

## **USE OF ABSORBABLE GELATIN SPONGE AS AN ADJUNCT TO "TOTALLY TUBELESS PERCUTANEOUS NEPHROLITHOTOMY"**

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**Summary.-** *OBJECTIVES:* To study the efficacy and safety of totally tubeless percutaneous nephrolithotomy (PNL) using absorbable gelatin sponge as an adjunct.

*METHODS:* From January 2004 to March 2009, 45 patients underwent totally tubeless PNL (no internal drainage either with double J stent or ureteric catheter). Inclusion criteria were no significant bleeding from the nephrostomy tract or injury to the pelvicalyceal system (PCS), single nephrostomy tract, infra-costal puncture

and complete clearance on fluoroscopy. Median stone size was 3cm (longest diameter recorded). The PNL tract was plugged with absorbable gelatin sponge at the end of the procedure. Drop in hematocrit, hospital stay, pain score by visual analogue scale, urinary leak and perirenal collection by ultrasonography were documented in all the patients.

*RESULTS:* Median age was 32 years (range 18-57 yrs). Median size of the stone (largest dimension was taken into consideration) was 3cm (1.8 to 4cm). All patients had complete stone clearance on postoperative X-ray KUB. Drop in mean haematocrit value recorded was 2.4% and none of the patients required blood transfusion. Median pain score was 3. Median value for oral and intravenous Diclofenac sodium was 200mg (150 mg-300mg). Perinephric collection was recorded in 3 patients who were managed conservatively. Median hospital stay was 3 days (2-5 days).

*CONCLUSION:* Totally tubeless PNL using absorbable gelatin sponge as sealant of percutaneous nephrostomy tract appears to be safe and effective in select group of patients.

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**Resumen.-** *OBJETIVO:* Estudiar la eficacia y seguridad de la nefrolitotomía percutánea (NLPC) sin catéter de nefrostomía, utilizando como complemento una esponja de gelatina absorbible.

*MÉTODOS:* Desde enero de 2004 a marzo de 2009, 45 pacientes se sometieron a NLPC sin catéter de nefrostomía (sin drenaje interno ya sea con catéter doblej o catéter ureteral). Los criterios de inclusión fueron hemo-

rragia mínima procedente del trayecto de la nefrostomía o lesión del sistema pielocalicial (SPC), nefrostomía de un solo trayecto, punción infra-costal y eliminación completa en la fluoroscopia. El tamaño medio de los cálculos fue de 3 cm (diámetro máximo registrado). La vía de la NLPC fue conectada con la esponja de gelatina absorbible al final del procedimiento. Se documentó en todos los pacientes, el descenso del hematocrito, estancia hospitalaria, dolor por escala analógica visual, fugas de orina y colecciones perirenales mediante ecografía.

**RESULTADOS:** La edad media fue de 32 años (rango 18-57 años). La mediana de tamaño del cálculo (se tuvo en cuenta el de mayor dimensión) fue de 3 cm (de 1,8 a 4 cm). En la radiografía abdominal postoperatoria, todos los pacientes aparecieron completamente limpios de cálculos. La caída media en el valor del hematocrito fue de 2,4% y ninguno de los pacientes requirió transfusión sanguínea. La mediana en la escala de dolor fue de 3. El consumo medio de diclofenaco sódico fue de 200 mg (150 mg-300 mg) por vía oral e intravenosa. Se registraron colecciones peri-renales en 3 pacientes que fueron tratados conservadoramente. La estancia hospitalaria media fue de 3 días (2-5 días).

**CONCLUSIÓN:** La NLPC totalmente sin catéter de nefrostomía con esponja de gelatina absorbible como sellador del trayecto percutáneo parece ser segura y efectiva en el grupo escogido de pacientes.

