A NEW TECHNIQUE FOR FAST AND SAFE COLLECTION OF URINE IN NEW BORNS

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ABSTRACT

INTRODUCTION
Clean urine samples are necessary to accurately diagnose several diseases in new-borns, especially Urinary Tract Infections (UTIs). A wide range of clinical interventions for urine collection is described in the literature including non-invasive and invasive methods. The most common non-invasive technique is urine collection using sterile bags, which is associated with significant patient discomfort and contamination of samples. Obtaining a clean-catch urine sample is the recommended method for urine collection in children able to co-operate. However, in children lacking sphincter control, urine catch is more difficult and time-consuming and invasive methods (catheterization and needle aspiration of urine from the bladder) are sometimes needed. There are some stimulation techniques that facilitate emptying of the bladder in situations of bladder dysfunction. We hypothesized that the use of such methods in new-borns could facilitate the collection of a clean-catch urine sample. The aim of this study was to determine the success rate and safety of a new non-invasive technique to obtain clean-catch urine samples in newborns.

AIM
To describe and test a new technique to obtain midstream urine samples in newborns.

MATERIALS AND METHODS
This was a prospective, feasible and safety study conducted in Mahatma Gandhi Memorial Hospital, Warangal, (A secondary centre with a 20-bed neonatal unit, a 130-beded pediatric ward). This study was carried out over 7 months (January-July 2015). Patients consisted of 100 consecutively admitted infants aged less than 30 days who needed a urine analysis according to their attending physician.

RESULTS
This technique was successful in 72% of newborns. Mean time to sample collection was 56.99 Sec. No complications other than controlled crying were observed.

CONCLUSION
A new, quick and safe technique with a high success rate is described, whereby the discomfort and waste of time usually associated with bag collection methods can be avoided.

KEYWORDS
Clean urine, Neonate, SPA and TUC, New born.

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INTRODUCTION: Sterile urine samples must be collected from many hospitalized neonates to rule out urinary tract infections.[1] A wide range of clinical interventions for urine collection is described in the literature, including non-invasive and invasive methods. Obtaining a clean-catch urine sample is the recommended method for urine collection in children able to co-operate. However, in children lacking sphincter control, urine catch is more difficult and time-consuming and invasive methods.

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There are two recommended methods for collecting sterile urine samples from neonates, Suprapubic Aspiration (SPA) and Transurethral Catheterization (TUC).[2] SPA is considered the —gold standard.[3] But TUC has an acceptable sensitivity of 95% and a specificity of 99% if colony counts greater than 1000 CFU/mL are considered positive.[3]

LIMITATIONS OF THIS STUDY: Include the lack of control group. Nevertheless, the time to obtain urine in other published series is much longer.[4] Neither method always successfully collects a sufficient volume of urine.[1,5,6] and both methods are invasive and painful.[1,5]

There are some stimulation techniques that facilitate emptying of the bladder in situations of bladder dysfunction.[3] We hypothesized that the use of such methods in new-borns could facilitate the collection of a clean-catch urine sample. The aim of this study was to determine the success rate and safety of a new non-invasive technique to obtain clean-catch urine samples in new-borns.[7,8]

Bag Urine: The genitals are inspected, thoroughly cleaned and dried and a self-adhesive urine collection bag is securely attached. Ideally, bag urine is unsuitable for culture, because contamination frequently causes false-positive findings.[9,10,11]

Clean-Catch Urine: For the acquisition of a fresh vesical urine sample, the baby is held on an adults lap with the genitals exposed; urine that is spontaneously voided after drinking is caught in a sterile vessel. This method yields false-positive findings in 5–26% of cases.[11,12]

Catheter Urine: A suitable urine sample for culture can be obtained from a female infant or toddler by one-time catheterization (i.e., not from an indwelling bladder catheter). In boys, suprapubic bladder puncture should be performed instead of transurethral catheterization.[13]

Suprapubic Bladder Aspiration (SPA): This is a simple (though rarely performed), relatively non-invasive means of acquiring a urine sample if pyelonephritis is suspected, particularly when the patient is an infant. Vesical puncture is indicated whenever bag urine can be expected to be contaminated, e.g., in patients with vulvovaginitis, anogenital dermatitis or phimosis. The puncture is most likely to be successful if the degree of filling of the bladder is assessed beforehand by ultrasonography in neonates and infants, ultrasonography increases the likelihood of an adequate urine sample from 60% to nearly 97%.[14,15] Suprapubic Aspiration (SPA) is regarded as the gold standard method for collecting urine samples with minimal false-positive results. However, this method is more invasive and painful than the others. Transurethral catheterization is a less painful method that has comparable sensitivity and specificity as SPA, making it more routinely used. The non-invasive and easily accessible collection and culturing of Collecting Bag Urine (CBU) is widely used in outpatient clinics and emergency units, despite its high contamination rate.[15]

