# Similarities for devices for ureteral procedures with those for cardiovascular devices

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**Biocompatible ureteral stent**

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**Biostability**
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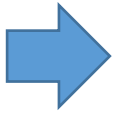


**Biological compatibility**
**Chemical compatibility**
**Mechanical compatibility**

**Additional Functioning**
**Dual therapy**

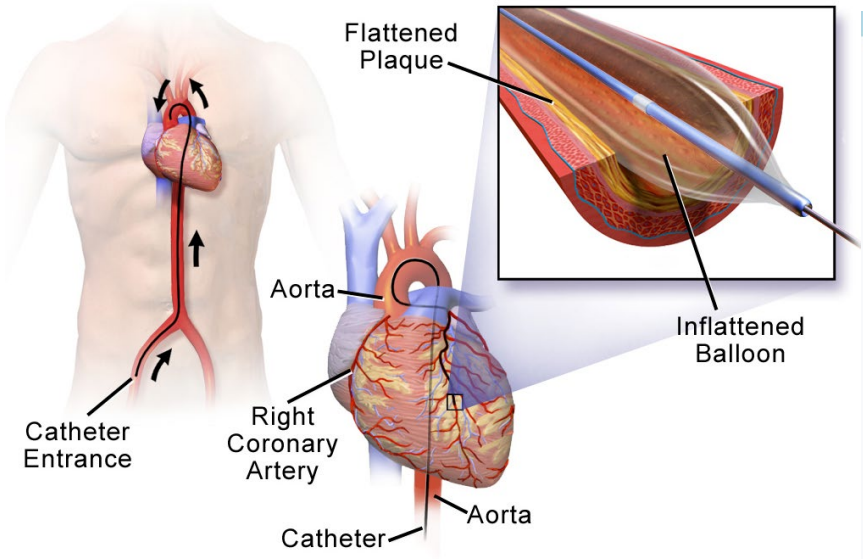
# Balloon catheter

- Angioplasty or balloon septostomy, via cardiac catheterization
- Tuboplasty via uterine catheterization
- Pyeloplasty or ureteroplasty
  using a detachable inflatable balloon stent

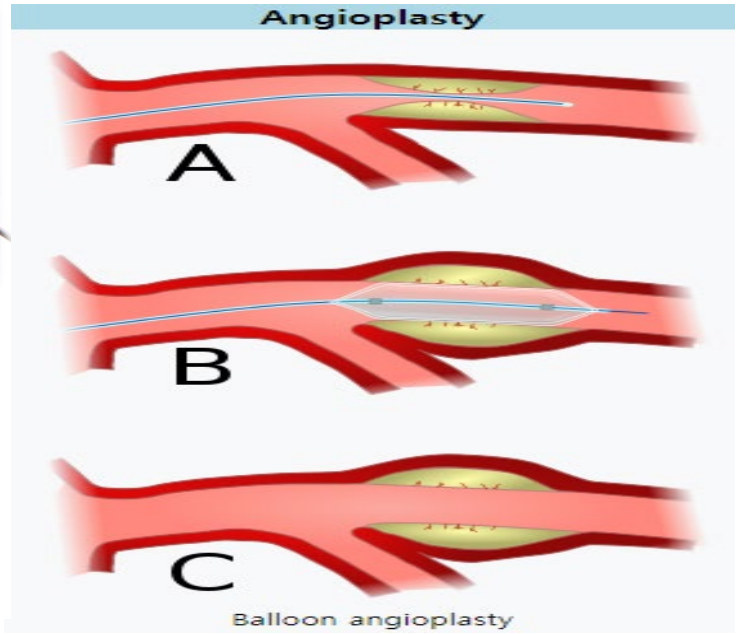
# Angioplasty

- Angioplasty, also known as **balloon angioplasty** and **percutaneous transluminal angioplasty (PTA),** is a minimally invasive endovascular procedure used to widen narrowed or obstructed arteries or veins, typically to treat **arterial atherosclerosis**.

**Coronary angioplasty**
**Peripheral angioplasty**
**Renal artery angioplasty**
**Carotid angioplasty**
**Venous angioplasty**