**Palabras clave:** Nefrostomía percutánea. Agentes hemostáticos.

## INTRODUCCIÓN

Tubeless PNL in select group of patients has been demonstrated to reduce the postoperative discomfort and improve patient satisfaction without compromising the safety (1-3). Most of the studies on tubeless PNL describe to place a double J stent or ureteric catheter to provide safeguard against bleeding and urinary extravasation. There are a very few studies describing total tubeless PNL i.e. avoiding double J stent and/or ureteric catheter (1, 4). As double J stent is associated with pain and discomfort in significant proportion of the patients, its omission without compromising the safety of PNL would be a welcome step towards minimally invasive approach. Herein we report our experience on totally tubeless PNL with simple technique of inserting gelatin sponge in the percutaneous tract (Spongostan™, Johnson & Johnson Medical Limited, U.K); conformed to the shape of a tube, after removal of the Amplatz sheath.

## METHODS

Between January 2004 and March 2009, select group of patients with renal and upper ureteric stone who fulfilled the exclusion criteria i.e. normal functioning opposite kidney, no significant intraoperative bleeding or injury to the pelvicalyceal system (PCS), single nephrostomy tract, infra-costal puncture and complete clearance on fluoroscopy were taken up for tubeless PNL. Fall in hematocrit, pain score by visual analogue scale, hospital stay, analgesic requirement and postoperative complications e.g. perirenal hematoma or urinary extravasation by ultrasonography were recorded.

## Technique

PNL was performed by standard technique. After placement of 5F ureteric catheter retrogradely, appropriate calyx was punctured under fluoroscopic guidance using double contrast technique (injecting contrast and air). Tract was dilated with Teflon sequential dilators and adequate size Amplatz sheath was positioned into the PCS. At the end of procedure, neither a nephrostomy tube nor a double J stent was placed after satisfying the criteria given in a Figure 2. After completion of the procedure a safety guide wire was kept across the PUJ into the ureter and Amplatz sheath was removed (Figure 1 A). Once the tract bleeding was found not alarming, a Spongostan™ was rolled in to the tubular shape and plugged into the nephrostomy tract (Figure 1B, C, and D). Skin incision was closed with 2-0 silk mattress suture taken through the Spongostan™ to fix it in place. Safety guide wire was then removed (Figure 1E).

Patients were given adequate analgesia in postoperative period. X-ray KUB was done in post operative period to confirm the absence of any residual fragment. Ultrasonography was done on 2<sup>nd</sup> postoperative day to look for perinephric collection in initial 25 patients and then whenever there was a leak or severe pain in subsequent patients.

## RESULTS

Of 45 patients (38 men and 7 women) with a median age of 32 years (range 18-57 yrs), 24 had stones on the right side and 21 on the left. Median size of the stone (largest dimension was taken into consideration) was 3cm (1.8 to 4cm). Of 42 patients with renal stones, 2 had partial stag horn and 6 patients had multiple stones. Three patients had upper ureteric stone. Overall median operative time was 55 minutes (range 35- 80 minutes). Stones were removed in toto in 02 patients whereas rest required

fragmentation with pneumatic lithoclast. None of the patients had residual fragment visible on intraoperative fluoroscopy and nephroscopy. All but one showed a 5 mm fragment on postoperative X-ray KUB which was treated with extracorporeal shock wave lithotripsy. Three patients who showed perinephric collection responded to conservative treatment only. The mean preoperative and postoperative hematocrit was 30.4 (range 27-38) and 28.2 (26-37) respectively, with a mean change of 2.4%. Median hospital stay was 3 days (2-5days).

None of the patients required re-hospitalization. One patient, who had persistent leak of urine, responded to double J stent placement in post operative period. This patient had an established tract of nephrostomy placed earlier as patient presented with renal failure. No patients had any complaint of recurrent fever, flank pain or infection at nephrostomy site in immediate follow up period.

## DISCUSSION

Placement of a percutaneous nephrostomy has been a standard practice over the years after

PNL. Nephrostomy tube not only provides a tamponade effect to the bleeding from the tract but also provides good drainage to the urine preventing urinary extravasation.