METHODOLOGY NEW TECHNIQUE: Two people (Trained nurses and/or physicians) were needed to perform the procedure and a third to measure the time taken. This technique involves a combination of fluid intake and non-invasive bladder stimulation manoeuvres. The first step is either breast-feeding or providing formula intake appropriate to the age and weight of the new born. In babies fed infant formula, 10ml was provided on the first day of life, increasing to 10ml per day during the first week. From the second week onwards, 25ml/kg were administered before the onset of stimulation. Twenty-five minutes after feeding, the infant's genitals were cleaned thoroughly with warm water and soap and dried with sterile gauze. A sterile collector was placed near the baby in order to avoid losing urine samples. Before performing the technique, we administered non-pharmacological analgesia, such as non-nutritive sucking or 2% sucrose syrup, to prevent/lessen crying. The second step is to hold the baby under their armpits with their legs dangling. One examiner then starts bladder stimulation, which consists of a gentle tapping in the suprapubic area at a frequency of 100 taps or blows per minute for 30s. The third step is stimulation of the lumbar paravertebral zone in the lower back with a light circular massage for 30s. Both stimulation maneuvers are repeated until micturition starts and a midstream urine sample can be caught in a sterile collector. Success is defined as the collection of a sample within 5 min of starting the stimulation maneuvers.

Inclusion Criteria:

- Term babies who are on breast feeding.
- Stable babies of septicaemia.
- Term/preterm/low birth weight babies with neonatal jaundice.

Exclusion Criteria:

- Babies who are on ventilators/CPAP.
- Very sick babies.
- Extreme preterm/very low birth weight/extreme low birth weight.
- Drug administration prior to urine collection.
- Congenital anomalies/congenital heart diseases / congenital urogenital abnormalities.

RESULTS: In our study, we selected 100 neonates both male and female babies of age less than 30 days.

Sl. No.	Female	Male
1	47	53

Table 1: Sex groups

Sl. No.	<7 Days	>7 Days
1	58	42

Table 2: Age groups

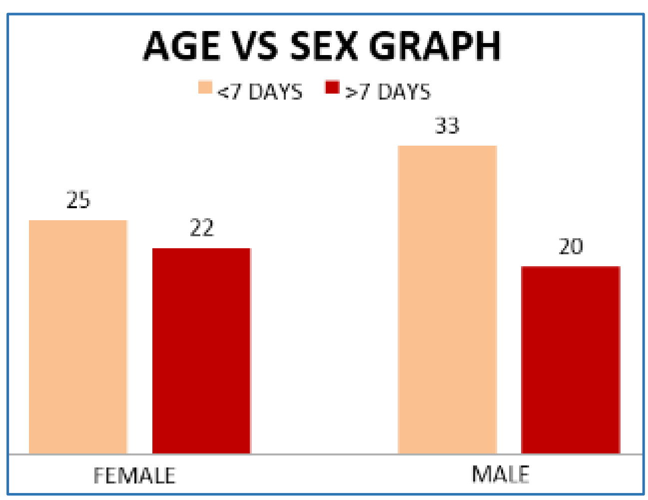


Fig. 1: Age vs. Sex graph

- Female babies less than age 7 days were 25, which is 43.10% of the total.
- Female babies more than age 7 days were 22, which is 52.40% of the total.
- Male babies less than age 7 days were 33, which is 56.90% of the total.
- Male babies more than age 7 days were 20, which is 47.60% of the total.

Sl. No.	Group	Age			Total
		Min	Max	Mean	
1	<7 days	2	6	4.48	58
2	>7 days	8	22	10.26	42
	Total	2	22	6.91	100

Table 3: Age groups

- Minimum age in <7 days is 2 days; maximum age is 6 days and mean age is 4.48 days.
- Minimum age in >7 days is 8 days; maximum age is 22 days and mean age is 10.26 days.
- Minimum age in total group 2 days, maximum ages is 22 days and mean age is 6.91 days.

AGE GROUP RESULTS: Following the new technique of urine collection, we did this technique in 100 babies who were admitted in our NICU department mahatma Gandhi memorial hospital, Warangal, Telangana, from January to July 2015; 72% of the babies passed urine within one minute with mean time being 56 seconds. The only complication being crying and no other complications were noted.