**Balloon-tipped Catheter**



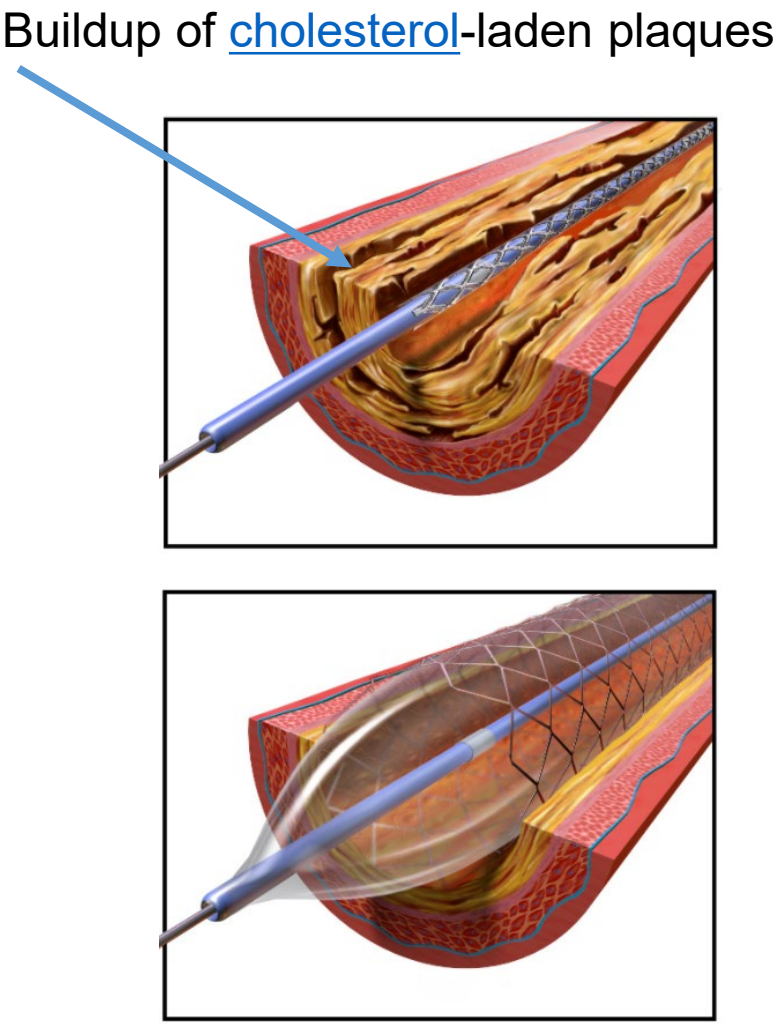
# Angioplasty

**Contraindications**

1) If no access vessel of sufficient size and quality is available, angioplasty is contraindicated.

2) Patients with left main coronary artery disease, due to the risk of spasm of the left main coronary artery during the procedure

3) less than 70% stenosis of the coronary arteries



# Ureteroplasty: Balloon dilation

Balloon dilatation is a minimally invasive procedure with acceptable results for benign short strictures and should be considered as first line management in such strictures.

**Contraindications**

malignant extrinsic obstruction

**Relatively contraindications**

Retroperitoneal fibrosis

The reported success rates vary between 48% and 88%, with a mean success rate of 55%, with most studies having follow-up of less than 2 years. *J Endourol 2009; 23: 1187.*

Byun et al. concluded that a benign ureteral stricture length of less than 2 cm was a significant prognostic factor for better outcome. *Yonsei Med J 2003; 44: 273.*

# Angioplasty

1) Access to the vascular system is typically gained percutaneously

2) X-ray fluoroscopy and radiopaque contrast dye to guide angled wires and catheters to the region of the body to be treated in real time

3) To treat a narrowing in a blood vessel, a wire is passed through the stenosis in the vessel and a balloon on a catheter is passed over the wire and into the desired position

**4)** Balloon is inflated using water mixed with contrast dye to 75 to 500 times normal blood pressure (6 to **20** atmospheres)

# Stent

**Stent** is a metal or plastic tube inserted into the lumen of an anatomic vessel or duct to keep the passage way open.

**Stenting** is the placement of a stent.

**The first use of a coronary stent** is typically attributed to Jacques Puel and Ulrich Sigwart when they implanted a stent into a patient in Toulouse, France, in **1986**.

**The First FDA-approved stent** in the USA was created by Richard Schatz and coworkers. Named the Palmaz-Schatz (Johnson & Johnson) it was developed in 1987.

To further reduce the incidence of restenosis, the **drug-eluting stent** was introduced in 2003.

