Stone and Pelvic Urine Culture & Sensitivity are better than Bladder Urine as Predictors of Urosepsis following Percutaneous Nephrolithotomy - a Prospective Clinical Study

> Dissertation submitted in partial fulfillment of the requirements for the degree of M.Ch (Urology)–Branch IV



GOVT. STANLEY MEDICAL COLLEGE & HOSPITAL

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY CHENNAI, TAMILNADU, INDIA.

AUGUST – 2014

DECLARATION

This is to certify that the thesis entitled "Stone and pelvic urine culture and sensitivity are better than bladder urine as predictors of urosepsis following Percutaneous Nephrolithotomy – a prospective clinical study", submitted by me to The Tamilnadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of the requirements for the award of the degree of M.Ch Genitourinary surgery is a bonafide record of research work carried out by me under the supervision of Prof. Dr. V.Selvaraj M.S., M.Ch., Department of Urology, Govt. Stanley Medical College, Chennai during the year 2011-2014. The contents of this thesis, in full or in parts, have not been submitted to any other Institute or University for the award of any degree, diploma, Associate ship, Fellowship or other titles.

Place: Chennai

Date:

(Dr. M. SIVARAJ)

CERTIFICATE

This is to certify that the dissertation entitled "Stone and pelvic urine culture and sensitivity are better than bladder urine as predictors of urosepsis following Percutaneous Nephrolithotomy – a prospective clinical study" is a bonafide record of original work done by DR. M. SIVARAJ in partial fulfillment of the Tamilnadu DR.M.G.R MEDICAL UNIVERSITY, Chennai, rules and regulations for the award of the degree M.Ch Urology Branch IV under my guidance and supervision during the academic year August 2011-2014.

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LIST OF ABBREVATIONS

| PCNL | Percutaneous nephrolithotomy |
|-------|---|
| SIRS | Systemic Inflammatory Response Syndrome |
| СТ | Computed Tomography |
| MRI | Magnetic Resonance Imaging |
| ALARA | As low As Reasonably Acceptable |
| KUB | Kidney, Ureter, Bladder |
| IVU | Intravenous urogram |
| RGP | Retrograde Pyelogram |
| UPJ | Uretero Pelvic Junction |
| TNF | Tumor Necrosis Factor |
| ACTH | Adrenocorticotropic Hormone |
| MRSA | Methicillin-Resistant Staphylococcus aureus |
| HUN | Hydro Uretero Nephrosis |
| ТС | Total Count (WBC) |
| DC | Differential Count |
| C&S | Culture and Sensitivity |
| PPV | Positive Predictive Value |
| NPV | Negative Predictive Value |
| CFU | Colony-forming unit |
| SD | Standard Deviation |
| RR | Relative Risk |
| MSU | Mid-Stream Urine |

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the procedure of choice for the management of large and complex renal stones and is one of the most frequent renal procedures done at our institution. Indications are larger stones (greater than 2 cms), stones not suitable for extracorporeal shock wave lithotripsy, and stones in kidneys with abnormal anatomy. Urosepsis and bacteremia following PCNL can be devastating despite sterile preoperative urine and prophylactic antibiotics. Despite careful pre-operative evaluation and ensuring strict aseptic precautions during the procedure, patients still have this complication of a life threatening Urosepsis. Infected stones, stone burden, hydronephrosis, prolonged manipulation, access difficulties, bleeding and comorbidity have been held responsible for Urosepsis, which often needs intensive care treatment that escalates the cost of treatment.

The present investigation analyzed and studied the culture and sensitivity of the three samples namely the bladder urine, pelvic urine, and extracted stone during PCNL and compared them to ascertain as the better predictors of urosepsis following the procedure.

AIMS AND OBJECTIVES

- To determine the correlation of culture and sensitivity between various sites of urine sampling in the form of bladder urine, pelvic urine and extracted stone during PCNL procedure.
- To monitor the Systemic Inflammatory Response Syndrome (SIRS) and Septic shock following PCNL procedure.
- 3. To determine the better predictors of Urosepsis following PCNL.

REVIEW OF LITERATURE

Dr Thomas Hillier MD was the first to publish a method of Percutaneous nephrostomy in 1865; he repeatedly drained a congenitally obstructed kidney in a 4- year old boy. Goodwin and Casey in 1955 placed a trocar percutaneously in the collecting system. Later, the Seldinger method of nephrostomy placement was adopted. The first percutaneous nephrolithotomy (PCNL) via a nephrostomy tract created for the sole purpose of stone removal was performed in 1976 by Fernstrom and Johansson¹. In 2005, the clinical practice guideline report for the management of staghorn calculi by the American Urological Association guidelines ⁴ panel confirmed that the percutaneous treatment of staghorn calculi should be considered as the first-line treatment for most patients.

Relevant Anatomy

The kidneys are paired organs in the retroperitoneum on the posterior abdominal wall. Each kidney is of a reniform shape, with an upper and a lower pole, a convex border placed laterally, and a concave medial border. The medial border has a marked depression, the hilum with the renal vessels and the renal pelvis.

Renal Morphometry

In adults, it is found that left kidney is larger than the right kidney, and this finding is in agreement with morphometric findings in fetal kidneys. The right kidney presented a mean length of 10.97 cms, while the left kidney presented a length of 11.21 cm mean. The right kidney presented 3.21 cms of mean thickness at the hilum, and the left kidney presented mean thickness of 3.37 cms. An interesting and worthwhile finding is that, in the same kidney, the superior pole has a greater width with a mean of 6.48 cms than the inferior pole (mean = 5.39 cms). The anterior and the posterior renal arteries are the two main divisions of the renal artery. There are four segmental arteries arising from anterior division which supply the anterior and polar regions of kidney.

The remaining parts of kidney are supplied by the posterior segmental artery. The segmental arteries give rise to the interlobar arteries beyond the renal sinus and form the arcuate arteries at the cortico medullary junction. The interlobular arteries branch from the arcuate arteries at right angles and run to the periphery giving rise to the afferent arterioles of the glomeruli. The kidney is supplied by the anterior and posterior segmental branches of the main renal artery. The anterior segmental artery supplies the anterior half of the kidney and the polar regions. The posterior segmental artery supplies only the posterior aspect of the kidney. An avascular plane separates the anterior and posterior blood circulation of the kidney, the Brodel's Line. The intrarenal veins do not follow a segmental structure. Unlike the arteries, the venous system is freely interconnected. Multiple anastomotic arcades between the veins prevent parenchymal congestion and ischemia from venous injury.

Collecting System Anatomy

The anatomic landmarks dividing the renal parenchyma from the collecting system are the renal papilla. Calyces in direct apposition to the renal papilla are defined as minor calyces and vary in number from 5 to 14 (mean: 8). A minor calyx may be single (draining only one papilla) or compound (draining two or three papillae)⁵. Minor calyces may drain directly into an infundibulum or join to form major calyces, which then drain into an infundibulum. The infundibula are the principal divisions of the pelvicalyceal system, draining directly into the renal pelvis. There are usually three renal calyceal groups: the superior, midzone, and inferior major calyces.

Barcellos Sampaio and Mandarimde-Lacerda⁵ (1988) analyzed 140 three dimensional polyester resin corrosion endocasts of human kidneys and contributed significantly to our understanding of the intricate anatomy of the pelvicalyceal system. They observed that the superior and inferior major calyces usually consist of compound calyces that project toward the Polar Regions at various angles. The midzone calyces, on the other hand, are generally arranged in paired sets of anterior and posterior calyces. These paired calyces have been observed to display one of two configurations. In the Brödel type configuration, the anterior calyx is short and medially directed (forming a 70-degree angle to the frontal plane of the kidney), whereas the posterior calyx is longer and more laterally directed (positioned only 20 degrees from the frontal plane of the kidney).

The second configuration is the Hodson type in which the posterior calyx is shorter and more medially directed and the anterior calyx is longer and closer to the lateral edge of the kidney. It has been shown that 69% of right kidneys exhibit the Brödel configuration and 79% of left kidneys exhibit the Hodson configuration.

Basic Pelvicalyceal Anatomy

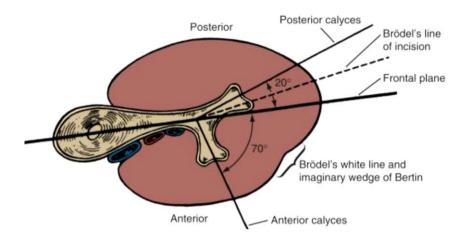
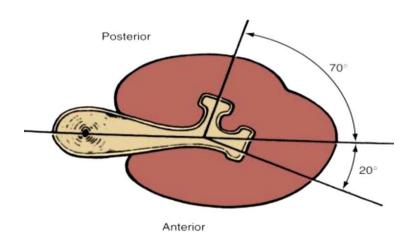


Plate 1: Brodel configuration

Plate 2: Hodson configuration



In the Brödel-type kidney, the longer posterior calyx is positioned 20 degrees from the frontal plane of the kidney and the shorter anterior calyx forms a 70-degree angle with the frontal plane. In the Hodson-type kidney, the shorter posterior calyx is positioned 70 degrees from the frontal plane of the kidney and the larger anterior calyx forms a 20-degree angle with the frontal plane.

In studying the pelvicalyceal endocasts, Barcellos Sampaio (1988) noted significant variability in the drainage patterns of the three calyceal groups. The midzone calyceal group was variably found to have drainage dependent on one of the polar calyceal groups (62%) or to drain directly into the renal pelvis independent of either polar group (38%). In 18% of the endocasts studied the midzone of the kidney was drained simultaneously by crossed calyces, of which one drains into the superior calyceal group and the other drains into the inferior calyceal group. In addition, a perpendicular minor calyx which drains directly to the pelvis was noted in 11% of the endocasts. The only consistently noted findings were that the superior calveeal group was drained by only one midline infundibulum (99%) and paired calyces drain the midzone. In 96% they were found to lie in two rows (anterior and posterior) 6 .

Clinical Relevance of Intrarenal Anatomy

A thorough understanding of intrarenal anatomy is essential for a safe percutaneous puncture and minimizes complications. Appreciation of the anterior and posterior segmental blood supply of the kidney can allow the urologist to utilize Brodel's line during percutaneous puncture. A needle traversing the renal parenchyma postero-laterally through this vascular plane avoids damage to any major blood vessels. More medial punctures in the superior calyx may injure the posterior segmental artery. The posterior segmental artery is the most commonly injured vessel in endourologic procedures. Knowledge of the Hodson and Brödel configurations of calyceal anatomy is crucial for precise preoperative localization of a stone or other lesion on intravenous pyelogram. Awareness of the great variability in calyceal drainage patterns can aid greatly during intraoperative decision making for appropriate puncture sites.

The results of the Sampaio endocasts study imply that it is easy to puncture a polar region which is drained by a single infundibulum than a polar region drained by paired calyces. Furthermore, the anatomic relationships of the intrarenal vessels to the kidney collecting system predict a high rate of vascular injury for attempted puncture directly into any infundibulum. This suggests that percutaneous entry which is direct into the fornix of a calyx is the safest route. Preview of any renal access involves examination of the desired calyx. The calyx is inspected for three factors: relation to the 12th rib, extent of hydronephrosis, and presence of malrotation. Whether the desired calyx resides above or below the 12th rib has critical significance for the technique chosen for renal access and the possibility of pleural injury. The degree of dilatation influences the difficulty of renal puncture. Improper technique may still result in failure even in a well dilated system. Finally, the unusual case of the malrotated or ectopic kidney may necessitate minor adjustments in the access technique.

