in Years (Range) at Conception  $25.63 \pm 5.29$  ( 20-48)

In phase 1 after assessment it was observed that only physicians were doing urethral calibration. There was no involvement of caregivers and nursing personnel in calibration of neo-urethra. In phase 2 the protocol on urethral calibration in hospital setting and in home setting was developed by extensive review literature and validated using Delphi technique. Inter-rater reliability was established for observational checklist by using Cohn's kappa. There was almost perfect agreement between investigator and expert ( $k=0.91$ ). During training, it was found that after first return demonstration none of the caregiver was fully trained, after second return demonstration 15.6% , third return demonstration 43.7% and rest of the caregivers were fully trained after fourth return demonstration (fig 1).

Related to nursing personnel after their first return demonstration 12.5% were fully trained, after their second return demonstration 87.5% were fully trained and rest were fully trained after their third return demonstration(fig 2).

Mean performance score of caregivers while getting trained for urethral calibration during subsequent observations were  $8.31 \pm 2.87$ ,  $14.38 \pm 2.93$ ,  $18.38 \pm 2.61$  and  $22.75 \pm 1.10$  in 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> observation respectively. The score for nursing personnel were  $13.50 \pm 2.97$ ,  $18.25 \pm 1.66$  and  $23.50 \pm 0.92$  in 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> observation respectively (table 2).

It was found that there was significant difference in mean scores with subsequent observations in both the groups.

**Table 2: Comparison of mean score of caregivers and nursing personnel during training on Urethral calibration**

(N=32)(N=8)

Observation	Mean ± SD	Range	F (df, df error) p-value
Observation 1	8.31±2.87	4-14	334.2 (2.47, 76.7) <0.001**
Observation 2	14.38±2.93	8-20	
Observation 3	18.38±2.61	14-22	
Observation 4	22.75±1.10	20-24	
Mean score of Nursing Personnel			
Observation 1	13.50±2.97	10-18	48.04 (1.29,9.09) <0.001**
Observation 2	18.25±1.66	16-20	
Observation 3	23.50±0.92	22-24	

Multiple comparisons between means of various observations of urethral calibration performed by caregivers of children revealed that a significant difference was observed in mean score of observation 1 compare to observation 2 and in other three subsequent observations ( $p < 0.001$ )(Table 3). Related to urethral calibration performed by nursing personnel, multiple comparisons between means of various observations revealed that a significant difference was observed in mean score of observation 1 compare to observation 2 and in other two subsequent observations ( $p < 0.001$ )(Table 4).

**Table 3: Multiple comparisons among means of various observations of urethral calibration performed by caregivers of children with hypospadias**

(N=32)

Observation (I)	Observation (J)	Mean Difference (I-J)	Std. Error	p-value
Observation 1	Observation 2	-6.06	0.564	<0.001*
	Observation 3	-10.06	0.520	<0.001*
	Observation 4	-14.43	0.522	<0.001*
Observation2	Observation 1	6.06	0.564	<0.001*
	Observation 3	-4.00	0.348	<0.001*
	Observation 4	-8.37	0.470	<0.001*
Observation 3	Observation 1	10.06	0.520	<0.001*
	Observation 2	4.00	0.348	<0.001*
	Observation 4	-4.37	0.386	<0.001*
Observation 4	Observation 1	14.43	0.522	<0.001*
	Observation 2	8.37	0.470	<0.001*
	Observation 3	4.37	0.386	<0.001*

(p <0.001)

**Table 4: Multiple comparisons among means of various observations of urethral calibration performed by nursing personnel posted in pediatric Surgery OPD, APC**

(N=8)

Observation (I)	Observation (J)	Mean Difference (I-J)	Std. Error	p-value
Observation 1	Observation 2	-4.750	1.191	<0.001*
	Observation 3	-10.00	1.195	<0.001*
Observation2	Observation 1	4.750	1.191	<0.001*
	Observation 3	-5.250	0.526	<0.001*
Observation 3	Observation 1	10.00	1.195	<0.001*
	Observation 2	5.250	0.526	<0.001*

(p<0.001)

## Discussion

Urethroplasty repair is associated with large number of complications which can further enhance disease burden. Most frequent complications associated with urethroplasty are urethrocutaneous fistula, meatal stenosis, urethral diverticulum and neo-urethra. There are various reasons behind the occurrence of these complications varies from country to country. In developing countries like India, various factors that

hinder the outcome and predisposes to complications of urethroplasty are low socio-economic status of caregivers, lack of knowledge regarding medical care and meagre resources to meet the cost of medical care. Burden of complications greatly increase volume of workload on surgeons and enhances feeling of distress among parents and children.