# Types of Stent

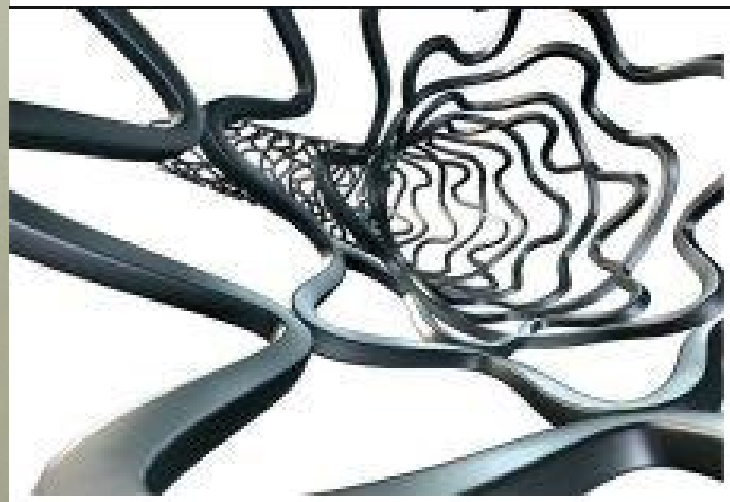
## Coronary stents

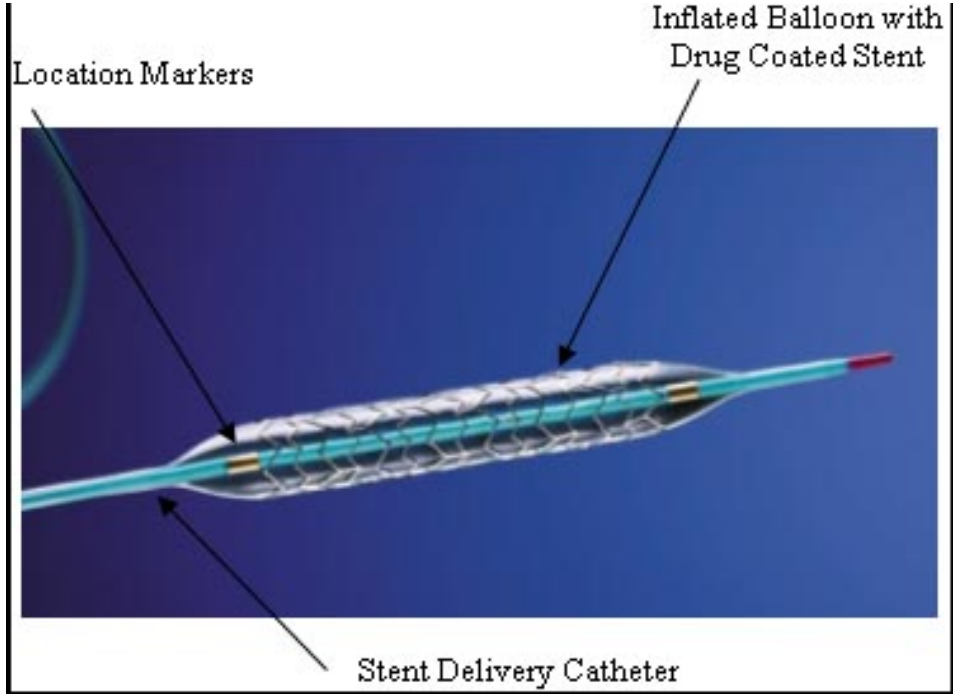
**Bare-metal stent**

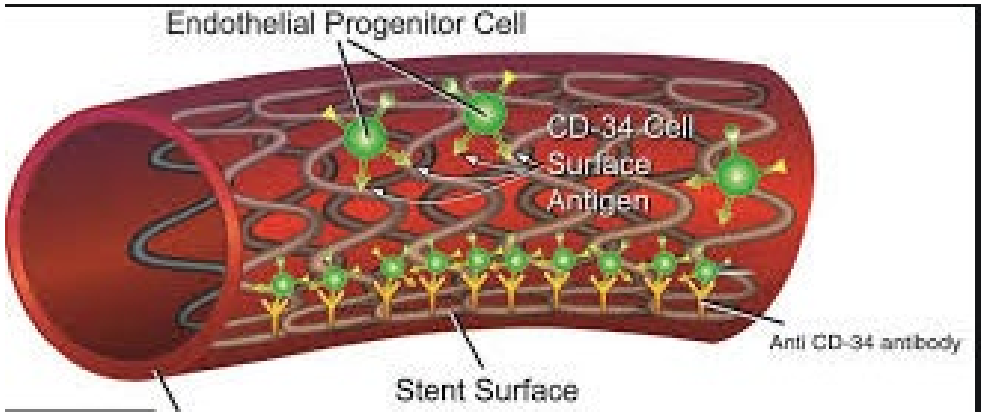
**Drug-eluting stent**

**Bioabsorbable stent**

**Dual-therapy stent (combination of both drug and bioengineered stent)**

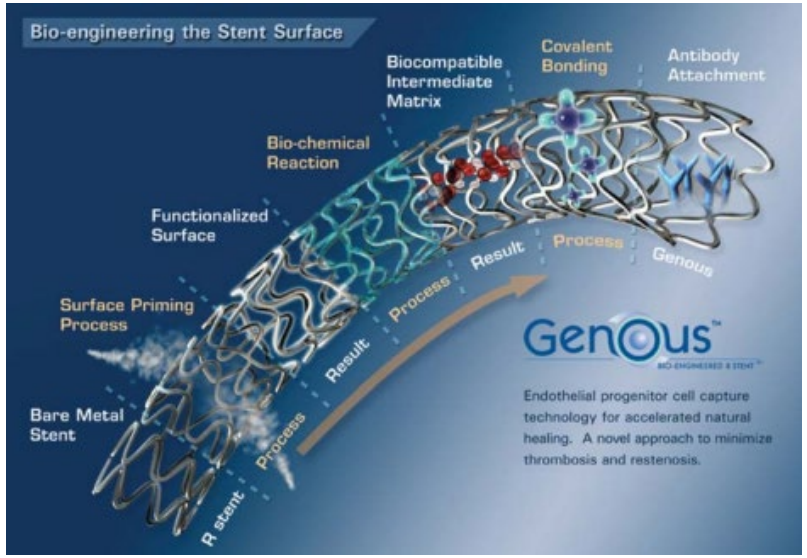




# Dual-therapy stent

The pro-healing technology has an antibody surface coating that captures **<u>circulating CD34+ endothelial progenitor cells</u>** to the device, forming a functional endothelial layer over the stent to protect against thrombus and minimize restenosis.