Despite these advantages nephrostomy tube has been blamed for tube related discomfort, prolonged hospital stay and increased analgesia requirement (5). In order to overcome these drawbacks, attempts have been made to either decrease the size of nephrostomy by using smaller size sheath (mini-Perc) (6), or to totally avoid it. Bellman and his group first tried to give away the need for a tube after PNL (5). Since then randomized trials have been published to prove that avoiding nephrostomy is as good as placing it in select group of the patients (3, 7, 8). Most of the published literature on tubeless PNL have recommended to put in double J stent (2, 3, 5, 7, 8, 9-12). Double J stent is not entirely free from problems and it negates the basic tenet of tubeless PNL.

As the apprehension of drainage always remains, many authors have used an internal stent either in the form of a double J stent (2, 3) or a ureteric catheter (13, 14). Putting in a double J stent is not without problems as many patients have severe stent

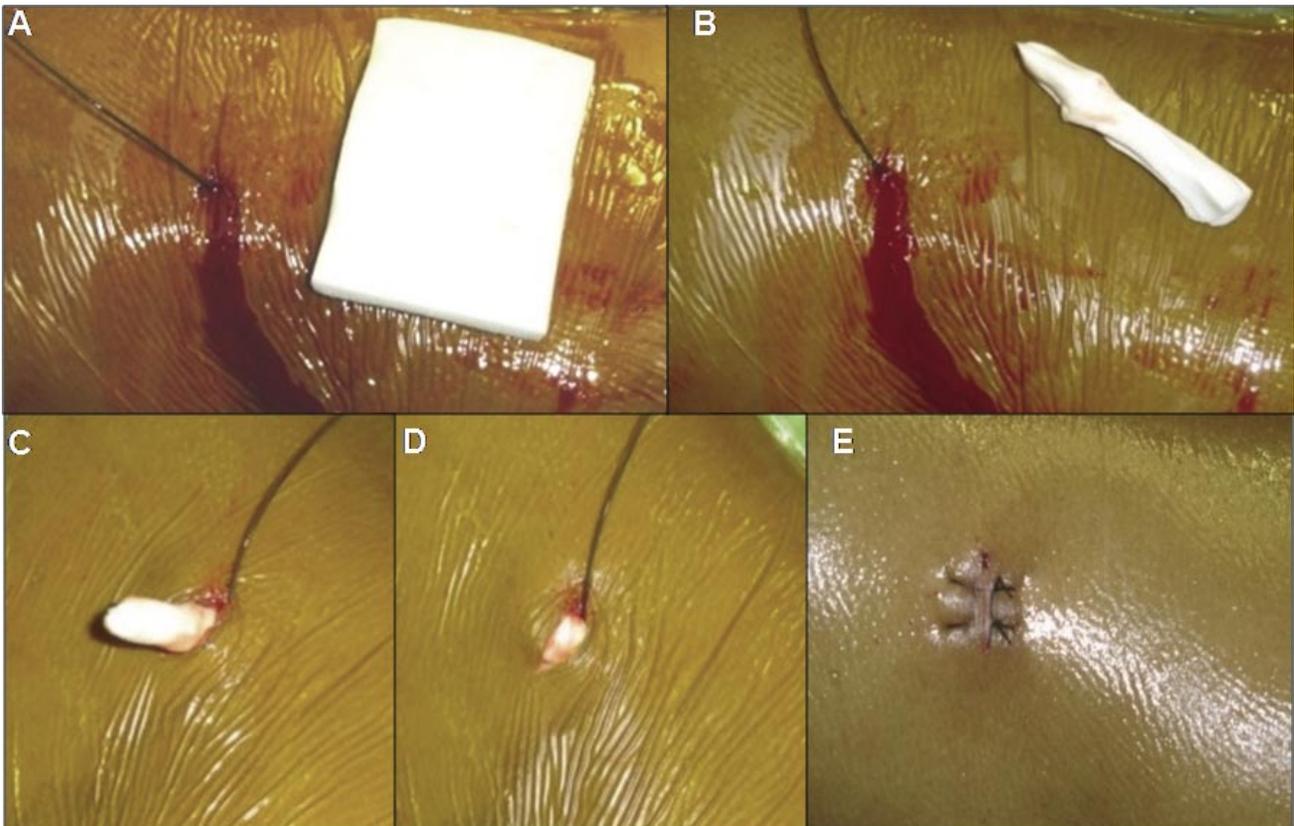


FIGURE 1. Various steps of tubeless PNL.

related symptoms necessitating their early removal (2, 3). In one study it was reported that 30% of patients had bothersome stent-related symptoms and 60% needed analgesics and/or antispasmodic medication to treat them (15).