Indications for PCNL:

Percutaneous stone extraction is the primary modality to treat patients with large stones size more than 2 cms, obstructing kidney stones (e.g., staghorn calculi) or stones with composition resistant to fragmentation with extracorporeal lithotripsy. In addition, for patients with concomitant renal stones and distal narrowing (e.g., infundibular stenosis and coexisting calyceal stones, stones in calyceal diverticula, or renal stones with ureteropelvic junction [UPJ] narrowing), the percutaneous route allows a convenient approach to address both problems simultaneously. For patients with UPJ obstruction (even in the absence of stones), percutaneous endopyelotomy provides an effective alternative to laparoscopic or open pyeloplasty with acceptable success rates 6 .

Imaging Modalities for Percutaneous Access

Ultrasonography

Percutaneous ultrasound-guided percutaneous access ⁷ is the simplest and most direct technique to drain a hydronephrotic kidney. It is most often used to place a temporary urinary diversion in the case of an obstructing stone or pyonephrosis and even to relieve obstruction secondary to malignant compression. Although the technique has been especially popular among interventional radiologists, it has gained popularity among endourologists who are comfortable with ultrasonography. The relative contraindications are topical lignocaine allergy and bleeding diathesis.

The ultrasound guided access has no radiation hazard and allows imaging the structures across skin and kidney. Ultrasound access is safe in pregnancy and where retrograde catheter could not be placed 7 .

Computed Tomography and Magnetic Resonance Imaging

CT-guided percutaneous access is useful in special situations⁸. A CTor MRI-guided approach is a time-consuming and expensive method that is not practical for most patients and needs to be considered only if the aforementioned techniques are not feasible or do not provide good results or if sophisticated preoperative planning is necessary. Patients with a retrorenal colon or an abnormal anatomy due to spinal anomaly predictably require cross-sectional imaging to facilitate safe access before percutaneous nephrolithotomy⁹. In addition, the CT guided approach may be useful in obtaining renal access in patients with ileal conduits, renal uric acid stones, or nephrolithiasis in the presence of angiomyolipomas at risk for bleeding. Three-dimensional CT has been described as a valuable tool for obtaining percutaneous access in the morbidly obese with malrotated kidneys and large staghorn calculi⁸. There are no specific indications for MRI-guided percutaneous nephrostomy, although the technique has been shown to be feasible and accurate in non-dilated collecting systems.

Fluoroscopy:

Endourologic procedures most often rely on fluoroscopy¹⁰. Although the risk is relatively small, everyone involved are exposed to radiation which includes the patient, surgeon and other staff. The endourologist, in particular, must undertake protective measures because he or she will have radiation exposure regularly. Likewise, children with nephrolithiasis secondary to cystinuria may be subjected to repeated fluoroscopy-based procedures. Children are more vulnerable to radiation¹¹. The two major risks are Radiation-induced injuries to the skin, and remote chances of developing a radiation-induced cancer later in life. The principle for radiation safety is ALARA: as low as reasonably achievable. The maximum yearly whole-body exposure allowed by the National Council on Radiation Protection is 5000 mrem. Though the risk with radiation above standard limit is a small health risk, it is substantial over lifetime of a surgeon (Castaneda, 1996)¹². Time, distance, and shielding are important factors for safe radiation. Reducing fluoroscopy time during endourologic procedures is of primary importance, because the exposure time determines the radiation dose to the operating room personnel.

Newer fluoroscopic equipment features, including under-table fluoroscopic sources, timer alarms, collimated x-ray beam, and lastimage-holding/memory capability help the urologist limit the fluoroscopy time. Grid-controlled fluoroscopic technique¹³ may also reduce overall radiation dose by decreasing the selected film frame rate. Use of this technique, as opposed to continuous fluoroscopy, has led to substantial dose reduction for the patient and fluoroscopy operator without sacrificing image quality or diagnostic confidence. The major source of radiation to the endo-urologist is scatter from the patient's body. Radiation is emitted from a source in all directions, and decreases with distance. Because scattered radiation follows the inverse square law, operators near the radiation beam can make significant reductions in exposure by increasing their distance from the patient. During fluoroscopy, the kilo voltage and milliamperage are adjusted automatically and the operator can control only the duration of the exposure. Exposure doses may be reduced significantly by minimizing the total "active" fluoroscopic time for a procedure through cautious use of the exposure switch to ensure that irradiation occurs only when there is a need for active viewing of the image.

The use of a last-image hold feature is of great importance in reducing the overall irradiation time. With this feature, anatomic details can be scrutinized without a competing concern about additional radiation dose. Thus, all fluoroscopes used for percutaneous surgery should have a last-image hold feature so the urologist does not need to "think with a foot on the pedal." The irradiated site of the patient affects the scatter rate to the endourologist. When the field is closer to the midline of the patient, less radiation is scattered to the operator because it is attenuated through a greater thickness of overlying tissue¹². Furthermore, in obesity there is a need for more radiation to form a quality image which leads to increased scatter. Protective surgical drapes composed primarily of bismuth, specialized urologic radiation shields, and special radio protective gloves can be used to substantially reduce scattered radiation dose¹⁴.

Collimation narrows the beam and limits the imaging area to the exact position of interest, thus reducing the scattered radiation to and from the patient. Keeping the image receiver nearer the patient minimizes the distance between the focal spot and the image receptor, keeps beam intensity as low as possible, decreases image blur, and is useful as a scatter barrier between the operator and the patient. In addition, the direction of the beam significantly influences the amount of scattered radiation reaching the operator. When the tube is above the operating table, there is a combination of leakage and scattered radiation. However, when the image intensifier is placed superiorly, radiation leakage is minimized, as an additional layer of material shields the emission tube. There is a reduction of scattered radiation to the operator. Shielding involves the use of flexible protective clothing such as aprons, skirts, thyroid shields, eyeglasses, and gloves.

The basic protection for every urologist during percutaneous surgery is a lead apron, thyroid shield, and eyeglasses. The use of protective glasses is prudent, even though there is debate about their absolute necessity. Nevertheless, approximately 1100 mrem/hr may be deviated toward the urologist's upper extremities as a result of radiation scatter, which certainly suggests that the use of eye protection may be beneficial. The standard flexible material for protective clothing is lead-impregnated rubber. The goal is to provide a barrier between the radiation source and the operator so that radiation is attenuated by the shield. Lead aprons are heavy and can become uncomfortable when the operator is wearing them for a protracted period of time. The amount of lead required for efficacy has been established as 0.5 mm, and it has been estimated that the weight of aprons with this much lead ranges from 2.5 to 7 kg. Finally, all personnel exposed to radiation should wear dosimeters positioned ¹⁵ where the operator receives the maximal radiation. It has been estimated that the radiation exposure to the underlying body is as little as 1% of the measured value.

Percutaneous Access without Imaging—"Blind Access"

Attempting percutaneous access without the aid of imaging is reserved for the rare instances when retrograde or intravenous opacification is precluded, the pelvicalyceal system cannot be opacified, or imaging machinery such as a fluoroscopic unit or sonography is inaccessible¹⁶. Poor renal function in the presence of ureteral obstruction, for example, may represent such a situation, especially if emergent collecting system decompression is required (i.e., urosepsis from pyonephrosis). Percutaneous access without imaging relies on anatomic landmarks and the assumption that anatomy is not aberrant. The lumbar notch, the boundaries being medially the sacrospinalis and the quadrates lumborum muscles, and laterally by the transversus abdominis and the external oblique muscles, superiorly by the latissimus dorsi muscle and the 12th rib, has been shown to be a useful anatomic window for successful blind percutaneous calyceal puncture. An 18-gauge access needle can be inserted into the lumbar notch at a 30-degree angle directed cephalad under the 12th rib to a depth of 3 to 4 cm.

Preparation before PCNL

A good imaging is necessary. X ray KUB, IVU were used earlier .CT urogram showed more details on anatomy of kidney and calculus ,and details of extra renal anatomy ¹⁷ e.g. retrorenal colon are delineated better. Urine should be sterile before PCNL. Bleeding tendencies should be corrected. Medications like aspirin, NSAIDS should be stopped.

During PCNL

Broad-spectrum parenteral antibiotics are given to all patients before surgery¹⁸. After inducing general anesthesia, the patient is placed in lithotomy position, cystoscopy and retrograde catherisation done with 5fr ureteric catheter. Alternatively patient is placed in prone flexible cystoscopy can be used for RGC. With utmost care to the face and extremity pressure points, padding of all pressure points ensured.

Site Selection

It is necessary to select the percutaneous nephrostomy tract that is most suited for a particular procedure. Puncturing the posterior calyx is preferred because it is straight, gives stability with trans parenchymal path and avoids major vascular structures. There are chances of Posterior segmental artery be injured if the pelvis is punctured directly. In general, the risk of injuring larger branches of the renal artery increases with progressively more medial punctures. There is less stability with more medial punctures as it lacks parenchymal support. Collecting system is visualized by injecting contrast through ureteric catheter. Alternatively, a small amount of air may be injected to provide an air pyelogram. The advantage of air is that it is lighter than urine or contrast material and therefore rises above such that it helps in identifying the posterior calves first, with the patient in the prone position. The typical appearance of air in a posterior calyx filled with contrast agent has been described as "Mickey Mouse ears." With a single stone in the renal pelvis or when the anatomy is unclear, the use of contrast material is recommended to precisely delineate the intrarenal anatomy.

However, in the case of multiple radiopaque calyceal or complete staghorn calculi, an air pyelogram will outlines the collecting system satisfactorily and interference with the evaluation of residual stones or fragments due to retained or extravasated contrast material. In general, anterior calyces are more laterally located and posterior calyces are more medially located.

Subcostal approach

With the C-arm in the vertical position, the collecting system is inspected and the appropriate calyx is identified. The ideal site provides the shortest tract to the calyx from below the 12th rib. With the C-arm at 90 degrees collecting system is examined which defines the medial vertical plane of the calyceal entry. The C-arm is then adjusted to 30 degrees towards the urologist. This places the axis of the C-arm in the same central posterior plane of the kidney, providing a straight end-on View of the posterior calyces. After the calyx is chosen, the overlying skin site is marked with a curved artery forceps. With the C-arm in the 30-degree position an 18-gauge needle is advanced in the plane of the fluoroscope beam. In general, the shorter the needle (11 to 15 cm) the easier it is to control. Longer needles are necessary for obese patients or when triangulation is utilized, because this latter technique may require a longer tract or more flexibility to "bend around" a rib. The appropriate direction for needle advancement is determined by obtaining a "bull's-eye sign" on the fluoroscopic screen¹⁰. This effect can be seen only when the needle hub is superimposed on the needle shaft and is evident when the plane of the needle is the same as that of the x-ray beam.

If the axis of the needle advancement is not parallel to the axis of the C-arm beam, a segment of the needle shaft is visible. After determination of the appropriate plane the hemostat held needle is advanced in 1to 2cm increments. Use of hemostat minimizes exposure. The needle should approximate the avascular line of Brödel, because this provides the safest access to the posterior calyceal system. The advantage of going through the parenchyma route will avoid injury to the hilar vessels and helps seal the nephrostomy tract from urine leakage. The depth of needle penetration is monitored by moving the C-arm back to the vertical position. With the C-arm in the vertical position, the approximation of the tip of the needle to the predetermined calyx can be seen and guided fluoroscopically.

For example, the needle is too deep if it appears to be past the calyx on the fluoroscopic screen. Periodically, it is important to evaluate the correct direction of needle advancement by rotating the C-arm 30 degrees toward the surgeon and observing for the bull's-eye effect. Both the appropriate axis and the needle depth are prerequisites for a successful percutaneous access. The needle has reached its intended target when its tip is in the desired calyx on both planes of fluoroscopy. When the needle appears to be in a calyx, the stylet can be removed and the correct needle position is verified by aspiration of urine. A 0.038 inch floppy-tip guide wire is inserted into the needle and either advanced into the ureter or coiled within the renal pelvis. With the needle left in place, a 1-cm skin incision is made. The needle is then removed and the tract is dilated over the wire.

