ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 9, Issue – 5, September – 2024 , Page No. : 131 – 135

Preclinical Evaluation of A Stone Retrieval Basket For Ureteral And Renal Stone Removal Using A Swine Model

[1]Minocha Dr. Pramod Kumar, Meril Medical Innovations Private Limited, Valsad, Gujarat
[2]Kothwala Dr. Deveshkumar, Meril Medical Innovations Private Limited, Valsad, Gujarat
[3]Shah Khusboo, Meril Medical Innovations Private Limited, Valsad, Gujarat
[4]Pandya Kamna, Meril Medical Innovations Private Limited, Valsad, Gujarat
[5]Patel Trupti, Meril Medical Innovations Private Limited, Valsad, Gujarat
[6]Rana Nirav, Meril Medical Innovations Private Limited, Valsad, Gujarat
[7]Deepak Gurang, Meril Medical Innovations Private Limited, Valsad, Gujarat
[8]Patel Vimal, Meril Medical Innovations Private Limited, Valsad, Gujarat
Corresponding Author: Pandya Kamna, Meril Medical Innovations Private Limited, Valsad, Gujarat

Citation this Article: Minocha Dr. Pramod Kumar, Kothwala Dr. Deveshkumar, Shah Khusboo, Pandya Kamna, Patel Trupti, Rana Nirav, Deepak Gurang, Patel Vimal, "Preclinical Evaluation of A Stone Retrieval Basket For Ureteral And Renal Stone Removal Using A Swine Model", IJMSIR - September - 2024, Vol – 9, Issue - 5, P. No. 131 – 135.
Type of Publication: Original Research Article
Conflicts of Interest: Nil

Abstract

Kidney stone disease is a relatively common urological disorder, affecting a significant portion of the global population. It is characterized by the formation of crystal concretions, typically within the kidneys. If left untreated, kidney stones can lead to an increased risk of end-stage renal failure. The etiology of kidney stones is multifactorial, with the most common type being calcium oxalate stones formed at Randall's plaque on the renal papillary surfaces. Currently, there is a lack of satisfactory drug treatments to cure or prevent kidney stone recurrences. For the retrieval of kidney stones, metal-based baskets are commonly used. To assess the efficacy and performance of these devices, preclinical studies are conducted using animal models. In this particular study, a porcine model is chosen as the test system, as swine have a urinary system similar to that of adult humans and provide a comparable size to the intended patient population for the device. The main objective of this study is to evaluate the efficacy of a stone retrieval basket in retrieving kidney stones from various locations within the urinary tract, including the ureter and kidney. The study is conducted under controlled experimental conditions to ensure adequate assessment of the device's performance before proceeding to clinical trials.

Keywords: Crystal Concretions, Renal Failure, Oxalate Stones, Metal-Based Baskets, Urinary System, and Swine Models.

Introduction

Kidney stones predominantly reside within the renal system, constituting one of the oldest known afflictions of mankind and representing a prevalent urinary tract disorder. Despite centuries of recognition, the recurrence of renal stones persists as a significant challenge in public health. Addressing this challenge necessitates a

comprehensive comprehension of the underlying mechanisms governing stone formation. Furthermore, kidney stone formation correlates with heightened risks of chronic kidney ailments, end-stage renal failure, cardiovascular complications, diabetes, and hypertension. Notably, there is a proposition suggesting kidney stones as a systemic ailment intertwined with metabolic syndrome. Nephrolithiasis, particularly when associated with nephrocalcinosis, contributes to 2-3% of end-stage renal cases. Symptoms of kidney stones vary depending on their location within the urinary tract, ranging from renal colic, flank pain, hematuria, to obstructive uropathy, urinary tract infections, urine flow obstruction, and hydronephrosis. These manifestations often lead to nausea, vomiting, and a significant economic burden due to treatment costs and loss of productivity, thereby impacting quality of life.

This study endeavors to address the treatment of stone disease in susceptible swine breeds and humans. Specifically, it examines the efficacy of a metal-based retrieval basket in extracting stones from the kidney. Throughout the study, meticulous observation, both physical and clinical, is conducted on the animal subjects. The research culminates in human euthanasia after a one-day acute study period, facilitating the retrieval of stones from the kidney for photographic documentation of the stone basket in situ, as well as an acute animal study.