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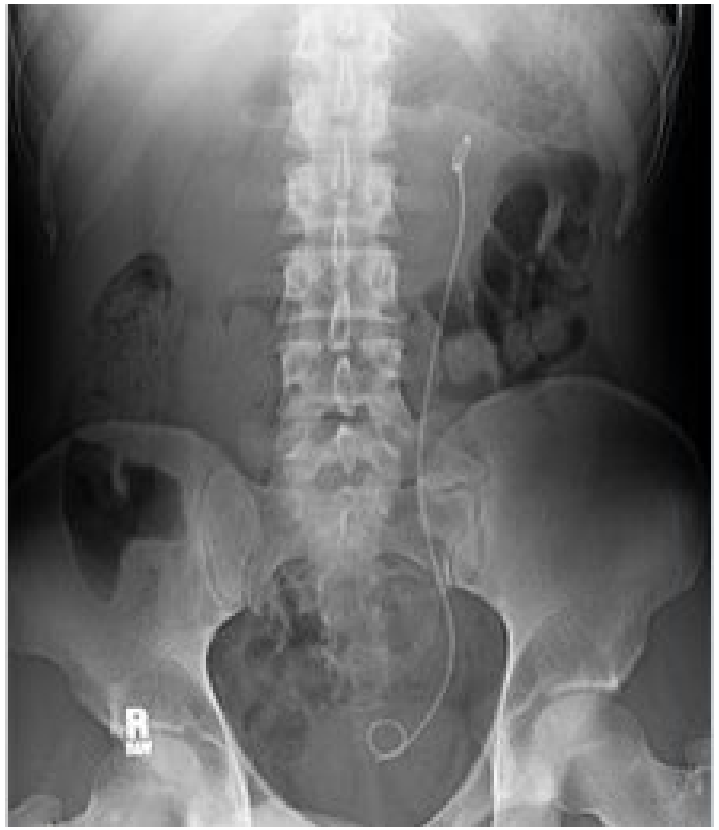
ORIGINAL STUDIES

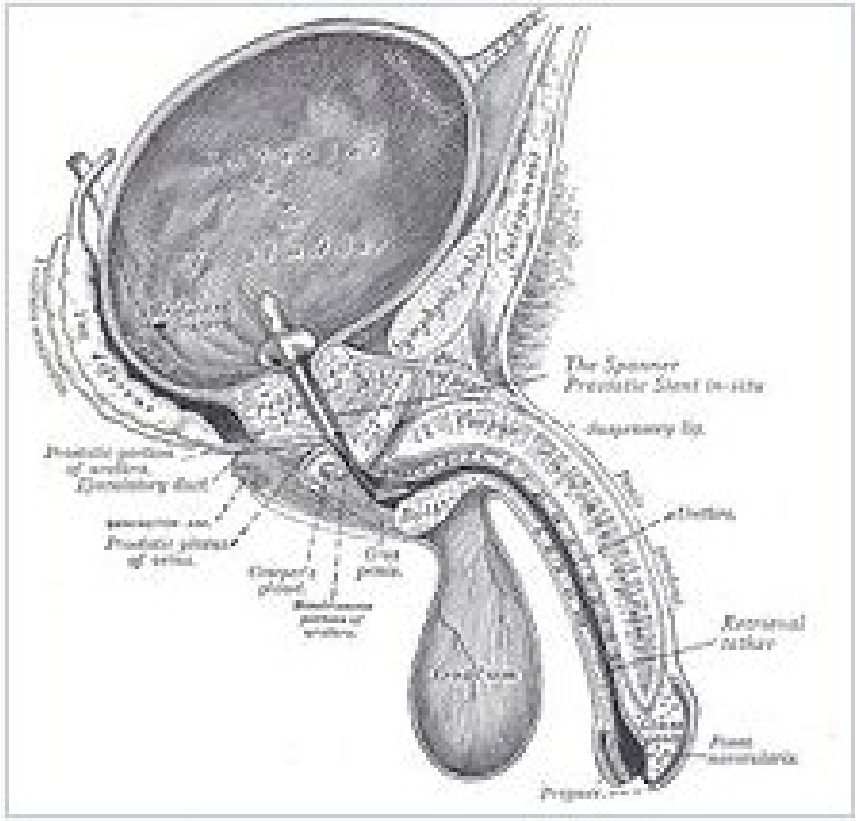
WILEY

**Five-year follow-up of the endothelial progenitor cell capturing stent versus the paxlitaxel-eluting stent in de novo coronary lesions with a high risk of coronary restenosis**

# Ureteral stent



# Prostatic stents



# Ureteral stent: Material and Design

| | |
|---|---|
| Polyurethane | Better drainage efficiency compared to silicone |
| Silicone | Better performance against encrustation compared to polyurethane |
| C-Flex | A thermoplast polymer from the family of silicones. Its surface of friction was lower compared to polyurethane and Percuflex™ |
| Percuflex™ | From the family of silicones. A biomaterial with a relatively long-term indwelling biodurability compared to polyurethane and silicone itself. |
| Titanium | Improvement in benign prostatic hyperplasia in over 80% of patients |
| Nitinol | A mixture of nickel and titanium that softens at temperatures below 10 °C and hardens as the temperature increases and allows better stent insertion and removal |
| Stainless steel | Does not have major insertion side effects and recognised as an operational tool in tumour associated hydronephrosis |

| | |
|---|---|
| Grooves | Providing multiple pathways for urine drainage |
| Spiral | Providing a stable and durable lumen |
| Self-expanding | Providing a wider pathway for urine compared to conventional stents |
| Tail | Provides less bladder irritation compared to the conventional stents |
| Dual-durometer | Provides less bladder irritation compared to conventional stents and better stability in the kidney |
| Magnetic-tipped | Provides an improvement towards stent removal and avoiding the use of cystoscopy |
| Resonant | Provides up to 12 months indwelling |