Urethral calibration is one of the preventive and curative approach for screening and treatment of urethroplasty associated complications.<sup>[9]</sup> Though the evidences support practice of urethral calibration which was performed by physicians, but no literature supported that this procedure is practiced by caregivers and nursing personnel. So this procedure was chosen for protocol development and implementation and the current study was undertaken to develop and implement protocol on caregivers and nursing personnel. The study involves pre-assessment, development of protocol, training and post evaluation of skill attained related to urethral calibration. Therefore novice to expert theory given by Dr Patricia Benner in 1982 was considered most appropriate to develop conceptual framework.

Total enumeration sampling technique was adopted for the selection of caregivers and nursing personnel working in pediatric surgery OPD so that uniformity in the practice can be ensured.

Current practices of urethral calibration by physicians before interventional phase were assessed, during the first phase of the study to collect baseline data. For current study covert participatory observations were made. Only the head of the unit was informed about the reason for investigators presence and reasons to make observations.

Since there were no standard guidelines available before operationalization, the protocol on urethral calibration was developed during second phase of the study. Socio-demographic data of caregivers and nursing personnel was obtained by employing questionnaires. Training sessions were conducted on individual basis for caregivers and for nursing personnel group wise demonstrations were given. Time and again demonstrations were given until the study subjects achieve 100% score as this helped them to learn with their pace. During 4<sup>th</sup> and 3<sup>rd</sup> observation all caregivers and nursing personnel were completely trained respectively. A detailed stepwise observation checklist was used to ensure the correct steps followed by caregivers and nursing personnel and is also ascertained adequate, appropriate and complete training of both caregivers and nursing personnel.

The multimodal training approach help to reinforce learning which include lecture cum discussion, use of posters, demonstration and return demonstrations, distribution of booklets for easy and quick reference. It was also seen that there was no association of age and educational status of caregivers on development of skills ( $p>0.05$ ) and it is not difficult to perform procedure of urethral calibration. In nutshell, it can be concluded that introduction of protocol and training of caregivers along with nursing personnel for doing urethral calibration can decrease the urethroplasty associated complications significantly.

## Conclusion



Urethral calibration is a safe and effective technique to improve the outcome of urethroplasty. Involvement of parents during urethral calibration makes children comfortable and allow health care personnel to do the procedure. Teaching of parents enable them to do the procedure at home with proper technique and contributing towards better outcome. Skill development using urethral calibration protocol proves to be a great tool for children, parents and nursing personnel.