By meeting the urgent demand for effective endoscopic interventions in urinary tract diseases, this research aims to offer valuable insights into the domain of urology, with implications for human clinical practice. The inclusion of diverse breeds such as mice, swine, and dogs underscores the potential translational impact on both animal welfare and human trials. Additionally, this research endeavors to identify gaps in current understanding and practices, thereby contributing to the advancement of urological care for both veterinary and human patients afflicted with urinary tract diseases.

Material and Method

Test System

The stone retrieval basket is designed for use in the kidney and ureter to capture and remove stones or foreign objects. The basket featuring four legs is shown in the Figure 1, that open near the target object. Upon opening, the basket is rotated, allowing the stone or foreign object to enter the basket. The object is then captured by the inward force of the basket and subsequently removed. Kidney stones ranging from 2 mm to 6 mm were retrieved using the stone retrieval basket.

In the current acute animal study, a metallic basket was used. This basket has a diameter ranging from 6 to 12 mm, a length of 9 to 10 mm, and a working length of 900 to 1200 mm. Two units of this product were tested, along with a guide catheter measuring between 1.3 to 3.0 French (F).

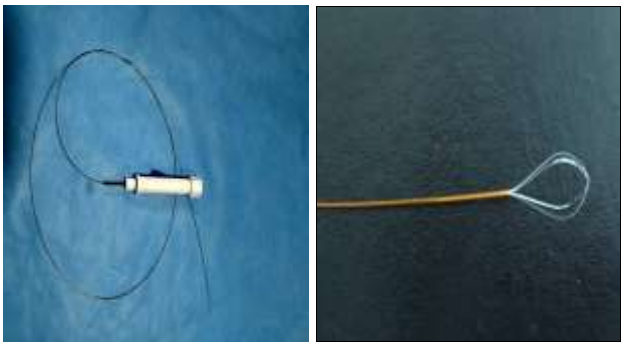

Figure 1: Stone Retrieval Basket Device along with delivery system

The investigation was initiated by utilizing a swine model as the experimental platform for conducting kidney stone retrieval procedures, primarily due to its physiological resemblance to the adult human urinary system. Although the swine model boasts distinct advantages, such as its physiological similarity to humans, it poses challenges attributed to its substantial

body size, which exceeds that of other commonly employed research animals and closely mirrors that of humans.

Within the confines of this specific study, the efficacy of the device was meticulously assessed employing a cohort of female swine models aged between 6 to 12 months. These swine subjects, characterized by mixed breed, exhibited an average weight of approximately 68.2 kilograms. The acute animal study was conducted in a designated animal room maintained at a temperature range of 18.0-26.5°C with a humidity level of 49-70%. The swine model was subjected to a light photo period of 12 hours followed by a dark photo period of 12 hours.

For identification, each animal was assigned a unique ear tag number. During acclimatization, animals were identified using the last five digits of the ear chip number, while during treatment; they were designated as P1, P2, and P3. Bore-well water purified with an RO water plant was provided ad libitum.

Throughout the study, human care and daily observation ensured the well-being of the animals, with no signs of illness or distress observed during the procedure.

Experimental Procedures

In this study, the animal was fasted, and water was withheld overnight before the procedure. Anesthesia was administered using Ketamine at 15 mg/kg (IM), Xylazine at 2.5 mg/kg (IM), and Protocol at 0.5 mg/kg (IV bolus), followed by inhalation anesthesia at 1-3% through a facemask. The neck, chest, and thigh areas were clipped free of hair to facilitate femoral vein and artery access and ECG lead application. Atropine (0.05 mg/kg IM) was administered to control respiratory tract secretions that could obstruct the endotracheal tube used for inhalation anesthesia. The animal was then prepared and draped for aseptic procedures with the appropriate medications.

During the procedure, the pig was placed in dorsal recumbency (supine). A folded towel was positioned under the rump to elevate the pelvis and lumbar spine, and the hind legs were pulled cranially. Although the urethral opening is midway to the cervix, the vaginal wall tends to collapse inward, making it difficult to locate. Inversion of the urethral opening can further complicate entry, so adjusting the angle of the pelvis and the direction of the hind limbs can aid in visualizing and accessing the urethral opening.

A lubricated vaginal speculum and a focused light source were used to visualize the vaginal wall and urethral opening. A 4 to 6F catheter with a stylet was then used to access the bladder. A double bridge 70-degree 22F cystoscope was employed to reach the vesicoureteric junction, allowing entry into the right ureter with the assistance of a 4 to 6F multipurpose diagnostic catheter, the depiction of it has been shown in the figure 2.