# Ureteral stent: Coating

| | |
|---|---|
| CAGs and heparin | A natural component of urine that could potentially delay encrustation for up to 12 months |
| DLC | With physical and chemical composition reducing encrustation and biofilm formation |
| Hydrogel | Preventing biofilm via creating a thin layer of water on the surface |
| PC | A natural component that provides a hydrophilic environment on the surface and as a result reduces encrustation and biofilm formation |
| Antibiotic | Disrupts bacteria formation and growth |
| PTFE | Has a low friction coefficient and resistance against van der Waals forces that prevents bacterial colonization |
| Antimicrobial triclosan and silver | Triclosan has a significant bacterial resistance however it is not approved by FDA, because of concerns over antimicrobial resistance. Despite resistance against biofilms, a prolonged use could lead to argyria. |
| Chitosan | It inhibits biofilm formation on the stent surface |

Clinical Data, No RCTs

In vitro Data

# Firm Percuflex Stent with HydroPlus™

## Experience with a New Ureteral Stent Made of a Biocompatible Copolymer[1]

Harold A. Mitty, MD
Marlene E. Rackson, MD
Sol J. Dan, MD
John S. Train, MD

**A double-pigtail ureteral stent made from a biocompatible copolymer was designed for antegrade insertion with a new coaxial system. Thirty-eight of these stents were successfully placed in 33 patients. Of eight stents used for benign temporary indications, two (two patients) occluded prematurely. One of these patients had retained stone fragments, which caused the 10-F stent to occlude 4 months after balloon dilation of a midureteral stricture. The second patient had a ureteroconduit stricture that was dilated and stented, but mucus occluded the 10-F stent 5 days after insertion. In 25 of the patients, 30 stents were placed for ureteral obstruction due to malignant neoplasms. Three patients died with patent stents, while surviving patients with malignancies continue to have functioning stents, for an overall mean patency of 5.1 months in these patients. No problems related to stent migration or brittleness have been encountered.**

PERCUTANEOUS transrenal placement of ureteral stents has become one of the basic procedures of interventional uroradiology. Early experience was reported in the placement of polyethylene and polyurethane stents over standard guide wires (1–3). These somewhat rigid stents have drawbacks including difficulty in placement, poor patient tolerance, and premature occlusion (4). Improvements in ureteral stent design should result in easier insertion and longer duration of patency. Successful transrenal stent placement is dependent in part on the design of the delivery system. Patency is related to the stent environment in vivo, as well as the material used to fabricate the stent.

Recent advances in the design of delivery systems have made possible the antegrade placement of stents made of silicone and other soft polymers. In this paper we present our early clinical experience with a stent system made of a biocompatible copolymer, Percuflex (Medi-tech, Watertown, Mass).

### Materials and Methods

loop through the proximal shaft of the stent, which allows retraction or withdrawal of the stent if necessary.

*Technique.*—The inner stiffening catheter with the coaxially loaded stent-pusher combination is advanced until the distal pigtail portion lies within the bladder. Fluoroscopic observation of both the distal and proximal ends of the stent during placement is important. One must be sure there is no looping or coiling of the assembly in the collecting system or perirenal space. Often, use of an extra-stiff wire provides additional support of the stent during placement. The position of the proximal (renal pelvis) end of the stent is easily ascertained because the stent is radiopaque, whereas the pusher is not.

Once the stent is properly positioned, the pusher is held in place and the inner stiffener is removed. The guide wire may then be withdrawn, and formation of the distal pigtail is seen in the bladder. The pusher is held in place during these manuevers so that the stent does not retract into the nephrostomy tract. The wire is then withdrawn into the pusher. At this

# Ureteral Metal Stents: 10-Year Experience With Malignant Ureteral Obstruction Treatment

long-term decompression of the upper urinary tract in **select** cases.

Evangelos N. Liatsikos,* Dimitrios Karnabatidis, Konstantinos Katsanos, Panagiotis Kallidonis, Paraskevi Katsakiori, George C. Kagadis, Nikolaos Christeas, Zafiria Papathanassiou, Petros Perimenis and Dimitrios Siablis

*From the Departments of Urology (EM, PK, PK, PP), Radiology (DK, KK, NC, ZP, DS) and Medical Physics (GCK), University of Patras, Patras, Greece*

**Purpose:** Ureteral patency in malignant ureteral obstruction cases is a therapeutic challenge. We report our long-term experience with palliative treatment for extrinsic malignant ureteral obstruction with percutaneous placement of metal mesh stents.

**Materials and Methods:** From January 1996 to December 2005, 90 patients with a mean age of 59 years (range 35 to 80) with ureteral obstruction due to extrinsic ureteral compression and/or encasement by primary or metastatic tumors, or retroperitoneal lymphadenopathy underwent implantation of self-expandable metal mesh stents. A total of 119 ureters were managed. Followup included urinalysis, blood biochemistry tests and transabdominal ultrasound or intravenous urography.

**Results:** The technical success rate of percutaneous antegrade insertion of ureteral self-expandable metal mesh stents was 100%. Renal biochemistry normal-

**Abbreviations and Acronyms**

MS = metal mesh stent

PS = polymeric ureteral stent

Submitted for publication April 1, 2009.

Study received institutional review board approval.