This study describes the role of totally tubeless PNL. In our practice tubeless PNL is a routine in select group of patients and whether patient should have double J stent or should have totally tubeless PNL, the decision is based on the situation described in Figure 2.

Recently, there are few reports without the use of any tube (total tubeless PNL) (1, 4). A possible adjunct to tubeless PNL is the placement of a haemostatic agent along the PNL tract. Haemostatic agents that are in wide spread use are fibrin glue and gelatin matrix haemostatic sealant. Fibrin glue contains high levels of fibrinogen and thrombin that form a stable fibrin clot. It has been proved useful in laparoscopic partial nephrectomy as it quickly forms a coagulum

that covers and adheres to the cut surface of the kidney (16). Mikhail et al have reported the usefulness of fibrin sealant in patients undergoing tubeless PNL (17). Eden et al used fibrin glue as a sealant during laparoscopic pyeloplasty (18). All these studies provide evidence regarding excellent haemostatic properties of this agent and its usefulness in preventing urinary extravasation and bleeding.

The gelatin matrix haemostatic substance consists of bovine collagen granules with a mean size of 500-600  $\mu\text{m}$ , which are cross-linked with glutaraldehyde. It is combined with a bovine thrombin solution just before use. It is an excellent haemostatic agent even on active arterial bleeding. However, when suspended in the urine, it remains as fine particles which are immediately re-suspended in the urine upon agitation. Thus an occlusion balloon catheter is used during injection of gelatin matrix haemostatic sealant to provide a backstop so that the sealant will setup in the tract rather than entering the urinary system. In addition, due to its construction with bovine collagen and