A 0.035 to 0.038", 100 to 110 cm guide wire was placed in the ureter, and the catheter was removed, followed by removing the cystoscope.

Figure 2: Placement of Guide Catheter and Guide wire in Vesicoureteric Junction

A 4 to 11.5F ureteric sheath was placed in the right ureter over the guide wire, and the guide wire was removed. Contrast fluoroscopic imaging was taken to confirm the placement of the ureteric sheath.

Figure 3: Right Ureteric Angiography

Right Ureteric Angiography provides a clear image of the right ureter's anatomical structure and surrounding vasculature through contrast-enhanced imaging as shown in Figure 3, aids in evaluating the health of the ureter by identifying any potential blockages or structural irregularities that might be connected to the development of stones or other diseases.

Stone retrieval from the renal calyces using a stone retrieval basket

Sonography (ultrasound) is a non-invasive and radiation-free diagnostic tool widely utilized for detecting kidney stones, allowing for assessment of stone size, shape, and position. In this case, a 6 mm stone was identified and successfully retrieved. Prior to the procedure, it is essential to ensure the sterilization of instruments, position the patient appropriately typically in a lithotomy. To access the stone, a ureteroscope or cystoscope is inserted through the urethra, with fluoroscopic imaging employed to visualize the stone and guide the retrieval basket. The stone retrieval basket is positioned to access the renal calyces of the urinary tract, showing its precise placement for reaching the target area (Figure 4). Next, the basket securely holds a stone within the renal calyces, demonstrating its ability to capture and retain the stone (Figure 5). It is then seen in the process of removing the stone from the renal calyces, illustrating the careful extraction procedure (Figure 6). Finally, the removal of the stone through the basket from the renal calyces is completed, emphasizing the basket's effectiveness in the stone retrieval process (Figure 7).

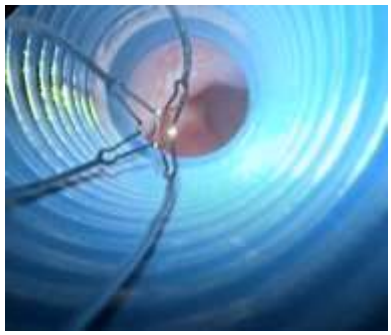

Figure 4: Stone Retrieval Basket Positioned for accessing into the Renal Calyces of the Urinary Tract

Figure 5: Basket Holding Stone in Renal Calyces

Figure 6: Basket Removing Stone from Renal Calyces

Figure 7: Removal of stone through Basket from the Renal Calyces

Results

The performance of the stone retrieval basket was evaluated on four key parameters: ease of opening and closing, ease of wire navigation through the working channel and lithoscope, holding strength of the basket wire, and the ability to retrieve stones from the body.

The study indicated that the stone retrieval basket showed smooth and controlled opening and closure motion throughout. The ease with which the basket negotiated its way through the sheath and the working channel of the lithoscope to all the calyces was smooth and efficient, without any delays or procedural complications. The holding strength of the basket was great; it gripped the stone tightly during retrieval. Finally, there was no complication in retrieving the stone from the body with the basket, thus ensuring a smooth completion of the procedure.

Discussion

The result of this review definitely supports the fact that this stone retrieval basket would fare well clinically and offers an advantage in several respects during stone extraction procedures. Smooth opening and closure minimize possible damage to surrounding tissue due to ease of wire navigation, which ensures effective placement even in more difficult areas of the calyces. Holding power is very strong in the case of the basket, which helps in grasping the stones firmly, minimising the chances of dropping or fragmenting stones while drawing them out.

The efficiency in the retrieval of the stone from the body reduces the overall time in the procedure. This contributes to an enhanced patient outcome by reducing further invasiveness of the procedure, thus promoting faster recovery. These performance characteristics indicate that this stone retrieval basket has the potential to gain preference in urological manipulations in case of stone removal because of its reliability, ease of use, and safety profile. Further studies may check its performance on a wider range regarding stone sizes and composition for further validation.

Conclusion

In the porcine model under controlled experimental conditions, the stone retrieval basket performed very effectively in retrieving the stones from the renal calyces. This preclinical test highlights the precision and reliability of the design of the basket, thus laying a solid foundation for future clinical studies. These findings will be helpful in further assessing the device's performance with a view toward possibly advancing it clinically and applying for regulatory approval. This study represents an important leap forward in urological novelties, providing further development of techniques of safer and more effective stone retrieval, and finally enhancing patient care in urology.

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