We took test result as positive if the baby passes urine within 5 min of the procedure in one attempt and negative if baby is unable to pass the urine after 5 minutes of the procedure.

Sl. No.	Age	Results		Total
		Success	Failure	
1	<7 Days	41	17	58
2	>7 Days	31	11	42
	Total	72	28	100

Table 4: Age vs. success and failure

- 58 babies were age less than 7 days of which 41 babies successfully passed urine.
- 31 babies were age more than 7 days of which 31 babies successfully passed urine.

Sl. No.	Age	Results		Total
		Success	Failure	
1	<7 DAYS	41	17	58
		70.70%	29.30%	100%
2	>7 DAYS	31	11	42
		73.80%	26.20%	100%
	Total	72	28	100
		72%	28%	100%

Table 5: Age vs. success and failure percentages

- In less than 7 days babies the success rate is 70.70% and 29.30% babies failed to pass the urine.
- In more than 7 days babies the success rate is 73.80% and 26.20% babies failed to pass the urine.
- Overall 72% of the babies passed urine within 5 min of time.

Sl. No.	Sex	Results		Total
		Success	Failure	
1	Female	33	14	47
2	Male	39	14	53
	Total	72	28	100
		72%	28%	100%

Table 6: Sex vs. success and failure

- 47 female babies gone through the test out of which 33 babies passed urine and 14 babies not passed urine.
- 53 male babies gone through the test out of which 39 babies passed urine and 14 babies not passed urine.

Sl. No.	Sex	Results		Total
		Success	Failure	
1	Female	33	14	47
		70.20%	29.80%	100%
2	Male	39	14	42
		73.60%	26.40%	100%
	Total	72	28	100
		72%	28%	100%

Table 7: Sex vs. success and failure percentages

- In female babies the success rate is 70.20%.
- In male babies the success rate is 73.60%.

Age	TIME		Total
	Success	Failure	
<7 Days	41	17	58
	70.70%	29.30%	100%
>7 Days	31	11	42
	73.80%	26.20%	100%
Total	72	28	100
	72%	28%	100%

Table 8: Age vs. Success and failure

- 58 babies were less than 7 days and the success rate in this group babies is 70.70%.
- 42 babies were more than 7 days and the success rate in this group babies is 73.8.

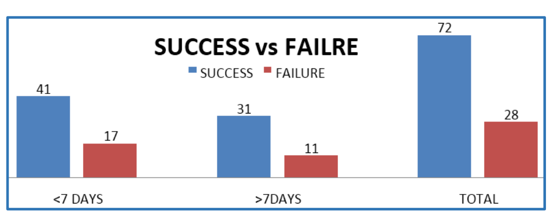


Fig. 2

Sl. No.	Sex	No. of Babies	Time		
			Min	Max	Mean
1	F	33	12	129	48.06
2	M	39	22	156	64.54
	Total	72	12	156	56.99

Table 9: Sex and time analysis

Sl. No.	Age	Time		
		Min	Max	Mean
1	<7 Days	20	156	59.12
2	>7 Days	12	126	54.16
	Total	12	156	56.99

Table 10

Age	Sex	Success	Failure	Total
<7 Days	F	19	6	25
	M	22	11	33
>7 Days	F	14	8	22
	M	17	3	20
Total		72	28	100

Table 11

Sex	Mean	Number	Minimum	Maximum	Median
F	48.06	33	12	129	44.00
M	64.54	39	22	156	49.00
Total	56.99	72	12	156	46.50

Table 12: Age, sex, mean and median

Age	Mean	Number	Minimum	Maximum	Median
<7 Days	59.12	41	20	156	46
>7 Days	54.16	31	12	126	48
Total	56.99	72	12	156	46.5

Table 13

AGE/SEX – MEAN AND STANDARD DEVIATION

MALES		FEMALES	
Mean	64.53846154	Mean	48.06060606
Standard error	5.690611412	Standard error	4.717179152
Median	49	Median	44
Mode	29	Mode	45
Standard deviation	35.53785687	Standard deviation	27.09813116
Sample variance	1262.939271	Sample variance	734.3087121
Range	134	Range	117
Minimum	22	Minimum	12
Maximum	156	Maximum	129
Sum	2517	Sum	1586
Count	39	Count	33
Largest (1)	156	Largest (1)	129
Smallest 1)	22	Smallest (1)	12

Table 14

MALES:

- Mean time for male is 64.53 sec and standard deviation is 35.5 sec and range is 134.
- Min time is 22 sec and max time is 156 sec.