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| | No. Ureters (%) |
|---|---|
| Ureteral lesion site: | 119 |
| Distal | 85 (71.4) |
| Mid | 26 (21.8) |
| Upper | 8 (6.7) |
| Stented: | |
| Restenosis | 45 (37.8) |
| Double-J® stent needed | 45 |

| Primary Ca Site | No. Obstructed Ureters |
|---|---|
| Colon | 31 |
| Ovary | 29 |
| Uterus | 24 |
| Prostate | 22 |
| Bladder | 9 |
| Breast | 4 |

# Drug-eluting stents

## A Novel Drug Eluting Ureteral Stent: A Prospective, Randomized, Multicenter Clinical Trial to Evaluate the Safety and Effectiveness of a Ketorolac Loaded Ureteral Stent

Amy E. Krambeck, Robert S. Walsh,* John D. Denstedt,* Glenn M. Preminger, Jamie Li,* John C. Evans* and James E. Lingeman†,‡ for the Lexington Trial Study Group

*From the Methodist Hospital Institute for Kidney Stone Disease, Indianapolis, Indiana (AEK, JEL), Boston Massachusetts (RSW, JL, JCE), St. Joseph's Health Center; London, Ontario, Canada (JDD), and Duke U North Carolina (GMP)*

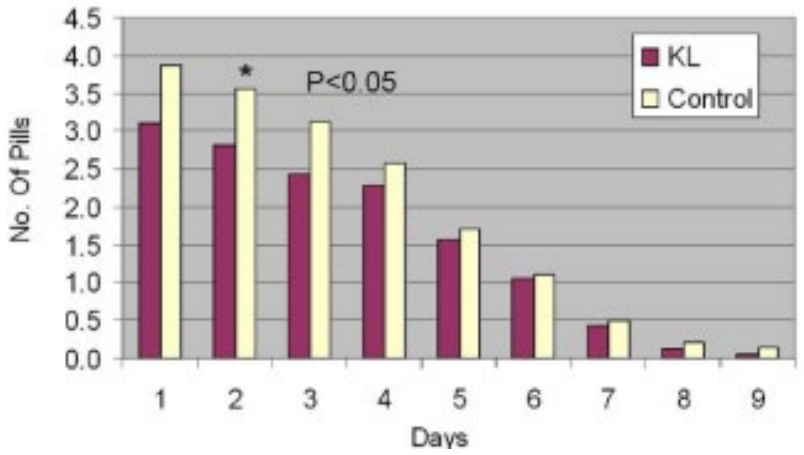
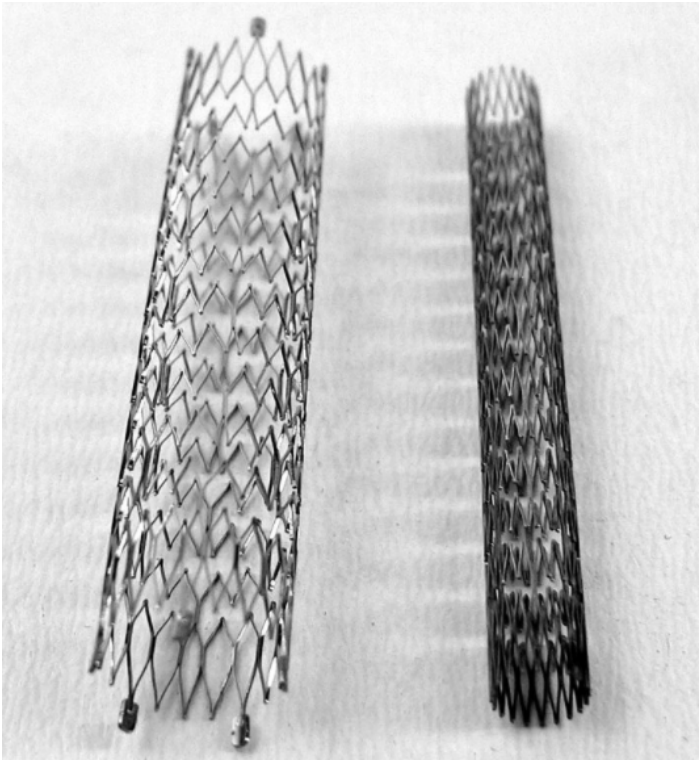



**Table 4.** *Comparison of device related adverse event rates*

| | Overall | Stent Indwelling | After Removal |
|---|---|---|---|
| No. KL (%): | | | |
| Mild | 53 (39.8) | 54 (40.6) | 4 (3.0) |
| Moderate | 61 (45.9) | 62 (46.6) | 2 (1.5) |
| Severe | 10 (7.5) | 8 (6.0) | 2 (1.5) |
| Totals | 124 (93.2) | 124 (93.2) | 8 (6.0) |
| No. control (%): | | | |
| Mild | 68 (47.6) | 68 (47.6) | 1 (0.7) |
| Moderate | 61 (42.7) | 60 (42.0) | 2 (1.4) |
| Severe | 8 (5.6) | 8 (5.6) | 1 (0.7) |
| Totals | 137 (95.8) | 136 (95.1) | 4 (2.8) |

# Stents



Vascular stents

advanced peripheral and cerebrovascular disease (carotid, iliac, and femoral arteries)