## **Declarations**

Ethical approval and informed consent	For all research papers only, please ensure that your manuscript includes details of the ethical approval granted including the body that granted it and any reference number. If ethical approval was not required, give a clear statement of the basis on which this assessment was made, with reference to the ICMJE requirements. This should include confirmation of informed consent by participants. Place this at the end of you methods section.	Yes..\..\Desktop\Ethics permission letter.jpg
Study registration	Give any study registration number (CTRI) in the abstract and in the body of the paper. For clinical trials ( the abstract should include the registration date and the date of first recruitment. [not applicable to letters / editorials]	CTRI/2018/02/012245
Funding sources	State sources of funding and the role of funders in the conduct of the research or include a statement 'no external funding' at the end of the paper.	Not applicable
Conflict of interests	State any actual or potential conflicts of interest in a section at the end of the paper. If there are none, include a statement "Conflicts of interest: none". The substance of this declaration should match details provided in file(s) uploaded at submission.	Not applicable
Availability of data	Data transparency	Yes
Consent for publication	Study has not been published anywhere.	Copyright transfer form.docx
Author's contribution	<p>Sweety was the principal investigator of the research. Data collection and writing of the main manuscript text and figures and tables was done by Sweety.</p> <p>Mrs. Rupinder Kaur was guide of the research. She has keenly observed every phase of research process and gave her valuable time and suggestions throughout the process.</p> <p>Dr.Sukhwinder Kaur was Co-guide of the research. She played very important role in tools made for data collection and analysis of the data.</p> <p>Dr.J.K.Mahajan was also Co-guide of the research. He made his contribution in the clinical setting who performed surgery of children with hypospadias and assessed the effect of urethral calibration on outcome of urethroplasty.</p>	
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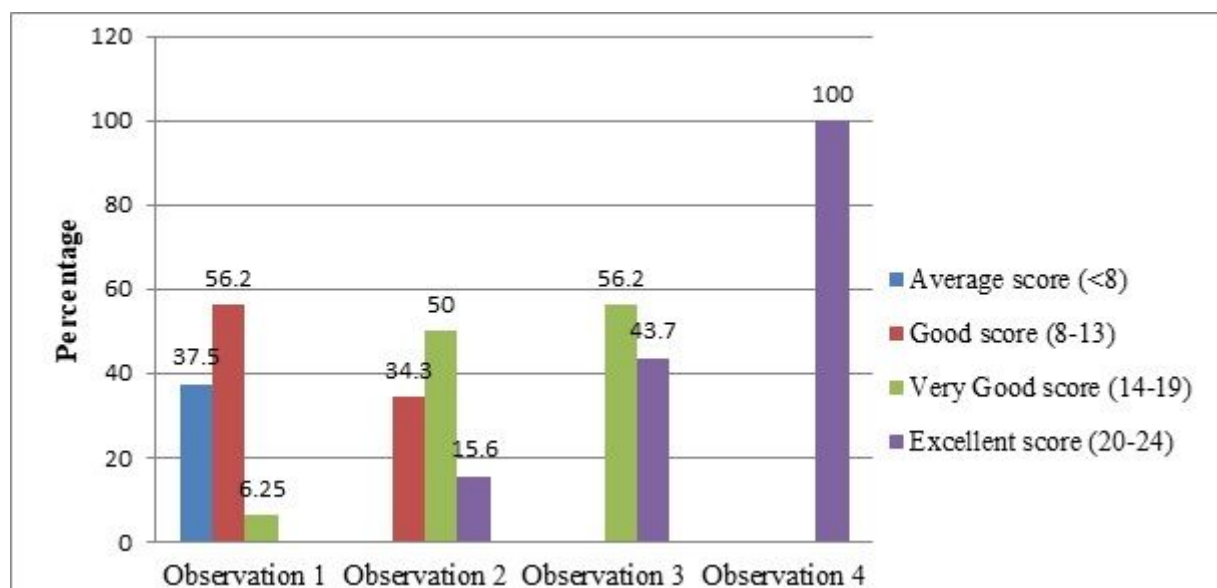
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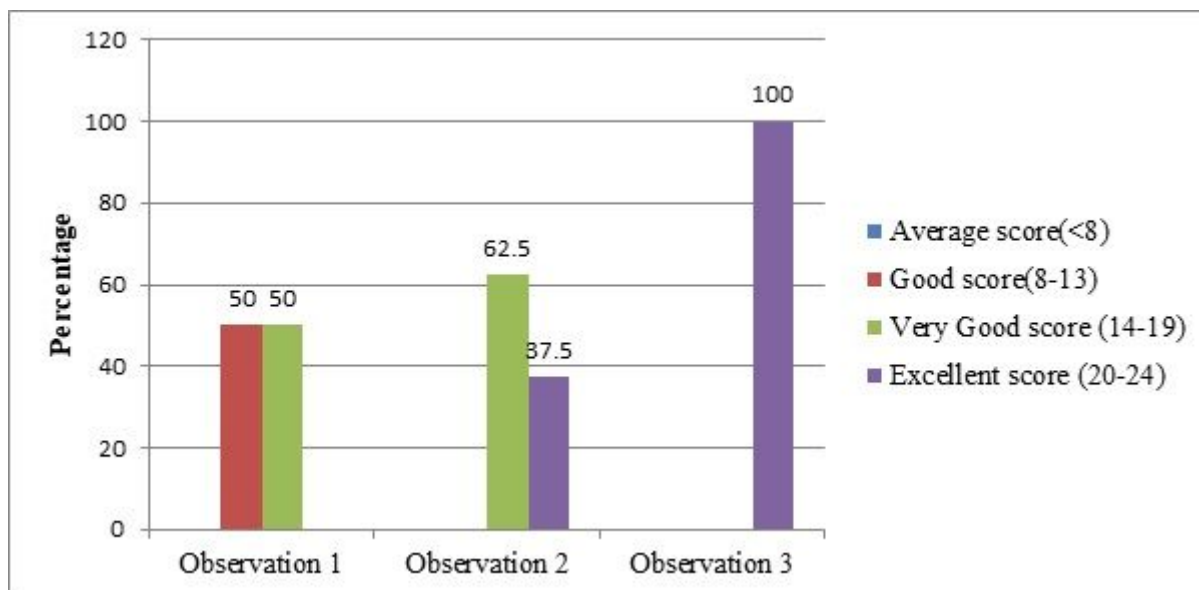
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## Figures



**Figure 1**

Observations conducted to completely train Caregivers for Urethral calibration



**Figure 2**

Observations conducted to completely train Nursing Personnel for Urethral calibration