FEMALES:

- Mean time for male is 48.06 sec and standard deviation is 27.09 sec and range is 117.
- Min time is 12 sec and max time is 129 sec.

Sl. No.	Category	Males	Females
1	Mean	64.53846154	48.06060606
2	Known variance	1262.92	734.3
3	Observations	39	33
4	Hypothesized mean difference	0	
5	Z	2.229301844	
6	p value	0.012896914	

Table 15: Z-Test

P value is less than 0.05(p value <0.05/p value=0.012 statistically significant).

DISCUSSION: Midstream urine collection is the preferred method for adults and older children and is suitable for diagnosing UTI. The collection of spontaneous urine in infants is also useful for UTI investigation, but is a time-consuming and unpredictable task that requires prolonged attention and patience, and so is not widely performed. The advantages of midstream urine collection and the difficulties performing it in new-borns encouraged us to develop a suitable technique for this age group. Invasive methods for obtaining clean urine (Suprapubic aspiration and bladder catheterization) are aggressive and have a high failure rate in new-borns due to their anatomical characteristics and irregular voiding pattern. We based the procedure on maneuvers described for patients with bladder dysfunction to stimulate bladder emptying through reflex contraction of the detrusor muscle.[16]

The detrusor muscle is innervated by the parasympathetic pelvic nerves (S2–S4). The spinal micturition reflex is a simple arch reflex. Distended bladder walls stimulate efferent fibers going to the medulla, the arch reflex is produced in S2–S4, and afferent fibers stimulate the detrusor muscle which contracts to pass urine. This reflex is voluntarily inhibited and controlled in continent individuals by the cortex, but not in new-borns. In neonates, it can be triggered as we propose.

We designed a stimulation technique and protocol and performed a study after nurses and physicians had been trained. We have demonstrated that this technique is effective in obtaining a urine sample in a majority of patients in an easy, safe and fast way. Bag changes, long waiting times and invasive techniques were avoided. Limitations of this study include the lack of control group.

Nevertheless, the time to obtain urine in other published series is much longer. Several factors may have influenced the efficiency of our technique: trained staff performed the procedure and a standardized fluid intake favoured the onset of urination after 20–30 min in this age group.[17]

As far as we know, there is no other standardized method to facilitate micturition in infants. This technique has replaced the use of collection bags as a routine method for new-borns in our centre. Other invasive and aggressive methods carrying some risk (Suprapubic aspiration or bladder catheterizations) were also avoided.

In infants and toddlers, urine must be obtained by clean catch, catheterization or bladder puncture; spontaneously voided urine is likely to be contaminated.

Urine should always be obtained at the same time of day from each patient, so that the findings will be comparable across tests. Spontaneously voided urine should not be kept before testing for any longer than 1–2 hours at room temperature, or 4 hours in a refrigerator (at 4°C), or else the cells will disintegrate, the bacterial count will increase and the pH will rise.[18]

Common indications for urine collection include the measurement electrolyte, albumin excretion, ketone bodies, bile salts and bile pigments, epithelial cells, pus cells and culture for any organisms. Urine should be collected in a clean vessel that is stored in a cool place. The starting point of collection is considered to be the time of the last spontaneous voiding before collection, and its endpoint is the time of the last collected voiding. The duration of urine collection are documented.

For urine culture, a fresh urine sample should be obtained and kept at 4–8°C until and during its transport to the laboratory. Alternatively, the sample can be pre-incubated in culture media and sent directly at 36°C. The bacterial count per millilitre is determined; its interpretation depends on the mode of acquisition of the sample. The diagnosis of a urinary tract infection requires the demonstration of at least $10.^5$ organisms/mL.[19] More recent studies call for a minimal count of $10.^6$ or 10^7/mL.[20] Lower counts in catheterized urine may be pathological, and any number of demonstrated organisms is pathological in urine obtained by bladder puncture. Depending on the mode of acquisition, urine culture often has false positive rates up to 25%, and the false-positive rate of bag urine culture ranges from 30% to 63%. Bladder puncture is superior to clean catch and thus provides a far more suitable sample than bag collection of the urine.[9,10,19,20]

UROBAG: The procedures were attempted if the infant had not urinated within approximately 30 minutes of feeding. All the patients were under cardiovascular and oxygen saturation monitoring for approximately 20 minutes before the procedures were started. A procedure was defined as successful when at least 2mL of urine was obtained. We measured the duration of the urine collection procedure with a stopwatch in seconds. No complications occurred during urine sampling in either new or urobag technique. There was no need to increase the oxygen support for any of the infants.