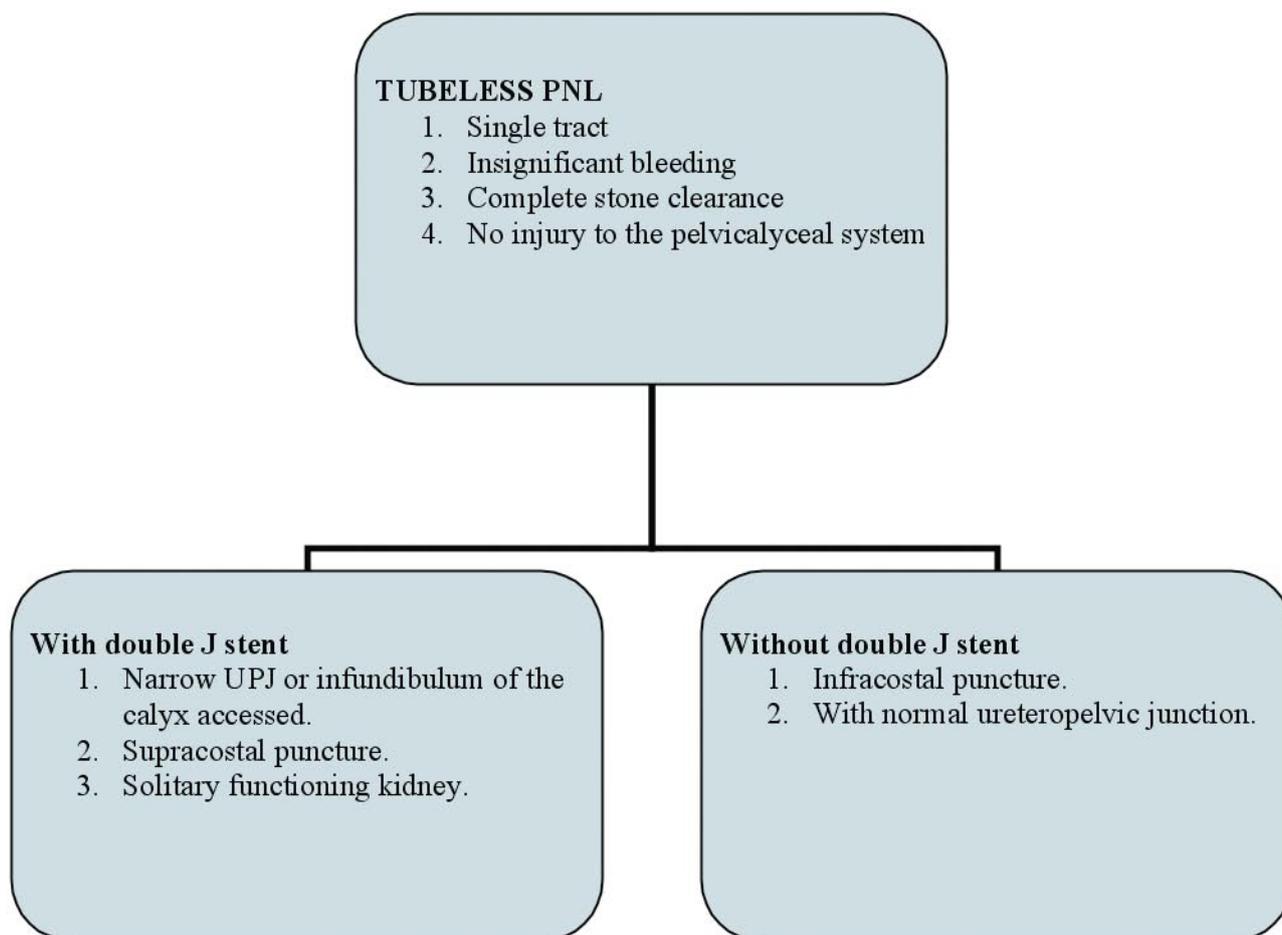


FIGURE 2. Flow chart of decision making for putting double J stent in tubeless PNL

thrombin, gelatin matrix haemostatic sealant forms a stable matrix that not only maintains its shape once activated by blood, but also expands further augmenting its haemostatic ability in a confined cavity such as percutaneous nephrostomy tract. Conversely, when in contact with urine fibrin sealant gets transformed into a mucoid substance that fails to dissolve even after 5 days of contact. Borin et al reported the use of gelatin matrix for nephrostomy tract closure (11). They have used an occlusion balloon and have sealed the renal parenchymal tract with gelatin matrix instilled through a syringe. This procedure is not only technically cumbersome but it adds to the cost also.

We report the use of gelatin sponge in a simple way by rolling it and inserting it into the tract and occluding it. Spongostan™ is absorbable gelatin sponge prepared from natural reacting purified gelatin foam of uniform density. It consists of 100% porcine gelatin and is water insoluble. It acts as a local haemostatic agent for venous bleeding or oozing where traditional hemostasis is difficult. It adheres to the bleeding site and absorbs approximately 45 times of its own weight. Due to its uniform porosity, platelets are caught and coagulation cascade is activated, transforming soluble fibrinogen into a net of insoluble fibrin, which stops the bleeding. When implanted in the tissues, it is absorbed within 3-5 weeks.

Recently Schick V et al reported the use of gelatin sponge but in a different form (19). Hemostyptic gelatin powder (Spongostan, Johnson & Johnson) was prepared as a doughy paste and few drops of contrast medium were added. The whole material was introduced through the Amplatz sheath into the working channel under imaging control. Imaging-controlled insertion of the doughy gelatin through the Amplatz sheath into the parenchymal part of the channel alone resulted in immediate hemostasis in all patients. The Amplatz sheath was retracted over a 28 Fr. rectal tube which was used to push the gelatin forward. There was no need for an additional tamponade of the renal fat capsule or the abdominal wall. After 2 minutes when no channel bleeding was apparent, the skin sutures were placed. This technique is effective and less costly however, slightly more complex than our technique.