Intercostal Approach

The risk of hydrothorax and hemothorax is increased when percutaneous access to the calyces is performed above the 12th rib. Various techniques to access the superior calyces while minimizing complications have been described. The direct intercostal approach, triangulation, indirect access by way of lower calyces, and retrograde percutaneous nephrostomy have all been described. Access to a superior pole calyx can be difficult by a subcostal approach, and the endourologist needs to be familiar with the intercostal approach. Many urologists favor this approach for gaining access to the upper pole and suggest that it is straight and gives viable access to most staghorn calculi, even though it carries minimal increase in morbidity. Contemporary series, in contrast to older literature, indicate that with caution intercostal puncture may be safe and effective. In particular, care should always be taken to maintain that the access sheath is secure in the collecting system. A technique for minimizing the potential morbidity of the intercostal approach by displacing the kidney caudally has been described. This is achieved by placing an Amplatz sheath through a central or lower pole calyx and rotating the back of the dilator cranially, to caudally displace the kidney that can be viewed fluoroscopically.

A second puncture or a Y-tract is created into the upper pole. This method was successful in majority of cases without complications. Also, an occlusion balloon catheter can be used to apply gentle caudal traction and displace the kidney downward and below the costal margin during the initial access approach. Alternatively, the needle can be advanced gradually only when the kidney is at its lowest excursion point, either incrementally during consecutive end inspirations or while the patient is made to perform a Valsalva maneuver by the anesthesiologist. Another technique used for access to a superior calyx is triangulation method. The C-arm is placed over the patient in the 90 degrees. A retrograde pyelogram is done, and the skin over the desired calyx is marked with an artery forceps while the C-arm is maintained in the vertical position. Medial extent of needle penetration for access to the desired calyx is defined by this plane. Then end –on view of posterior calyx is seen with C-arm in 30 degrees. With the C-arm at 30 degrees, the skin site over the calyx is marked lateral to the first site.

The surgeon uses this point on the skin surface to move in a vertical line inferiorly until a site 1 to 2 cm below the 12th rib is reached. This third site is marked and serves as the site of needle entry. From this point, the needle is advanced to the junction of the vertical plane and the 30-degree plane. Access is achieved at the junction of all three axes, hence the term triangulation. In the latter approach, the bull's-eye sign does not exist and thus the axis for needle advancement is based on the surgeon's observation of the principles of two-plane fluoroscopic viewing, especially regarding the needle tip and calyceal position. It is also very important to be familiar with the orientation of the angle of advancement of the needle as it relates to the depth of puncture along the medially defined plane determined already.

Special Circumstances

anomalous kidneys for endourologic Percutaneous access to procedures requires excellent radiographic imaging for guidance¹⁹. CT or MRI is imperative to properly define anatomy and guide puncture. In some instances laparoscopic guidance may be needed. Malrotated kidneys and horseshoe kidneys are relatively easy to access percutaneously. In these kidneys, the majority of the calyces are facing posteriorly while the renal pelvis is anterior. In general, the more medial the calyx, the more likely it is to be posterior. Because of the possible aberrant vasculature, however, preoperative CT is extremely helpful in deciding which calyx is best to access in terms of safety and efficacy (being able to reach the pathologic site). One advantage of horseshoe kidneys is that their embryologic ascent is limited by the inferior mesenteric artery, resulting in an inferior location compared with orthotopic kidneys. This results in a low incidence of pulmonary complications because the tract is almost always subcostal. The tract may be long, however, because these kidneys are more anterior; and in obese patients extra-long dilators and nephroscope may be necessary.

Also, these kidneys tend to have supernumerary calyces, making maneuvering from one calyx to another difficult. Access is more difficult with pelvic kidneys and cross-fused ectopic kidneys.

The very anterior location of these kidneys with surrounding bowel often precludes safe access. Laparoscopic displacement of bowel with subsequent combined laparoscopic and fluoroscopically guided puncture has been used successfully. Cross-fused ectopic kidneys associated with UPJ obstruction may be able to be accessed through the anterior abdominal wall providing there are no intervening bowel segments. This can be ensured with a combination of a preoperative CT scan and intra operative ultrasound and/or cross-table lateral fluoroscopy to guide the puncture.

Guide Wires and Catheters

In general, the wire preferred by most surgeons for initial access is the J-wire. This wire has the benefit of being no perforating, because its distal end is in the shape of a soft J. It has a tendency to coil in the calyx of access or in the renal pelvis and can be maneuvered in the collecting system with low risk of injury. J wires come in various lengths, coatings, and stiffness. Hydrophilic coated wires are also commonly used for initial access, because they are very slippery and

are most likely to find their way through a tight infundibulum, past an impacted stone, or through the UPJ. The major advantages of these wires are their ability to find their way through obstructions, to coil generously in the collecting system or bladder, and to have innate resistance to kinking. The disadvantages are their extreme slipperiness when wet, which can result in inadvertent loss of access; their blunt tip, which can cause perforation of the collecting system; their high coefficient of friction when dry, which can cause difficulty passing catheters over them; and their lack of memory, which can result in recoil if not physically held in position. A third wire commonly used for access as well as for manipulating down the UPJ is the coaxial wire. This wire has an inner movable core, allowing the end of the wire to be flexible or stiff, depending on the desire of the surgeon and the particular situation. Once access is obtained to the collecting system with the distal end of the wire being flexible, the shaft of the wire leading into the collecting system can be stiffened, allowing for easier dilation and preventing kinking and loss of access. Catheters are necessary once guide wire access has been obtained to the collecting system. The tract initially should be serially expanded to 10 to 12 Fr. This can be achieved using short fascial dilators²⁰. These are tapered, Teflon-coated, and malleable but stiff enough to go over a guide wire and dilate through fascia, muscle, and renal capsule. If a guide wire gets kinked during passage of a dilator, the kinked portion can be pulled into the dilator and the dilator is then advanced with back tension on the wire. Once the dilating catheter is in the collecting system, the guide wire can be changed to a stiffer wire or an attempt can be made to maneuver a new wire down the UPJ. Other catheters, such as a coudé-tipped catheter, Kumpe catheter, or a Cobra catheter, can be used. Previously operated patients or those who have scarring from infections, the fascia may be too fibrotic to dilate with a Tefloncoated catheter or a balloon. In these situations a fascial incising needle may be helpful. This device is a butterfly-shaped needle that goes over a guide wire. The wings of this device have a cutting surface that can slice through the scar tissues, allowing subsequent catheter placement.

Dilation of the Nephrostomy Tract

The entry of needle into the desired location of the pelvicalyceal system represents the first step of a successful percutaneous intervention. The tract also must be secured and dilated to allow for the passage of nephroscopic equipment or drainage catheters. In the early experience with percutaneous techniques, dilation of existing nephrostomy tracts was carried out gradually using sequentially larger telescopic dilators over a period of 8 days ²⁰. Acute dilatation of the nephrostomy tract in a single session with no untoward effects has been described. Since then, multiple techniques have been developed that allow for safe, rapid nephrostomy tract dilation so that percutaneous access and intrarenal surgery now can be routinely performed during the same setting.

Guide Wire Introduction

The main principle of acute tract dilation is that it must always be performed over a guide wire. After needle enters into the collecting system it is confirmed by return of urine after removal of the stylet, the Seldinger technique is used to advance a guide wire through the needle into the collecting system ²¹. The passage of wire via the ureter into the bladder should be attempted to minimize the risk of wire dislodgement during fascial dilation. In situations in which this is not possible (e.g., impacted ureteral stone, narrow UPJ), the wire should be positioned in a calyx that is far from the initial puncture tract to prevent dislodgement during dilation. In patients with complete staghorn calculi, the guide wire may coil within the punctured calyx because it cannot pass into the renal pelvis. In this case, dilation must be performed very gently because the guide wire can be easily displaced. It's better to place a second safety guide wire. The second safety wire is inserted immediately along the working wire and it helps to protect access to the nephrostomy tract in case the working wire becomes displaced, kinked or withdrawn accidentally. Insertion of the safety guide wire requires the use of a double lumen catheter or a coaxial system to accommodate two wires. This coaxial system consists of an inner dilator tapered to the size of the guide wire and an outer sheath. After the inner dilator is removed, the external sheath allows the safe insertion of the second guide wire, ensuring its correct positioning within the ureteral lumen. Various safety guide wire introducers are available.

Types of Dilators

A variety of techniques exist for acute dilation of the nephrostomy tract. The most commonly used systems include progressive fascial dilators, metal coaxial dilators, malleable dilators and high-pressure balloon dilators ²⁰. The decision of which type of dilation system is used varies among urologists on the basis of personal preference and experience. Multiple investigators have found no differences in renal parenchymal damage among the various dilation methods. It should be

noted, however, that when comparing balloon dilators and malleable dilators several groups of investigators observed lower renal hemorrhage rates and lower transfusion rates in patients undergoing balloon dilation 22 .

Fascial Dilators

The fascial dilator system consists of progressively larger Teflon polytetrafluoroethylene tubes designed to slide over a 0.038- inch guide wire. They range in size from 8 to 36 Fr and are inserted in a rotating, screw-type fashion with the entire dilation procedure performed under fluoroscopic control. The main advantage of this system is that it is safe. Once the 8-Fr catheter is in place, subsequent dilation is unlikely to kink the guide wire. The stability conferred by the firm polytef composition also makes fascial dilators ideal for dilation of fibrous tracts such as may be seen in patients with a history of retroperitoneal surgery, percutaneous surgery, or inflammatory processes of the kidney.

The main drawback of this system is its dependence on the integrity of the guide wire. In addition, despite their purported safety, caution must be exercised when introducing fascial dilators because their tips can perforate the renal pelvis medially, causing excessive blood loss or extravasation of irrigating fluid into the retroperitoneum.

Malleable Dilators

Malleable dilators were developed in 1982 by Kurt Amplatz to improve upon some of the weaknesses of the older fascial dilators and are now widely referred to as Amplatz dilators. A tapered 8-Fr angiographic catheter is initially inserted down the ureter over the working guide wire, and progressively larger polyurethane catheters are serially passed over the catheter/guide wire combination. The additional stability conferred by the tapered 8-Fr catheter facilitates the entire dilation process by preventing the guide wire from kinking and by allowing the larger dilating catheters to slide more easily. These dilating catheters range in diameter from 12 to 30 Fr in increments of 2 Fr. The dilators must be advanced over the working guide wire until they enter the calyceal lumen.

However, further insertion may damage the integrity of the pelvicalyceal system and should be avoided. Thus, to avoid collecting system tears, the distal end of the dilators should not be advanced across the UPJ. When nephrostomy tract dilation is performed to treat large renal stones, the dilators should be advanced only to the peripheral edge of the stone. Calyceal or infundibular lacerations have been reported when large dilators were forced past stones that were impacted in the Pelvicalyceal system. Once the tract is adequately dilated, an outer sheath is passed in coaxial fashion over the polyurethane dilators. The external sheath helps secures the access and allows the repeated introduction and withdrawal of Nephroscope.

The sheaths range in size from 28 to 34 Fr, and the outer diameter exceeds the inner diameter by 4 Fr. The sheaths are impregnated with polytef to reduce the friction and to minimize buckling. Complications that may occur with the malleable dilators include perforation of the pelvicalyceal system, extravasation, hemorrhage, and trauma to the renal capsule. Nephrostomy tract dilatation must always be done under fluoroscopic observation. If excessive force is used during the insertion of the dilators, the renal pelvis may be perforated despite the presence of the 8-Fr catheter. When the medial segment of the renal pelvis is perforated, there is the possibility of extravasation of irrigation fluid into the retroperitoneum. Trauma to the renal capsule with resultant perirenal hematoma can be caused by irregularities on the leading edge of the Amplatz dilator. The disposable dilator sets ensure a smooth leading edge on the sheath each time.