Urine specimens were collected using an aseptic technique, according to our departmental guidelines. After cleansing the perineum with antibacterial cotton (Povidone iodine), a urine collection bag was attached to the patient's perineum by trained pediatric nurses. The urine bag was left in place for up to 1 hour, without changing the bag, unless there was evidence of leakage, stool contamination, or the bag separated from the skin. Whether the urine was collected via a urine bag or catheterization, the first few drops were routinely discarded because of potential bacterial contamination from the distal urethra.[15,21] Within 30 minutes of collection, the urine specimens were sent to the laboratory for prompt urinalysis and culture.

This study included infants 0–1 months of age of both sexes who were admitted to the NICU or neonatal ward of MGM Hospital and who were required to undergo urine collection for microbiological studies. The exclusion criteria were a clinical diagnosis of a decreased level of consciousness, congenital anomalies in the central nervous system, genitourinary and gastrointestinal tracts, abdominal distention, abdominal wall cellulitis, colostomy, inguinal hernia; organomegaly; any hemorrhagic disorder and the use of any sedative or hypnotic drug.

REVIEW OF LITERATURE: Catheters (from the Greek ―send down‖ or ―thrust into‖) are not new. In the first century AD, Celsus, writer of the Roman medical encyclopedia ―de edicina‖ noted the use of bronze UCs (Kirkup 1998) and UCs were found in the house of a surgeon in Pompeii (Carr 2000). In later centuries, vivid accounts describe the use of materials such as glass, pewter, reeds and animal skin to relieve urinary obstruction (Kirkup 1998). Heister (1743, p91) reported using a small goose quill to catheterize a female patient with good effect.

The use of such devices was understandably far from routine. The invention of gum elastic tubing in around 1782 facilitated the production of more malleable devices. In 1844, Charriere (After whom the unit of specifying the gauge of catheters is named) issued a catalogue offering UCs made from silver, pewter, and gum elastic and ivory. When latex became available in the 1930s, Foley and Belnap produced and described a double - channelled balloon catheter similar to products still used today (Foley 1937). This technological advance heralded the start of the routine use of urinary catheters in healthcare. Currently, over 100 million IUCs are used annually (Nasr 2010).

Commonly used methods of collection and measurement of urine output on a continuous basis include indwelling catheters, polythene urine collection bags, when these methods cannot be used; the only record of urine output is the number of wet diapers (Hill, 1958, p.570).

An UC is a tube that goes into the urethra and enters the bladder. It provides a route to either drain or to in still medicines into the bladder. UCs can be made from various materials such as latex or silicone. They may have hydrophilic, silver or other coatings which are added with the aim of reducing UC-related complications such as trauma and infection.

UCs vary in length and diameter (gauge) with shorter UCs, generally more suitable for women and the longer UCs for men. Modern indwelling urinary catheters have small balloons on one end (Usually between 2.5ml for a small child and 10ml for an adult) that are inflated once in the bladder to hold the IUC in place. The IUC may then be attached to a drainage tube and bag to collect urine (Gelliffe 2003).

Research showed the danger of the indwelling catheter as a source of infection (Beeson, 1958; Hildebrant, 1964; Levin, 1964; and Lireman, 1969). Kass and Sossen (1959) reported that after 24 hours with a retention catheter bacteriuria occurred in 50 percent of the patients, and that after four days 98 to 100 per cent of the patients had 100,000 bacteria per cubic centimeter of urine. This hazard is increased in the infant female with a short urethra. The trauma caused by the insertion of the catheter cannot be over emphasized.

Urine collection bags with tubing attachments, despite various modifications (Clifton, 1969; Hsi-Yen and Anderson, 1967; and Wilkinson and Baldwin, 1969) have various limitations. The necessity of an intact skin makes them unusable in patients with burns and severe rashes involving the perineal area. Both legs must be restrained to prevent interference with the drainage tube. The bags may tear or the adhesive material may become moist with urine and fail to adhere, thus requiring reapplication. Frequent reapplication of these bags causes irritation with erythema and even excoriation of the perineal skin. At such times the collections must be discontinued to allow the skin to heal (Sato, 1969, p. 804).

The data of Braude, Forfar, Gould, and McLeod (1967) suggested contamination of urine during the application of the bags. Cell and bacterial counts for both sexes were significantly increased in such urine samples.