Absorbable gelatin sponge can be rolled simply and plugged into nephrostomy tract where it can stay by itself and overlying skin defect can be sutured making it a very simple, effective and cheaper alternative than fibrin glue or gelatin matrix. With this study we hypothesized that once the Amplatz sheath is out and there is not much bleeding, Gelatin sponge stops the extraparenchymal bleed and bleeding from the parenchyma itself get tamponade due to a

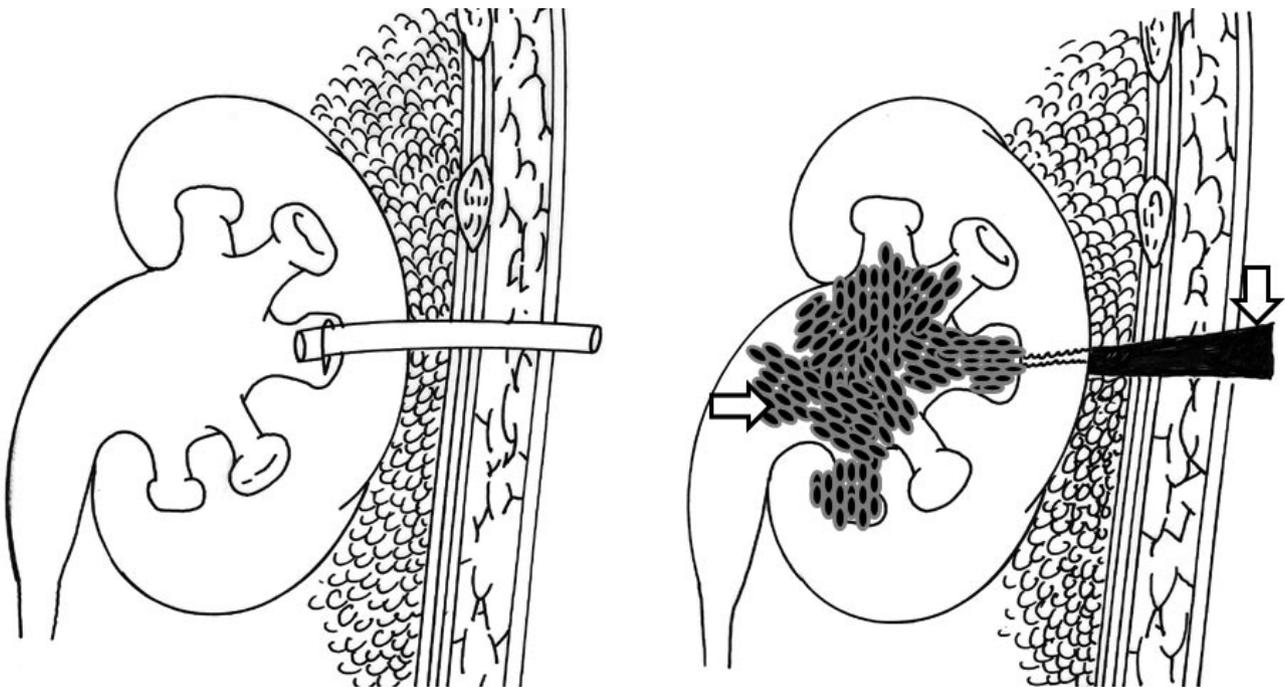


FIGURA 3. Hypothesis of tamponade of bleeding and prevention of urinary extravasation, right arrow indicates blood clot in the pelvicalyceal system and up arrow indicates gelatin sponge.

close compartment created between Gelatin sponge outside the renal parenchyma and blood clot inside the pelvicalyceal system (Figure 3). Once the bleeding stops then pelvicalyceal clot gets lysed by the urine and free flow of urine through the ureter to the bladder is established. We did not encounter problem of any major bleed or urinary leak requiring intervention which indirectly support this hypothesis. Objective proofs in future studies will further highlight this issue. Therefore a totally tubeless PNL in select group of the patients as described in this study is a useful alternative to standard PNL.

## CONCLUSION

Totally tubeless PNL in very select group of patients is a useful alternative. Percutaneous tract sealing with rolled up absorbable gelatin sponge is simple, safe and effective method to manage the acute nephrostomy tract after tubeless PNL. Absorbable gelatin is not associated with any untoward side effects and can be used successfully as an adjunct to totally tubeless PNL.

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