Metal Coaxial Dilators

Metal coaxial dilators are made of stainless steel and are mounted together in a telescopic fashion, mimicking a collapsible radio antenna. Progressively larger dilators are added until the tract is dilated to the desired size (Alken²⁰, 1981). The metal telescopic dilators consist of an 8-Fr hollow guide rod that slides over a guide wire and a set of six metal tubes ranging in diameter from 9 to 24 Fr. Each dilator adapts exactly to the lumen of the next dilator. A bulge at the end of the rod represents the endpoint for the progression of the dilators, ensuring that they cannot be advanced farther. After all dilators have been advanced, their tips are in the same horizontal plane, close to the tip of the guide rod. The metal coaxial dilation system is rigid and theoretically is excellent for patients with previous surgery and associated peri-renal fibrous tissue. However, several notable drawbacks have limited its use. The main disadvantage is that it is difficult to control the pressure exerted during dilation.

Balloon Dilation Catheters

For the fascial, malleable, and metal coaxial dilation systems, the major risk of injury stems from the uncontrolled repetitive passage of progressively larger dilators. In an attempt to minimize the morbidity of nephrostomy tract dilation, balloon dilation catheters capable of achieving tract dilation in a single step were developed. Before inserting the balloon catheter, a 30-Fr polytef working sheath is back loaded behind the uninflated balloon. The catheter is then inserted over the Guide wire until the inflatable segment traverses the nephrostomy tract. The tip of the balloon, indicated by the radiographic marker, is advanced just inside the calyx. Passing the balloon tip beyond the calvx or stone may result in infundibular tears or urothelial injury from the impaction of the stone. Once appropriately positioned, the balloon is inflated to acutely dilate the tract. Pressures of 15 to 20 atm can easily be reached with the balloon catheter. In patients with no previous renal surgery, pressures of 4 to 5 atm are usually enough to dilate a nephrostomy tract. In those who have had surgery, higher pressures are required to achieve the final dilatation. As the balloon is inflated, in areas of high resistance a characteristic "waist" appears, such as the renal capsule or a previous operative scar. With persistent inflation, the balloon expands fully and the waist disappears, allowing the back loaded sheath to be advanced into the collecting system in a rotating fashion. This sheath is advanced into the tract to the end of the balloon, not the end of the catheter. The balloon is then deflated and retrieved from the tract. The

working sheath provides the access for further endourologic manipulations. The purpose of balloon dilation is to achieve tract formation in a single step, avoiding the need for serial dilation. Among the major advantages of the balloon dilation system is its ease of use. Also, unlike serial dilators, which repetitively generate angular shearing forces, the balloons generate lateral compressive forces and are therefore less traumatic. Theoretically, balloon dilation should generate less hemorrhage, but this has yet to be definitively proved. Among the drawbacks of the balloon dilation system are the relative inability to dilate dense fascial tissue or scar tissue and the greater expense compared with other dilation systems.

Novel Dilation Methods

In contrast to the traditional method, this employs sequential insertion of dilators of increasing size; a "one-shot" method consisting of a single dilation of the tract with a 25- or 30-Fr Amplatz dilator has been described. Similar to the "one-shot" method, 21 single-step dilation using an expanding malleable sheath preloaded on a laparoscopic trocar has also been described (Goharderakhshan *et al.*, ²³(2001). Preliminary results using these novel methods suggest that they may be feasible and perhaps less time consuming than some of

the traditional methods of tract dilation (Goharderakhshan *et al.*, 23 (2001). The indication for percutaneous access and the size of the endoscopic instruments that will be used dictate the final extent of tract dilation. With the access tract dilated, either endourologic equipment or a nephrostomy tube is introduced. When simple renal drainage is needed, a 10-Fr nephrostomy tube may be sufficient and there is no need for greater tract dilation. The final diameter of the tract should exceed the tube or instrument size by 2 to 4 Fr, to allow adequate flow of fluid around the instrument. When percutaneous access is needed for the management of stone disease, the tract is usually dilated to 30 Fr to accommodate a rigid nephroscope.

Various authors have investigated the use of a "mini-perc" technique in which the tract is dilated between 13 and 20 Fr. The early literature suggests that a smaller volume of renal parenchyma is dilated, leading to a corresponding decrease in blood loss and postoperative pain . However, the only randomized study in the literature comparing the mini-perc and standard techniques showed no advantage with the mini-perc technique suggesting instead that poorer visualization and more difficult instrument handling may even place the mini-perc technique at a slight disadvantage. Even though PCNL is a minimal invasive procedure for renal stones it's not without complications. Prompt recognition and management of complications are critical. Equally important are prevention and minimization of these complications.

COMPLICATIONS OF PERCUTANEOUS RENAL SURGERY²⁴

The risk of hemorrhage is increased by more medial punctures, multiple punctures, and punctures into kidneys with abnormal anatomy.

□A tamponading balloon catheter (Kaye catheter) should be readily available in the surgical suite in case brisk bleeding or bleeding refractory to a large-bore nephrostomy catheter is encountered.

Delayed bleeding after percutaneous procedures usually indicates the presence of a pseudoaneurysm or an arteriovenousfistula.

□ If the renal pelvis is perforated during percutaneous surgery, maximal decompression with a ureteric stent and a nephrostomy tube should be accomplished and the procedure should be discontinued.

□Because the risk of injury to the lungs or pleura increases with more superior punctures, a postoperative chest radiograph should be obtained for all patients in whom an intercostals puncture is performed.

□ In the case of colonic perforation during percutaneous renal surgery, the gastrointestinal and urinary systems should be separated to avoid fistula formation. A double-pigtail stent should be placed in the ureter and a nephrostomy tube should be placed in the colon

Sepsis although rare can sometimes complicate PCNL eventhough the urine culture is negative ²⁵. 25% of stones particularly staghorn calculi harbor bacteria. Death is a very rare complication after PCNL mostly due to cardiovascular causes ²⁶.

Septic complications in PCNL-overview

There is no uniformity in the literature available to define infection and sepsis, which accounts for the wide range of incidences of urosepsis reported. It is vital to recognize patients at risk of urosepsis with a complete preoperative workup to ensure there is an early diagnosis and prompt treatment in the event of a postoperative urosepsis using modified Clavien grading system ^{27, 28}.

Pathogenesis of Urosepsis

An infection during urologic surgery occurs when urinary bacteria enter the bloodstream via vascular, lymphatic, or cell disruption. Manipulation of infected urine or infection stones with an increase in renal collecting system pressure causes liberation of bacteria and its endotoxins. The mechanisms of systemic absorption are due to direct absorption, pyelovenous, pyelolymphatic or pyelotubular backflow, and calyceal forniceal rupture, which eventually trigger a systemic inflammatory response syndrome (SIRS) or septic shock.

Systemic inflammatory response syndrome (SIRS) occurs as a result of neurohumoral pro- and anti-inflammatory response to bacterial endotoxins. The neutrophils, macrophages, and monocytes by interacting with endothelial cells via various pathogen recognition receptors are activated. This activation leads to variety of host response which includes the release of various plasma substances, such as tumor necrosis factor (TNF), interleukins, proteases, kinins, reactive oxygen species, nitric oxide, caspases and arachidonic acid, and platelet activating factor. Out of these, IL-1 and TNF alpha are the most important proinflammatory cytokines. They act on the temperature regulatory centers in the hypothalamus, resulting in pyrexia. They also cause release of adrenocorticotropic hormone (ACTH), which stimulates the adrenal gland.

They also act on the brain stem formation reticularis, which is responsible for patient's somnolence and even coma. They stimulate the hematopoietic growth factors, and to the formation of new neutrophils and the release of stored neutrophils. B and T lymphocytes are also stimulated causing humoral and cellular immune reaction respectively. During the continuing septic process, apoptosis of CD-4 T helper cells, B cells and dendritic cells causes an anti-inflammatory immune response, called transient immune paralysis. Activation of the complement and coagulation cascades further amplifies these events. Tissue ischemia and necrosis occurs due to microvascular ischemia, thrombosis of vessels and capillary leak phenomenon. This diffuse endothelial disruption is the reason for multiple organ dysfunctions that is a part of septic shock.

Bacteriology of urinary infections and sepsis

Over the last decade, the pathogens associated with UTIs and urosepsis have not varied considerably. To formulate an appropriate antibiotic prophylaxis schedule a continuous audit of the local incidence of the infective pattern is necessary. *Escherichia coli* remain the most common microbe responsible for clinical urinary tract infections. This is followed by *Klebsiella* and *Proteus*. Also there is increasing prevalence of Gram positive bacteria such as *Enterococcus* and *Staphylococcus*. According to Das Gupta *et al.*, 40% of urology patients admitted for treatment of urinary tract infections grew Gram positive organisms, of which Enterococcus culture accounts for about 27%. Several other studies have also confirmed that other microorganisms have increased in their incidence. And there is also concern over their resistance pattern to antibiotics, many of which are commonly used in urology practices, which includes trimethoprim, quinolones, cephalosporins, and aminoglucosides. There is also increased prevalence of methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas, Serratia, and Clostridium difficile. There is 20% incidence of pseudomonas being resistant to quinolones with increased multiresistant Pseudomonas outbreaks in endourologic units. In a retrospective study by Kashanian et al., there is 25% incidence of E.Coli being resistant to quinolones. The increase in the resistance pattern of quinolones has been reported to occur worldwide and the reason might be due to the fact that it has been used most frequently in urology practices.

The dose, timing and duration of the treatment which depends on Guy's stone score ^{2, 3} are needed to ensure that the prophylactic antimicrobial regimens are optimally effective. Culture should be done preoperatively and based on the culture and sensitivity reports culture specific treatment should be given and documentation of the response and effectiveness of the treatment should be done with follow up culture whenever possible. While making the patients urine sterile prior to the procedure is desirable for all the endourologic procedures, practically this is not always possible, because of the colonization of the stones and urinary tract. In such instances, a week prior to the procedure prophylactic antibiotics should be started. Every possible effort should be made to make the urinary tract sterile before manipulation of the urinary tract. Although practically it is difficult to get culture reports just before the day of surgery and hence the need for appropriate instituitional based prophylactic antibiotic regimen to cover both gram positive and gram negative microbes.

There are various factors that predispose a patient to the increased risk of acquiring postoperative septic complications. These can be related either to the patient's factors or the disease itself. These are described in the table below.

Risk factors associated with postoperative infections in genitourinary surgery²⁸

| Patient related factors | Disease related factors | Procedure related |
|--|--|---|
| Malignancy Immunocompromised individuals Steroid use Diabetes mellitus Autoimmune disease Poor nutritional status Severe renal failure Severe liver dysfunction older age Female gender | Disease related factors Hydronephrosis Voiding dysfunction Bacteriuria Renal stone disease Stents/Indwelling catheters Endogenous material Anomalous kidneys Poor blood flow | Procedure related • Incisional therapy • long duration • Genital tract involvement • Involvement of gastrointestinal tract • Prosthesis |
| coexistent infection hospitalization for prolonged duration | | |

PCNL and Urosepsis:

Although PCNL has a low reported overall incidence of urosepsis of 0.3–1%, there is a very high mortality rate of 66–80% following sepsis. It is widely accepted fact that the preoperative urine must be sterile before percutaneous renal surgery. Unfortunately, this is not

always possible due to the colonization of the stones and the urinary tracts; hence the role of appropriate antibiotic therapy that should be started at least a week before the procedure. The urine culture reports from patients with stones are not predictive of stone bacteriology most of the times. Therefore, these patients should receive a broad-spectrum antibiotic course sensitive to the cultured bacteria and those that are likely to be effective against urease-producing organisms residing in the stone, especially struvite stones.