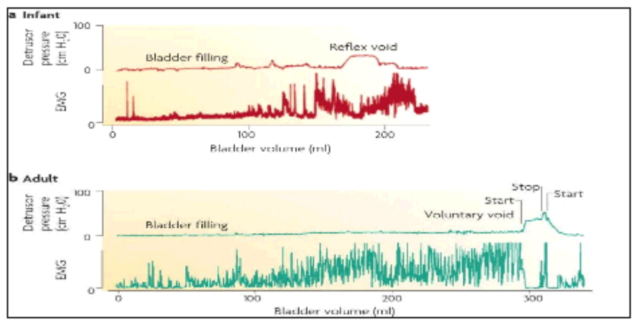
Definition: Micturition or urination, occurs involuntarily in infants and young children until the age of 3 to 5years, after which it is regulated voluntarily. The neural circuitry that controls this process is complex and highly distributed: it involves pathways at many levels of the brain, the spinal cord and the peripheral nervous system and is mediated by multiple neurotransmitters.

The storage and periodic elimination of urine depend on the coordinated activity of smooth and striated muscles in the two functional units of the lower urinary tract, namely a reservoir (the urinary bladder) and an outlet consisting of the bladder neck, the urethra and the urethral sphincter. The coordination between these organs is mediated by a complex neural control system that is located in the brain, the spinal cord and the peripheral ganglia.

The lower urinary tract differs from other visceral structures in several ways. First, its dependence on CNS control distinguishes it from structures that maintain a level of function even after the extrinsic neural input has been eliminated. It is also unusual in its pattern of activity and in the organization of its neural control mechanisms. For example, the bladder has only two modes of operation: storage and elimination.

Thus, many of the neural circuits that are involved in bladder control have switch-like or phasic patterns of activity, unlike the tonic patterns that are characteristic of the autonomic pathways that regulate cardiovascular organs. In addition, micturition is under voluntary control and depends on learned behaviour that develops during maturation of the nervous system, whereas many other visceral functions are regulated involuntarily.

Developmental Changes: The mechanisms that are involved in the storage and periodic elimination of urine undergo marked changes during prenatal and postnatal development.[22,23] In the fetus before the nervous system has matured, urine is presumably eliminated from the bladder by non-neural mechanisms; however, at later stages of development voiding is regulated by primitive reflex pathways that are organized in the spinal cord. As the human CNS matures post-natally, reflex voiding is eventually brought under the modulating influence of higher brain centres. In adults, injury or disease of the nervous system can lead to the re-emergence of primitive reflexes.[24,25]



Reflex voiding responses in an infant, a healthy adult

Combined cystometrograms and sphincter electromyograms (EMGs, recorded with surface electrodes), allowing a schematic comparison of reflex voiding responses in an infant (a). and in a paraplegic patient (c). with a voluntary voiding response in a healthy adult (b). The abscissa in all recordings represents bladder volume in millilitres; the ordinates represent electrical activity of the EMG recording and detrusor pressure (the component of bladder pressure that is generated by the bladder itself) in cm H_2O. On the left side of each trace (at 0ml), a slow infusion of fluid into the bladder is started (bladder filling). In part b the start of sphincter relaxation, which precedes the bladder contraction by a few seconds, is indicated ('start'). Note that a voluntary cessation of voiding ('stop') is associated with an initial increase in sphincter EMG and detrusor pressure (a myogenic response). A resumption of voiding is associated with sphincter relaxation and a decrease in detrusor pressure that continues as the bladder empties and relaxes. In the infant (a) sphincter relaxation is present but less complete. On the other hand, in the paraplegic patient (c) the reciprocal relationship between bladder and sphincter is abolished. During bladder filling, involuntary bladder contractions (detrusor overactivity) occur in association with sphincter activity.

Each wave of bladder contraction is accompanied by simultaneous contraction of the sphincter (detrusor–sphincter dyssynergia), hindering urine flow. Loss of the reciprocal relationship between the bladder and the sphincter in paraplegic patients thus interferes with bladder emptying.

CONCLUSION: A new method to obtain midstream urine in new-borns is described. It consists of feeding, bladder stimulation and paravertebral lumbar massage. The technique has been demonstrated to be safe, quick and effective. The discomfort and waste of time usually associated with bag collection methods can be avoided, as well as invasive techniques.

Ethics Approval: The clinical research ethics committee of Mahatma Gandhi memorial hospital, Warangal, Telangana, approved this study.

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TAPPING OVER THE SUPRAPUBIC REGION

PASSING URINE AFTER DURING THE PROCEDURE

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