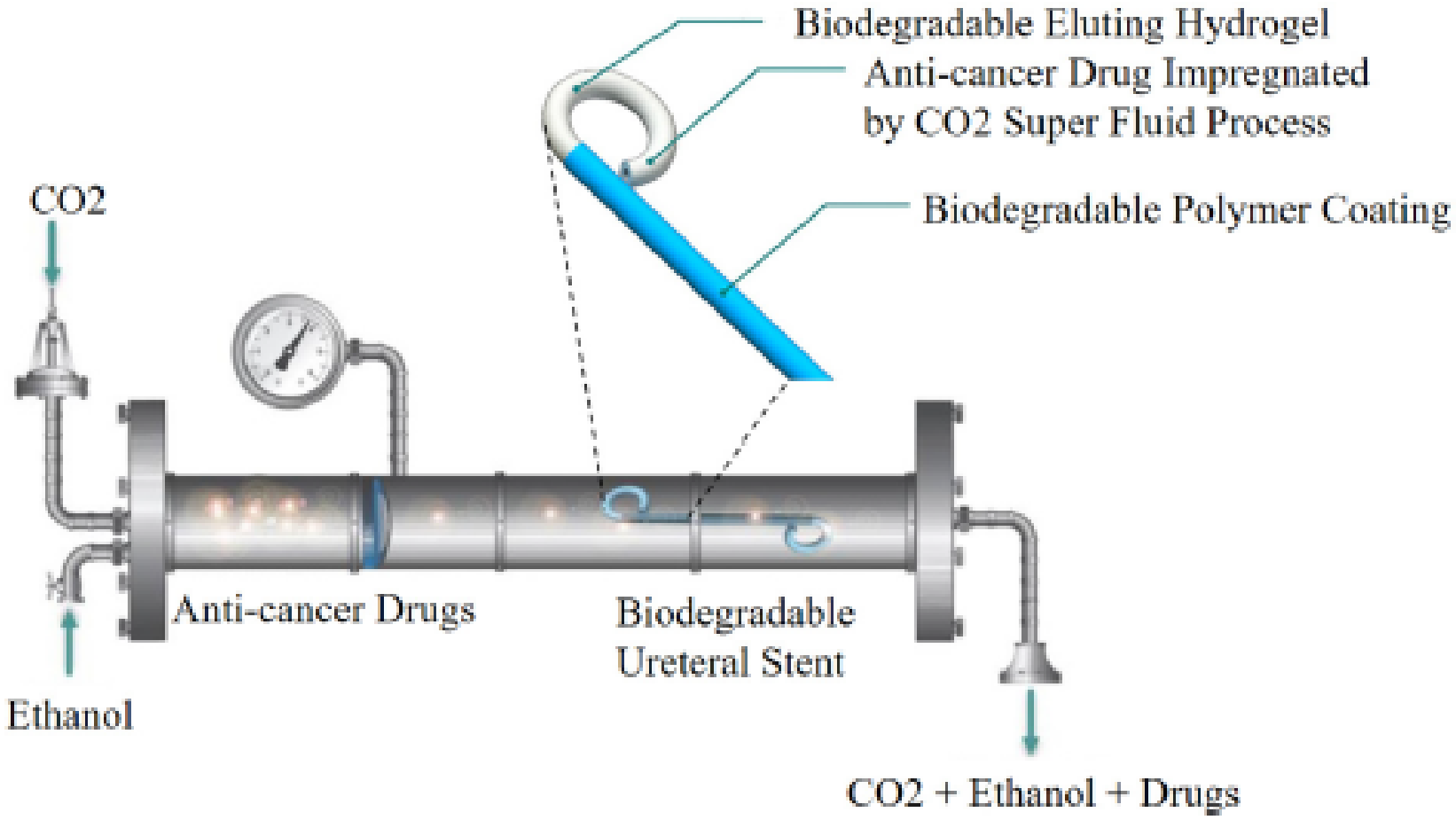
Because of the **external compression** and **mechanical forces** subjected to these locations, flexible stent materials such as **nitinol** are used in a majority of peripheral stent placements

# Flexible Nitinol ureteral stent

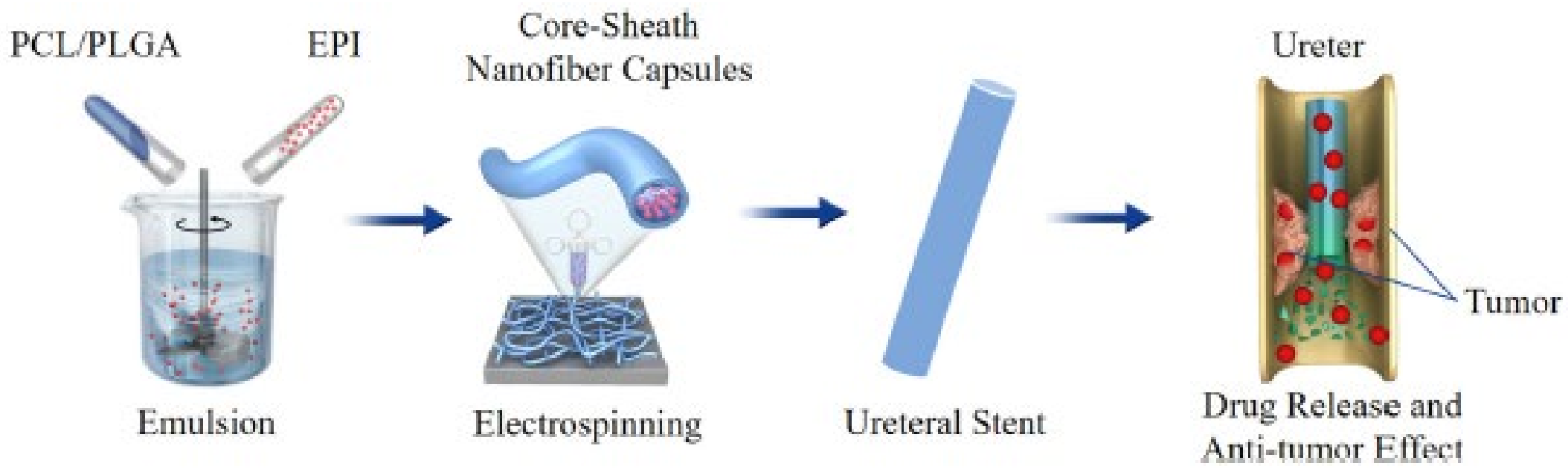
**Super elastic, bio-compatible material** vs conventional polyurethane stent