Mariappan *et al.*,³⁵(2005) concluded that in patients undergoing PCNL, stone and pelvic urine cultures are better in predicting urosepsis than bladder urine; bladder urine cultures were positive in 11.1% of cases versus 35.2% and 20.4% of stone and pelvic urine cultures, respectively. Stone culture had the greatest positive predictive value (0.7). Infected bladder urine did not always carry identical bacteria as those found in the upper tract. It was also noted the patient's with stone and pelvic urine culture positivity had a relative risk of 4 to develop Urosepsis. In this study, the bladder urine did not predict SIRS. Also, they found that preoperative HUN and stones larger than 2cms correlated with positive upper urinary tract cultures. Although published literature suggests that antimicrobial prophylaxis regimen is unnecessary following termination of

percutaneous renal surgical procedures or an endoscopic procedures, because PCNL are associated with a pre-existing infection, infective stones, or involves manipulation with stents and indwelling catheter, the subsequent course of antimicrobials that is therapeutic rather than prophylactic might extend beyond 24 hours after the procedure. There is also no evidence that suggests continuing the prophylactic antibiotics if there is no evidence to suggest pre-operative colonization of urinary system. In patients who need to retain the nephrostomy tube for prolonged duration, the antibiotic treatment would be considered therapeutic rather than prophylactic, due to the fact that bacterial colonization would have happened by that time.

Pyelovenous or pyelolymphatic backflow occurs when the renal pelvic pressure is greater than 30mmHg. In a prospective study involving 31 patients who underwent PCNL, Troxel and Low, noticed that renal pelvic pressure was greater than 30mmHg in only 8 patients (26%) and there was no significant correlation between renal pelvic pressure and postoperative pyrexia. Contrary to the above mentioned study, Zhong *et al.* demonstrated that intrapelvic pressure greater than 30 mmHg and accumulated renal pelvic pressure greater than 30 mmHg may cause pyelovenous backflow that causes bacteremia and postoperative sepsis. Renal pelvic pressure can be lowered by using

an open low pressure access system, by operating through an Amplatz sheath (operating instrument 4 F sizes less than the access sheath). The inflow of irrigant fluid should be under gravity and no pressure should be applied to the irrigant fluid. One of the recommendations is to use forced diuresis i.e. 20mg Furosemide at the beginning of irrigation of fluid and repeated every 60 min of surgery or the irrigation time, which helps to reduce the pyelorenal backflow that can aggravate the bacteremia. Other factors that lead to postoperative fever and bacteremia are higher Guy's stone score longer operative time, larger stone burden, and larger volume of irrigating fluid. The Guy's stone score^{2, 3} grades the complexity of PCNL procedures as follows,

Grade I: Solitary stone in mid / lower pole or solitary stone in pelvis with simple anatomy

Grade II: Solitary stone in upper pole or multiple stones in patient with simple anatomy or solitary stone in patient with abnormal anatomy

Grade III: Multiple stones in a patient with abnormal anatomy or

Stones in a calyceal diverticulum or partial Staghorn calculus

Grade IV: Staghorn calculus or any stone in a patient with spina bifida

Manipulation and fragmentation of infected stones can cause urosepsis due to endotoxemia. McAleer et al., in his study measured the levels of Endotoxins level in renal stones and found it to be higher in stones that were infected. It is interesting to note that various intracorporeal lithotripters have an antibacterial effect. In vitro studies have revealed that after the use of intracorporeal lithotripters in fragmenting the stones, there is a decrease in the viability of the bacteria. It is reported recently that extracorporeal shock-wave or intracorporeal lithotripsy, are effective in reducing the viability of bacteria inside the artificial stone models, including the struvite stones models infected with Proteus. Whether this antibacterial phenomenon observed is significant is still to be answered and raises question to the possibility that endotoxins level might actually increase due to disruption of the bacterial cell and release of endotoxin that might actually occur. It is also noted that bleeding and prolonged manipulations increased the chance of bacteria entering the systemic circulation leading to septicemia.

Key points in prevention of infection/sepsis in PCNL³⁰:

- 1. Identification of high risk patient eg.old age, diabetic, renal failure
- 2. Preoperative urinary tract infection should be promptly treated

3. In the presence of active infection, never perform percutaneous surgery

4. make sure the preoperative urine is sterile.

5. Antimicrobial prophylaxis to be started in all cases.

6. On puncture if purulent fluid is aspirated, stop the procedure, leave a nephrostomy tube and stage the management.

7. The renal intrapelvic pressure should be kept low.

8. Use only enough irrigation to maintain adequate visibility under gravity, without using pressure.

9. Use of a wide renal access sheath (ideally 4F wider than nephroscope).

10. The quantity of irrigant fluid should be limited.

11. Limit the duration of operative time whenever possible.

12. Follow culture specific antibiotic course.

13. Continue post procedural antibiotic prophylaxis regimen.

MATERIAL AND METHODS

| Study Design | : | Prospective study |
|-----------------|------|--|
| Duration | : | December 2012 to February 2014 |
| Setting | : | Department of Urology, Govt. Stanley Medical College and Hospital, Chennai |
| Inclusion Crite | ria: | Patients with renal calculi undergoing Percutaneous Nephrolithotomy |

Exclusion Criteria:

- Diabetes mellitus
- Pyrexia prior to procedure
- Renal failure
- Patients with a stent, nephrostomy tube or indwelling catheter
- Contralateral renal and ureteric calculus
- Any previous procedures or manipulations done

PATIENTS AND METHODS

Our study included 68 patients who had symptomatic renal calculi who underwent PCNL during the period between December 2012 to February 2014. We excluded patients with a stent, nephrostomy tube or indwelling catheter, who are diabetic, with renal failure, with episodes of fever prior to surgery, previous manipulation/procedure, and presence of contralateral renal/ureteral stones.

All patients had basic investigations, renal function tests, x ray KUB, ultrasound KUB, intravenous urogram and CT urogram. Our standard protocol is to evaluate the patient with midstream bladder urine culture and sensitivity a week prior to the planned procedure and treat them with appropriate antibiotics according to the culture and sensitivity reports to make the urine sterile prior to PCNL. All patients received IV Cefotaxime prior to anesthesia induction as per our institutional protocol. Midstream bladder urine was collected a day prior to the surgery. Under general anesthesia, after strict asepsis preparation with betadine, a 5F ureteral catheter was inserted in a retrograde fashion into the ipsilateral ureter with standard cystoscope and retrograde pyelogram obtained. Patient is repositioned to prone position.

Puncture was done into the appropriate calyx with 18 – gauge needle under C arm guidance using Triangulation technique/Bull's eye technique. The first aspirated urine following a successful puncture into the collecting system is collected and is labelled as Pelvic urine which is sent for culture and sensitivity. A 0.035-inch terumo guide wire was placed into the collecting system and coiled into the pelvis or negotiated into the ureter. It is followed by multiple serial dilatations using Amplatz dilator set from 8F to 28 F dilators under Fluoroscopic guidance. Then, a 28F dilator was passed and a 30F Amplatz sheath was advanced over it.

Nephroscopy was done and the stones were identified. Lithotripsy was done with the help of pneumatic lithotripter under low pressure irrigation. The fragments were retrieved out. Once all the stone fragments are removed, after confirming with fluoroscopy, 20fr percutaneous nephrostomy drain was deployed, and Amplatz sheath removed. The extracted stones were processed by Nemoy & Stamey Technique and sent as stone culture & sensitivity.

Plate 3: Ureteric Catheterisation Under Cystoscopic Guidance



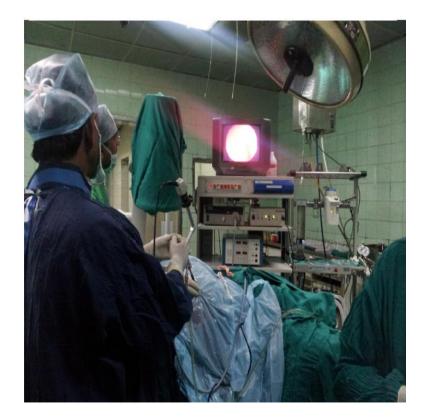
Plate 4: Fascial Dilators





Plate 5: Calyceal Puncture Using C-Arm Guidance

Plate 6 : Performing Nephroscopy in our OT.



In the post-operative period patient was monitored for SIRS and sepsis. defined as the development of 2 of 4 criteria, namely temperature less than 36C or greater than 38C, pulse rate greater than 100 beats per minute, respiratory rate greater than 20 breaths per minute and white cell count greater than 12×10^{9} /l or less than 4×10^{12} 10^{9} /l. The development of hypotension below a systolic blood pressure of 90 mm Hg or 40 below baseline for the patient in the presence of SIRS was considered septic shock. Urosepsis in this study was defined as either the presence of SIRS or septic shock. Patients temperature, pulse rate, respiratory rate, blood pressure, urine output were monitored. Patients with manifestations of sepsis were investigated with Hemoglobin, TC, DC, blood urea, S. Creatinine, S. Electrolytes, urine culture and sensitivity. Blood culture was sent for those patients with septic shock. PCN was removed on the post-operative day 1 and Foley's catheter with the retrograde catheter removed on the second post-operative day.

Stone Culture and sensitivity technique:

We followed Nemoy & Stamey Technique of processing stones for culture and sensitivity. The basic principle is to wash off surface contaminants and culture bacteria within the stone and avoid cross contamination. The stone fragments were washed in 5 sequential bottles containing sterile saline and then crushed in the fifth bottle, of which the contents were sent as stone C&S. The stone is crushed with sterile pestle and mortar. It is then mixed with Typtic soy broth and inoculates the paste onto Blood agar, Macconkey agar, CLED medium (Plate 7, 8, 9, 10). It is then incubated at 37C for 24 hours. We received the culture reports in second post-operative day and culture specific antibiotics given.

We performed statistical analysis of the data obtained using the Fisher exact and Mantel-Haenszel chi-square tests to determine associations among the three groups. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) of the three methods was calculated. A literature search was made in PUBMED and Google for comparison of results and information.

ILLUSTRATIONS OF CULTURE GROWTH ACCORDING TO INTERPRETATIVE GUIDELINES



Plate 7: Swarming growth of $\ge 10^5$ CFU/ml of Proteus vulgaris on Blood agar plate in urine sample of a patient

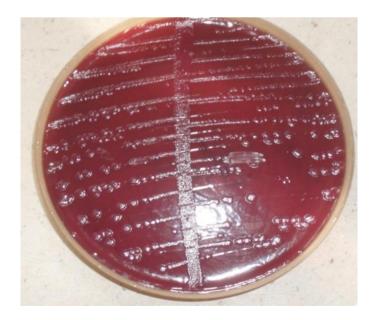


Plate 8: Growth of $\ge 10^5$ CFU/ml of Escherichia coli on Mac Conkey agar plate in urine sample of a patient



Plate 9: Mucoid growth of $\ge 10^5$ CFU/ml of Klebsiela Mac Conkey agar plate in urine sample of a patient



Plate 10: Growth of $\geq 10^4$ CFU/ml of Pseudomonas aeruginosa on CLED agar plate in urine sample of a patient

RESULTS

A total of 68 patients who underwent PCNL and satisfied the selection criteria during December 2012 to February 2014 were included in this prospective clinical study. There were equal numbers of male and female patients. The mean age of patients is 43 years and we dealt with stone sizes ranging between 25 to 40mm (Table 1). The mean operative time was 88.4 minutes with almost all patients had a single puncture for stone management.

| Age | |
|----------------------|-----------|
| Range | 18-80 |
| Mean (SD) | 43 (13.3) |
| Gender | |
| Male, n(%) | 34 (50) |
| Stone Size (mm) | |
| Range | 25-40 |
| Mean | 28 |
| Operative time (min) | |
| Range | 70-140 |
| Mean | 88.4 |

Table 1: Patients and Stone demographics

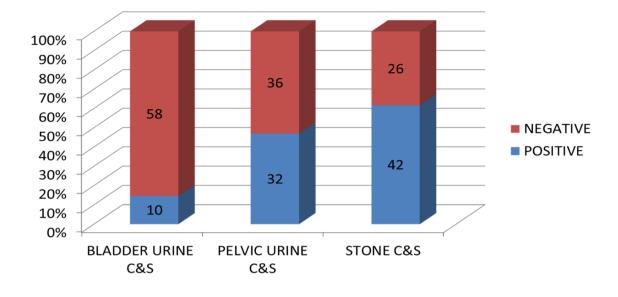


Figure 1: Culture positive prevalence

Of the three samples sent for culture and sensitivity, the most prevalent culture positive specimen is stone culture with 61.8% positivity when compared to other two specimens, with bladder culture being only 14.8% positive. The most common microbes cultured were *Escherichia coli* in all three samples. The other common microorganism that grew was *klebsiela*, *proteus*, coagulase negative *Staphylococcus aureus*, and *Pseudomonas*. Most of the bladder urine culture was of mixed growth of organisms.

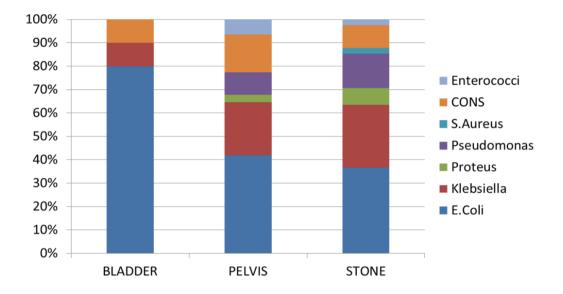


Figure 2: Types of microorganisms in various samples

All the three samples were simultaneously positive in 8 cases but however none grew identical microorganisms, and when bladder culture was negative the stones were positive in 34 patients.

| | No. bladder urine culture | |
|-----------------------|---------------------------|----------|
| | Positive | Negative |
| Stone positive: | | |
| Pelvic urine positive | 8 | 22 |
| Pelvic urine negative | 0 | 12 |
| Stone Negative: | | |
| Pelvic urine positive | 1 | 1 |
| Pelvic urine negative | 1 | 23 |

Table 2: Culture results in individuals

| | Bladder urine C &S | Pelvic urine C&S | Stone C&S |
|-----------------|-----------------------|---------------------|----------------|
| Sensitivity (%) | 25 | 83 | 97 |
| Specificity (%) | 97 | 94 | 78 |
| PPV | 0.90 | 0.94 | 0.81 |
| NPV | 0.47 | 0.83 | 0.96 |
| RR (95% CI) | 1.9 (1.4-2.7) | 5.6 (2.7-11.7) | 21 (3.1-145.4) |
| p value | 0.01 | < 0.01 | < 0.01 |

Table 3: Comparisons of diagnostic performances

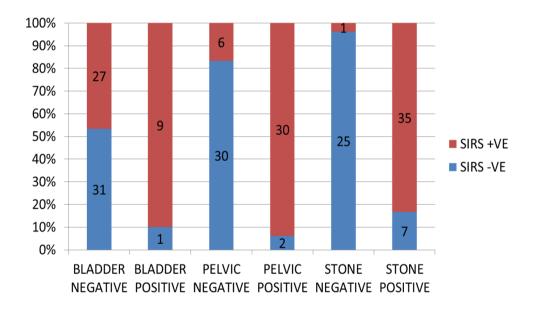


Figure 3: Correlation between SIRS and Specimens collected

| | No. identical | No. different |
|---------------------|---------------|---------------|
| Bladder urine | | |
| Stone | 0 | 8 |
| Pelvic urine | 2 | 7 |
| Pelvic Urine | | |
| Stone | 24 | 5 |
| Stone+bladder urine | 0 | 10 |

Table 4: Specimen simultaneously infected with identical anddifferent microorganisms

Pelvic urine C&S and stone C&S grew identical microbes in 24 patients (82.8% of upper urinary tract culture positive). Infected bladder urine did not carry bacteria identical to that found in the Stone. Infected bladder urine and pelvic urine grew similar microbes in only 2 patients; hence the possibility of cross infection among samples was reduced. Since infections in stones were highly prevalent, we used bladder and pelvic urine to predict the infection in stones (table 5). The sensitivity was only 19% compared to pelvic urine (69%) to predict infection in stones and hence sepsis. However both pelvic and bladder urine has almost similar specificity rate(92%) in predicting infection, which emphasis the role of preoperative culture sensitivity based treatment of bladder infection prior to PCNL and the need for prophylactic antibiotics prior to PCNL which is our standard protocol.

| | Bladder urine | Pelvic Urine |
|-------------|---------------|--------------|
| | C&S | C&S |
| Sensitivity | 19% | 69% |
| Specificity | 92% | 92.3% |
| PPV | 0.81 | 0.94 |
| NPV | 0.55 | 0.35 |
| RR | 1.4 | 2.6 |

Table 5: Comparision to predict infection in stones

Pelvic urine was the more accurate of the two specimens with a 3 fold risk of being associated with infection in the stone. All the 30 patients had at least 1 culture positive specimen. 30 patients (44.1) showed features of SIRS. Septic shock developed In 6 patients (8.8 %). There was no mortality.

DISCUSSION

In most centers it has been a standard practice to do routine urine culture sensitivity a week before planning PCNL in the management of renal calculus disease. The patients were treated based on culture and sensitivity reports with a course of appropriate antibiotics and urine culture was repeated. Antibiotic prophylaxis with oral ciprofloxacin is given a day before PCNL, as per the American Urological Association recommendations. Despite this appropriate antimicrobial prophylaxis sepsis occurs in patients undergoing PCNL. Urosepsis and shock occurs in direct correlation with the duration of the procedure, urine microbes, severity of obstruction by stone and the infective microorganism in stones.

In a retrospective study, O'Keefe *et al.*, ³² (1993) reviewed 700 patients who underwent upper urinary tract manipulations and noticed that severe septicemia developed in 9 patients and of whom 66% died of sepsis. Rao *et al.*, ³³ (1991) observed that in 27 patients who underwent PCNL, 37% developed minor forms of urosepsis. In another study by Charton *et al.*, ³⁴(1986) with 216 patients who underwent percutaneous renal surgery with no prophylactic antibiotic course developed no major forms of sepsis although 35% had infected urine preoperatively. The difference in all these studies was mainly

due to different protocols that were used and the difference in definition of sepsis. It is necessary to have clear definitions of sepsis, organ dysfunctions and to recognizable clinical and lab findings that defines these complications. In our study patients were carefully selected to ensure that other factors like diabetes, renal failure, prior fever, and prior intervention, indwelling stents and contra lateral stones that might cause SIRS were excluded.

In the present study, we used Sepsis definition by Consensus Committee 2001to define SIRS. Urosepsis included either development of SIRS or septic shock. This is a novel approach to define the postoperative septic complications of percutaneous renal surgery. Macdonald and Cadeddu et al., 37(1998) confirmed no correlation between operative time and postoperative fever. Cadeddu et al., ³⁷(1998) from The Johns Hopkins reported in their retrospective study (n=66), 28.8% of patients with post op fever greater than 38° C; but none had positive blood culture or postoperative urine culture. More over Caddedu et al, ³⁷ (1998) confirmed no correlation between fever and stone composition. The limitation of this study was that the stone culture was not performed. Fever alone as a criterion cannot be used as an indicator of sepsis/septicemia, as evidenced in the study by Rao et al.,³³(1991) in which 74% of patients with PCNL had postoperative fever of which only 41% had endotoxemia and 37% had bacteremia. It was also noted that Bacteriuria had a PPV of 0.53 for detecting endotoxemia. In our present study none of the patients has a positive blood culture although one of the three samples of bladder urine, pelvic urine and stone culture were positive in patients with postoperative SIRS.

Shigeta *et al.*, 40 (1995) in their study (n=57) found infected stones in 10% of cases and that bacteriuria was more prevalent in stones greater than 30 mm size. In our present investigation a series of stone bulk correlated with urosepsis and most of the larger stones (greater than 20 mm) were found infected.

In our study, strict measures were taken to avoid cross contamination between samples collected. The stones were serially washed in five sterile test tubes before finally crushing them and sending it for culture and sensitivity as per Nemoy and Stamey technique of processing the stones for C&S. this ensured that cross contamination between the stone and pelvic urine is avoided. Pelvic urine C&S and stone C&S grew identical microbes in 24 patients (82.8%) of upper urinary tract culture positive). Infected bladder urine did not carry bacteria identical to that found in the Stone. Moreover, infected bladder urine and pelvic urine grew similar microbes in only 2 patients.

Fowler *et al.*, ³⁸ (1984) reported stone culture positivity rate as 77.3% while it was 61.8% in our present study. In the same series, bladder urine C&S was simultaneously positive in only 12.5% of patients with infected stones and in our index study the positivity rate was found as 19% but none of them grew the same microbes. Similarly McCartney and Bratell *et al.*, ³⁹(1985) confirmed a poor correlation between infection in the stone and in bladder urine specimens.

Mariappan and Loong ³⁵(2004) confirmed the correlation between stone C&S and pelvic urine C&S, with 2 specimens having identical microorganisms two third of the times. We had 51.2% correlation between stone and pelvic urine cultures. Since stone culture positivity was high we used bladder and pelvic urine to predict culture positivity in them and found that pelvic urine had PPV of 0.94% whencompared to bladder urine. This further emphasized that there is a good correlation between pelvic urine and stone culture when compared to bladder urine.

Although the definitions used vary, as discussed before, the septic shock rates have been reported to be 1% to 2%. While the incidence of

septic shock in our series is higher (8%), this probably reflects our tertiary referral practice, which deals with complex stones and poor socioeconomic status of our patients. In our study the sensitivity of bladder urine in predicting sepsis is only 25%, when compared to stone culture which is about 97%. Yet, it is also noted that the bladder urine had 97% specificity which emphasizes the role of prophylactic antibiotics prior to the procedure and make urine sterile before attempting PCNL. Pelvic urine has highest PPV of 0.94 in predicting sepsis, highlighting the importance of upper urinary tract culture sensitivity specific antibiotic course to overcome this catastrophic complication following PCNL.

Because many patients with renal stones are being treated for recurrent urinary tract infections, the potential for antibiotic resistance becomes high. Irrational use of higher antibiotics only based in clinical features leads to increased incidence of antibiotic resistance, Upper urinary tract culture based antibiotic therapy will salvage the situation in most instances.

CONCLUSIONS

In our study, Upper urinary tract cultures have higher sensitivity and NPV for determining urosepsis post PCNL than bladder urine culture. The Profile of organism cultured in stone as well as pelvic urine has better agreement. Stone culture had highest positivity rate as compared to bladder urine. Pelvic urine had highest positive predictive value in predicting sepsis. Hence, routine upper urinary tract culture is highly recommended following PCNL. Whenever possible culture specific antibiotic regimen has to be followed and samples collected from the upper tract will be the best guide to therapeutic antibiotic use.

Our study has helped us to define our department protocol, in sending pelvic urine and stone for culture sensitivity and following culture specific antibiotics in better management of postoperative fever following PCNL.

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Proforma

Name:

Age: Sex: M/F

IP No:

History:

- Loin pain
- Fever
- Dysuria
- H/o a stent, nephrostomy tube or indwelling catheter
- Diabetes mellitus/Hypertension/Renal failure
- Previous manipulation/procedure
- On therapeutic antibiotics
- Contralateral renal/ureteral stone

Clinical Examination:

Pallor/pedal edema/fever

- Pulse: BP:
- CVS: RS:
- P/A:

Investigations:

- Urine C&S:
- TC:
- B.Urea:
- S.Cr:
- Guys score:

Intra OP:

- Puncture: single/ multiple
- Operating time:
- Pelvic Urine C&S:
- Stone C&S:

Post op:

| Pulse: | BP: | Temp: | RR: | Urine output: |
|-----------|--------------|-------|-------|---------------|
| PCNL drai | n: | | | |
| Inv | estigations: | | | |
| | TC: | B.U | Jrea: | S.Cr: |
| | Blood C& | S: | | |

IV antibiotics

Blood transfusions if any:

நோயாளிகளுக்கான ஆலோசனை

சிறுநீரகத்தில் கற்கள் பல காரணங்களால் உருவாகலாம். சிறுநீரகத்தில் கற்களுக்கு முறையான சிகிச்சை கொண்டு அகற்றவில்லயென்றல் நாளடைவில் சிறுநீரகம் பாதிக்கப்பட்டு செயலிழக்கும் . சிறுநீரக கற்களுக்கு பல சிகிச்சை முறைகள் உள்ளன. அவற்றில் திறந்த அறுவை சிகிச்சை(Open Nephrolithotomy) விட சிறுதுளை மூலம் நுண்ணோக்கி கருவி கொண்டு கற்களை அகற்றும் முறை (PCNL-Percutaneous Nephrolithotomy) சிறப்பானதாகும் . இம்முறையினால் கற்கள் முழுமையாக அகற்றப்பட்டு ,வலி குறைவாக , விரைவில் முழு நலத்துடன் வேளைக்கு செல்வது சாத்தியமாகின்றது என்பது கண்டறியப்படுளது .அரிதாக சிறுநீர் மற்றும் சிறுநீரக கற்களில் உள்ள நுண்ணுயிர் கிருமிகளால் அறுவை சிகிச்சைக்கு பின் காய்ச்சல் மற்றும் குருதியில் நச்சுதன்மை (Sepsis) ஆகிய பின்விளைவுகள் ஏற்படலாம் . அதற்கு நம் அரசு மருத்துவமனையில் அகனை குணமடைய செய்யும் சிறந்த மருந்துகள் உள்ளன . இம்முறை சிகிச்சையினால் ஏற்படும் பின்விளைவுகளை சிறுநீர் மற்றும் சிறுநீரக கற்களில் நுண்ணுயிரியல் உணர்திறன்(Culture & Sensitivity) மூலம் கண்டறியும் ஆய்வு ஒன்றை மேற்கொள்ள நன் முனைந்துள்ளேன் .

இந்த கண்காணிக்கப்பட்ட மருத்துவ ஆய்விற்கு தாங்களும் பதிவு செய்து தங்களது முழு ஒத்துழைப்பை நல்குமாறு தங்களை அன்புடன் கேட்டுகொள்கிறேன் .

<u>நோயாளிகள் ஒப்புதல்</u>

இந்த நோய், அதற்க்கான பரிசோதனை மற்றும் நடத்தப்படும் ஆய்வை பற்றி முழுமையாக மருத்துவர் விளக்கினார். நான் இந்த ஆய்வில் பங்கெடுக்க முழு மனதுடன் சம்மதம் தெரிவிகின்றேன் .

நோயாளியின் கையொப்பம்

அனுப்புனர்

| பெயர் | : |
|-------------|---|
| தந்தை பெயர் | : |
| முகவரி | : |
| வயது | : |

பெறுநர்

ஐயா

நான் மேற்சொன்ன முகவரியில் வசித்து வருகிறேன்.தற்போது தொழில் செய்து வருகிறேன். எனக்கு வயிற்றுவலி இருந்த காரணத்தினால் அரசு ஸ்டான்லி மருத்துவமனைக்கு சிகிச்சைகாக வந்திருந்தேன் . என்னை முழுமையாக பரிசோதித்த மருத்துவர் எனக்கு சிறுநீரக கற்கள் உள்ளதாக கூறினார் . இந்த கற்களினால் வரும் பின்விளைவுகள் பற்றி கூறினார். இந்த கல்லினை அகற்ற உள்ள பல்வேறு அறுவை சிகிச்சை முறைகளை விரிவாக விளக்கினர் .இந்த கல்லினை சிறு துளை மூலம் நுண்ணோக்கி கருவி கொண்டு அகற்றும் முறையில் (PCNL) அகற்றினால் ஏற்படும் நன்மைகள் மற்றும் பின்விளைவுகள் பற்றி எனக்கு நன்கு புரியும் விதத்தில் விளக்கினார் . நான் எழுப்பிய சந்தேகங்களுக்கு மருத்துவர் விளக்கமாக பதிலளித்தார் .

இந்த ஆய்வினால் எனக்கும், பொதுவாக நோயாளிகளுக்கும் கிடைக்க கூடிய நன்மைகள் எனக்கு எடுத்துரைக்கப்பட்டன. இந்த ஆய்வு குறித்து, நான் எழுப்பிய வினாக்கள் மற்றும் சந்தேகங்களுக்கு மருத்துவர் விளக்கமாக பதிலளித்தார். இவற்றை தெரிந்து கொண்ட நான் எனது சுய நினைவுடன் இந்த ஆய்வில் பங்கேற்க எனது விருப்பத்தின்பேரில் யாருடைய நிர்பந்தமும் இல்லாமல் என் சுய நினைவுடன் இந்த ஆய்வில் பங்கேற்க எனது விருப்பத்தை தெரிவித்துக்கொள்கிறேன். இந்த ஆய்வு, என்னுடைய, மற்றும் என் போன்ற நோயாளியர் நலன் கருதியே செய்யப்படுகிறது என்பதை அறிந்ததால் இதற்கு என்னை ஆட்படதுகின்றேன்.

இந்த ஆய்வு குறித்து முழு விவரங்களை நான் கேட்டு பெற்றுள்ளதாலும், என்னுடைய விருப்பத்தின்பேரில் பங்கு கொள்வதாலும், இது குறித்து எந்த குற்ற முறையீட்டையும் மருத்துவர் மீதோ, ஏனைய மருத்துவ ஊழியர்கள் மீதோ, மருத்துவமனை மீதோ எந்த நிலையிலும் வைக்க மாட்டேன். இதையே என்னுடைய ஒப்புதல் மற்றும் வேண்டுகோள் கடிதமாக ஏற்றுக்கொள்ளுமாறு கேட்டுக்கொள்கிறேன்.

நோயாளியின் கையொப்பம்

நுண்ணோக்கி கொண்டு சிறுதுளை மூலம் கருவி சிறுநீரக முறையில் கற்களை அகற்றும் கிருமிகளால் (PCNL) நுண்ணுயிர் ஏற்படும் பின்விளைவுகளை கற்கள் மற்றும் சிறுநீரின் சிறுநீரக நுண்ணுயிரியல் உணர்திறன் மூலம் முன்னறிதல் பற்றிய ஆய்வு

நோயாளியின் ஒப்புதல் படிவம்

| ஆராய்ச்சி நிலையம் 600001 | : | அரசு ஸ்டான்லி மருத்துவமனை, சென்னை |
|-----------------------------|---|-----------------------------------|
| பங்கு பெறுபவரின் பெயர் | : | |
| பங்கு பெறுபவரின் கையொப்பம் | : | |
| பங்கு பெறுபவர் இதனை () | | குறிக்கவும் |

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்ட என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது .

நான் இந்த ஆய்வில் தன்னிச்சையாகத்தான் பங்குபெருகிரேன் .எந்த காரணத்தினாலோ எந்த சட்டசிக்கல்களுக்கும் உட்படாமல் நான் இந்த ஆய்வில் இருந்து விலகிக்கொள்ளலாம் என்று அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற் கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன்.நான் ஆய்வில் இருந்து விலகிக்கிகொண்டாலும் இது பொருந்தும் என அறிந்தேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் , பரிசோதனை முடிவுகளையும், மற்றும் சிகிச்சை தொடர்பான தகவல்களையும்





மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட அறிவுரைகளின் படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதி அளிகின்றேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத, வழக்திர்க்குமாறன நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணிக்கு தெருவிப்பேன் என உறுதி அளிக்கிறேன்.

இந்த ஆய்வில் எனக்கு ரத்தம், சிறுநீர், எக்ஸ்ரே, ஸ்கேன், உட்பட அனைத்து பரிசோதனைகளையும் செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்.....தேதி

கட்டைவிரல் ரேகை.....

ஆய்வாளரின் பெயர்

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

| Title of the Work | : Stone and pelvic urine culture and sensitivity are better Than bladder urine as predictors of urosepsis following percutaneous nephrolithotomy: A prospective clinical study |
|------------------------|---|
| Principal Investigator | : Dr.M.Sivaraj |
| Designation | : PG in M.Ch.(Uro) |
| Department | : Department of Urology Government Stanley Medical College, |

Chennai-10

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 07.02.2013 at the Council Hall, Stanlay Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

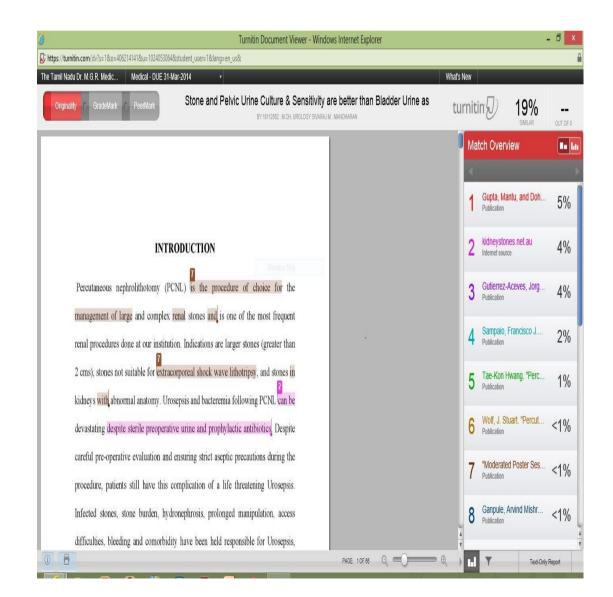
The Principal investigator and their team are directed to adhere to the guidelines given below:

- You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
- You should not deviate from the area of the work for which you applied for ethical clearance.
- You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
- You should abide to the rules and regulation of the institution(s).
- You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
- You should submit the summary of the work to the ethical committee on completion of the work.

19/12/13

MEMBER SECRETARY, IEC, SMC, CHENNAI

PLAGARISM CERTIFICATE



| | | | | | | MA | ASTER CHART | | | |
|------|--------------------------|--------|-----|-------|---------------------------|----------------------|--|---------------------------------|------|--------|
| | | | | | | | | | | |
| S.No | Patient Name | Gender | Age | IP No | Provisional Diagnosis | Urine C&S | Pelvic urine C&S | Stone C&S | SIRS | Sepsis |
| 1 | Valarmathy | Female | 33 | 51557 | Lt staghorn calculi | NG | ENTERO-AMPI/VANC/PIPTAZ | ENTERO-AMPI/VANC | + | |
| 2 | Sakunthala | Female | 60 | 49609 | Rt renal calculi | ECOLI-GM/CIPRO/TAXIN | NG | NG | | |
| 3 | Juli | Female | 52 | 50370 | Rt renal calculi with HN | NG | NG | NG | | |
| 4 | Rajeshwari | Female | 54 | 48951 | Rt renal calculi | NG | ECOLI-CIPRO/GM/TAXIM | ng | | |
| 5 | Abdul kani | Male | 18 | 49219 | Lt renal calculi | NG | NG | NG | | |
| 6 | Beemarao | Male | 65 | 48062 | Lt renal calculi | KLEBS-VANCO/AK/GM | ECOLI-CIPRO/GM/TAXIM | ECOLI-GM/CIPRO/TAXIM | + | |
| 7 | Revathy | Female | 35 | 46969 | RT renal calculi | NG | NG | ECOLI-CIPRO/GM/AK/TAXIM | | |
| 8 | Anaikounder | male | 80 | 43240 | Rt renal with HUN | NG | ENTERO-AMPI/VANC/PIPTAZ | ECOLI-TAXIM/CIPO/GM | | + |
| 9 | Karthick | Male | 21 | 44196 | RT renal calculi | NG | NG | NG | | |
| 10 | Ramu | Male | 38 | 43031 | Lt renal calculi | NG | NG | NG | | |
| 11 | Vijaya Kumar | Male | 50 | 41389 | Lt staghorn calculi | NG | KLEB-CIPRO/TAXIM/GM/AK: ENTERO COCCI -GM | KLEBS-AK/TAXIM | + | |
| 12 | Nagaraj | Male | 47 | 41400 | Rt Renal calculi | NG | PROTEUS:CIP/GM/IMIP | PROTEUS:CIP/GM/IMIPENAM | + | |
| 13 | Janitha Reeta | Female | 52 | 40370 | Pt pelvic calculi with HN | NG | NG | ECOLI-CIPRO/GM/TAXIM/AK | | |
| 14 | Vasantha Kumar | Male | 23 | 40137 | Rt renal calculi | NG | NG | NG | | |
| 15 | Ramesh | Male | 27 | 39115 | Lt renal calculi | NG | NG | NG | | |
| 16 | Venkatammal | Female | 55 | 38331 | It Renal staghorn calculi | ECOLI-GM/CIPRO/TAXIN | CONS-CIPRO/TAXIM/NOR/GM | PSEUDOMONAS-CIPRO/GM/CEFTAZI | DIME | + |
| 17 | Albert | Male | 45 | 34874 | Rt renal calculi with HN | NG | NG | NG | | |
| 18 | Laxmi | Female | 62 | 35476 | Lt renal calculi | NG | NG | NG | | |
| 19 | Senthil kumar | Male | 35 | 34975 | Lt renal calcui | NG | CONS-CIPRO/TAXIM/NOR/GM | CONS-CIPRO | + | |
| 20 | Ramesh | Male | 27 | 34091 | Rt Renal calculi | NG | NG | NG | | |
| 21 | Arthur | Male | 36 | 32414 | Lt renal calculi | NG | NG | NG | | |
| 22 | Parameswari | Female | 31 | 31921 | Rt pelvic calculi with HN | NG | NG | NG | | |
| 23 | Lakshmi | Female | 30 | 30875 | Rt pelvic calculi | NG | NG | NG | | |
| 24 | Rajeshwari | Female | 31 | 30648 | lt renal calculi | NG | KLEB-IMIPENAM | KLEB-IMIPENAM | + | |
| 25 | Rishvan (a) Ritchiach | Male | 40 | 27600 | Rt renal calculi with HN | NG | NG | PROTEUS-CIPRO/PIPTAZ/IMIPENAM | + | |
| 26 | Sri Devi | Female | 28 | 26155 | Rt renal calculi | | NG | E.COLI-GM/CEFTAZIDIME :NS-CIPRO | | |
| 27 | Malliga | Female | 56 | 27607 | Rt renal calculi | | NG | ECOLI:GM/CIPRO/CEFTAXIGIME | | |
| 28 | Kumari | Female | 55 | 23794 | It renal calculus with HN | NG | NG | ECOLI-GM/CIPRO/TAXIM | + | |

| 29 | Harikrishnan | Male | 68 | 77282 | rt renal calculus | ECOLI-GM/CIPRO/TAXIM | ECOLI-CIPRO/TAXIM/PIPTAZ | PROTEUS:GM/CIPRO/TAXIM | + | |
|----|--------------|--------|----|-------|----------------------------|----------------------|--|---------------------------------|---|--|
| 30 | Veera Selvam | Male | 22 | 25702 | rt renal calculi | NG | NG | NG | | |
| 31 | bhuvaneswari | Female | 52 | 23076 | rt renal calculi | ECOLI-GM/CIPRO/TAXIM | KLEBS-TAXIM/AK/PIPTAZ/VANC | KLEBS-AK/TAXIM | + | |
| 32 | Sumathi | Female | 28 | 24973 | Rt renal calculi with HN | NG | NG | NG | | |
| 33 | Venkatesan | Male | 41 | 22758 | Rt pelvic calculi with HN | NG | NG | NG | | |
| 34 | Lakshmi | Female | 42 | 22249 | lt renal calculi | NG | NG | ECOLI.CIPRO/PIPTAZ/GM/AK | | |
| 35 | Indrani | Female | 52 | 20639 | Rt pelvic calculi with HN | ECOLI-GM/CIPRO/TAXIM | ECOLI-GM/CIPRO/TAXIM.AK | KLEBS-AK.VANC.IMIPENAM | + | |
| 36 | Deivegam | Male | 26 | 21192 | Rt Renal calculus | NG | NG | NG | | |
| 37 | Sudha | Female | 31 | 19747 | It pelvic calculus with HN | NG | NG | NG | | |
| 38 | Jothi | Female | 45 | 18000 | rt renal calculi | NG | ECOLI-CIPRO/GM/AK | ECOLI.CIPRO/PIPTAZ/GM/AK | | |
| 39 | Raman | Male | 55 | 17038 | Lt renal calculi | NG | PSEDO-CIPRO/GM/IMIPENAM | PSEDO-CIPRO/GM/IMIPENAM | | |
| 40 | Kokila | Female | 65 | 16977 | rt staghorn calculus | ECOLI-GM/CIPRO/TAXIM | CONS-CIPRO/TAXIM/NOR/GM | CONS-CIPRO/GM/TAXIM | | |
| 41 | Sagayam | Male | 40 | 15711 | rt renal calculi | NG | CONS-CIPRO/TAXIM,AK | CONS-CIPRO/TAXIM,AK | + | |
| 42 | Sadhanandam | Male | 55 | 10229 | Rt renal calculus | ECOLI-GM/CIPRO/TAXIM | ECOLI-GM/CIPRO/TAXIM.AK | NG | + | |
| 43 | Gopi | Male | 39 | 13471 | rt renal calculi | NG | NG | NG | | |
| 44 | jeevan kumar | male | 40 | 8737 | right renal calculus | NG | CONS-CIPRO/GM/TAXIM | CONS-CIPRO/GM/TAXIM | + | |
| 45 | Jaya | Female | 40 | 10444 | lt renal calculi | NG | NG | PSEDO-CIPRO/AK | + | |
| 46 | Gopal | Male | 42 | 8821 | Rt Renal calculi | NG | NG | KLEBS-TAXIM/CIPRO/AK | | |
| 47 | Alamelu | Female | 45 | 6986 | rt staghorn calculi | NG | ECOLI-CIPRO/CEFTAZIDIME/IMIPENAM/GM/AK | ECOLI-CIPRO/CEFTAZIDIME/IMIPENA | + | |
| 48 | Venkatesan | male | 52 | 5246 | left renal calculus | NG | ECOLI-CIPRO/CEFTAZIDIME/IMIPENAM/GM/AK | ECOLI-CIPRO/CEFTAZIDIME/IMIPENA | + | |
| 49 | Mariammal | Female | 63 | 6053 | Rt pelvic calculus with HN | ECOLI-GM/CIPRO/TAXIM | ECOLI-CIPRO/CEFTAZIDIME/IMIPENAM/GM/AK | KLEB-CIPRO/CEFTAZIDIME/AK | + | |
| 50 | Perumal | Male | 35 | 6242 | lt renal calculi | NG | NG | NG | | |
| 51 | Rajkumar | Male | 23 | 4998 | rt renal calculi | NG | NG | NG | | |
| 52 | Suguna | female | 34 | 57530 | left pelvic calculus | NG | KLEB-CIPRO/TAXIM/GM/AK: ENTERO COCCI -GM | KLEB-CIPRO/CEFTAZIDIME/AK | + | |
| 53 | Jakkubai | Female | 42 | 3661 | Left staghorn calculi | NG | NG | KLEBS-CIPRO/IMI/PIPTAZ | + | |
| 54 | Vijaya | Female | 40 | 4079 | Lt pelvic calculus with HN | NG | KLEB-CIPRO/TAXIM/GM/AK/PIPTAZ | KLEBS-CIPRO/AK/TAXIM/PIPTAZ | + | |
| 55 | Sebastin | Male | 47 | 2137 | Rt renal calculi with HN | NG | NG | KLEBS-CIPRO/AK/TAXIM | + | |
| 56 | Chandran | Male | 45 | 44244 | lt renal pelvic calculi | NG | NG | NG | | |

| 57 | jayalakshmi | Female | 50 | 52784 | lt renal pelvic calculi | CONS-CIPRO PSEDO-CIPRO/AK PSEDO-CIPRO/AK:CONS-CIPRO/TAXI | | A | + | |
|----|-------------|--------|----|-------|---------------------------|--|----------------------------|--------------------------------|---|---|
| 58 | sureshbabu | Male | 32 | 52212 | RT renal pelvic calculi | NG | NG | NG | | |
| 59 | Damodaran | Male | 19 | 52751 | RT renal pelvic calculi | NG | NG | NG | | |
| 60 | Rajalakshmi | Female | 35 | 55855 | lt renal pelvic calculi | NG | NG | PSEDO-CIPRO/G/IMIPENAM | + | |
| 61 | valli | female | 45 | 41504 | rt renal calculus | NG | NG | STAPH AUREUS-CIP/AK/VANC/AMPI | + | |
| 62 | Kamala | Female | 38 | 51206 | RT renal calculus | NG | KLEB-CIPRO/TAXIM;PIPTAZ | KLEBS-CIPRO/PIPTAZ/VANCO | + | |
| 63 | Baskaran | Male | 44 | 51008 | It renal calulus | NG | ECOLI-CIPRO/TAXIM/AK | ECOLI-GM/AK/TAXIM/PIPTAZ | + | |
| 64 | Sivakumar | Male | 42 | 55500 | Rt renal calculus with HN | NG | PSEDO-AK/GM/PIPTAZ/VANCO | PSEDO-PIPTAZ/IMIPENAM/VANCO | | + |
| 65 | Bhavani | Female | 44 | 53409 | RT renal calculus | NG | ECOLI-CIPRO/TAXIM/AK | ECOLI-CIPRO/TAXIM/GM/AK | + | |
| 66 | Gandimathi | Female | 57 | 54282 | Rt renal calculi | NG | ECOLI-CIPRO/TAXIM/GM/AK | ECOLI-CIPRO.TAXIM.GM.AK | + | |
| 67 | Vinayagam | Male | 61 | 52305 | Rt renal calculi | NG | KLEBS-TAXIM/AK/PIPTAZ/VANC | KLEBS-TAXIM/AK/PIPTAZ/CETAZDME | + | |
| 68 | Chellama | Female | 20 | 56793 | Rt renal calculus | NG | ECOLI-CIPRO/TAXIM/VANCO | ECOLI-CIPRO/TAXIM/GM/AK | + | |
| | | | | | | | | | | |
| | | | | | Lt: Left | Psedo-Pseudomonas | | | | |
| | | | | | Rt:Right | CONS-Coagulase Negat | tive Staph. Aureus | | | |
| | | | | | HN:Hydronephrosis | GM-Genatamycin | | | | |
| | | | | | NG:No Growth | AK-Amikacin | | | | |
| | | | | | KLEB:Klebsiella | Taxim-Cefotaxime | | | | |
| | | | | | Entero-Enterococci | Piptaz-Piperacillin Tazob | pactum | | | |