No clinical data

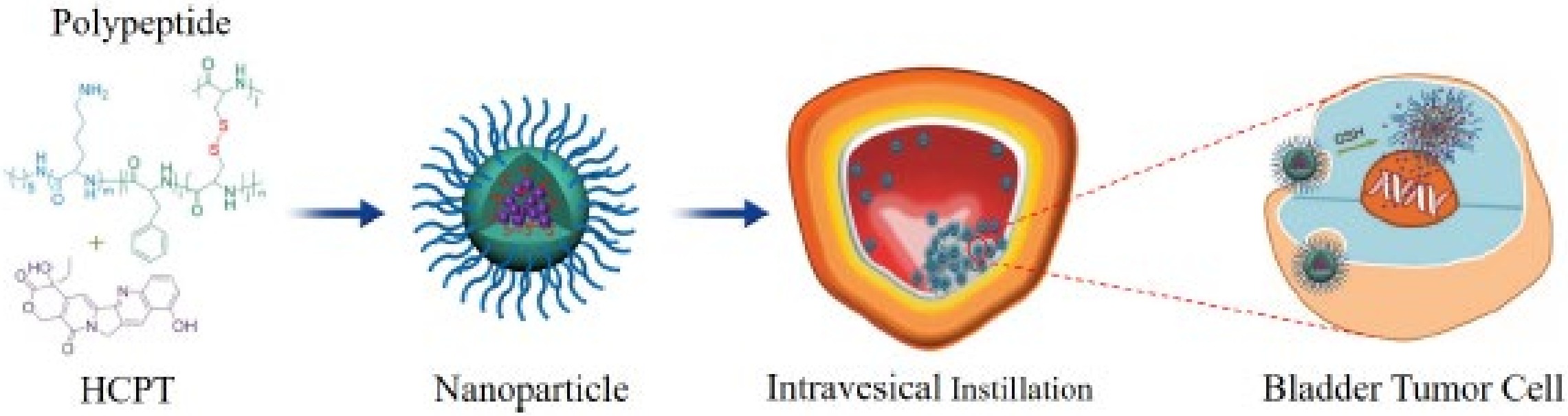
# Advances in Drug Delivery via Biodergradable Ureteral Stent



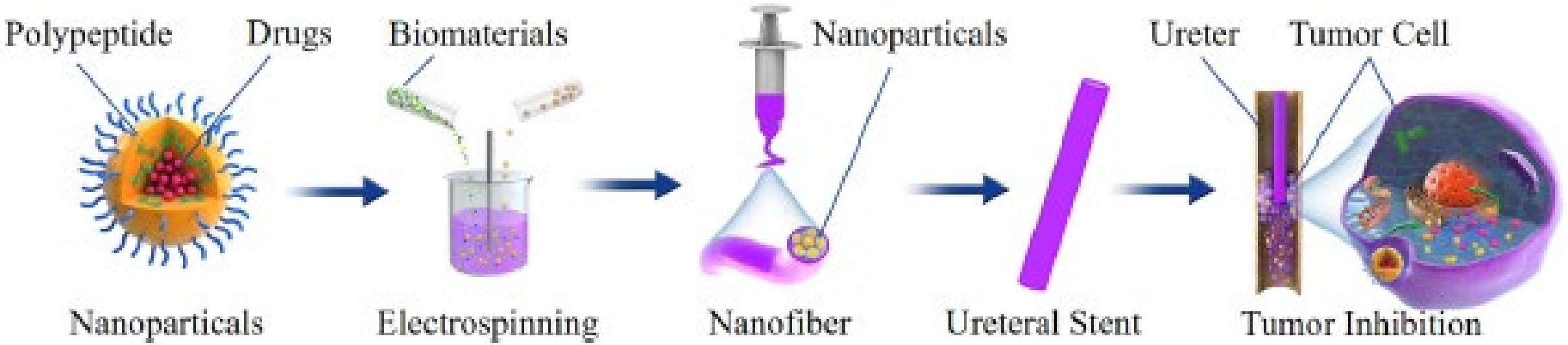

Schematic representation of CO2 impregnation drug-eluting BUS




Schematic illustration of preparation and antitumor effect of Epirubicin-loaded BUS




Schematic illustration of chemical structure of polypeptide/HCPT nanoparticles and its metabolic process



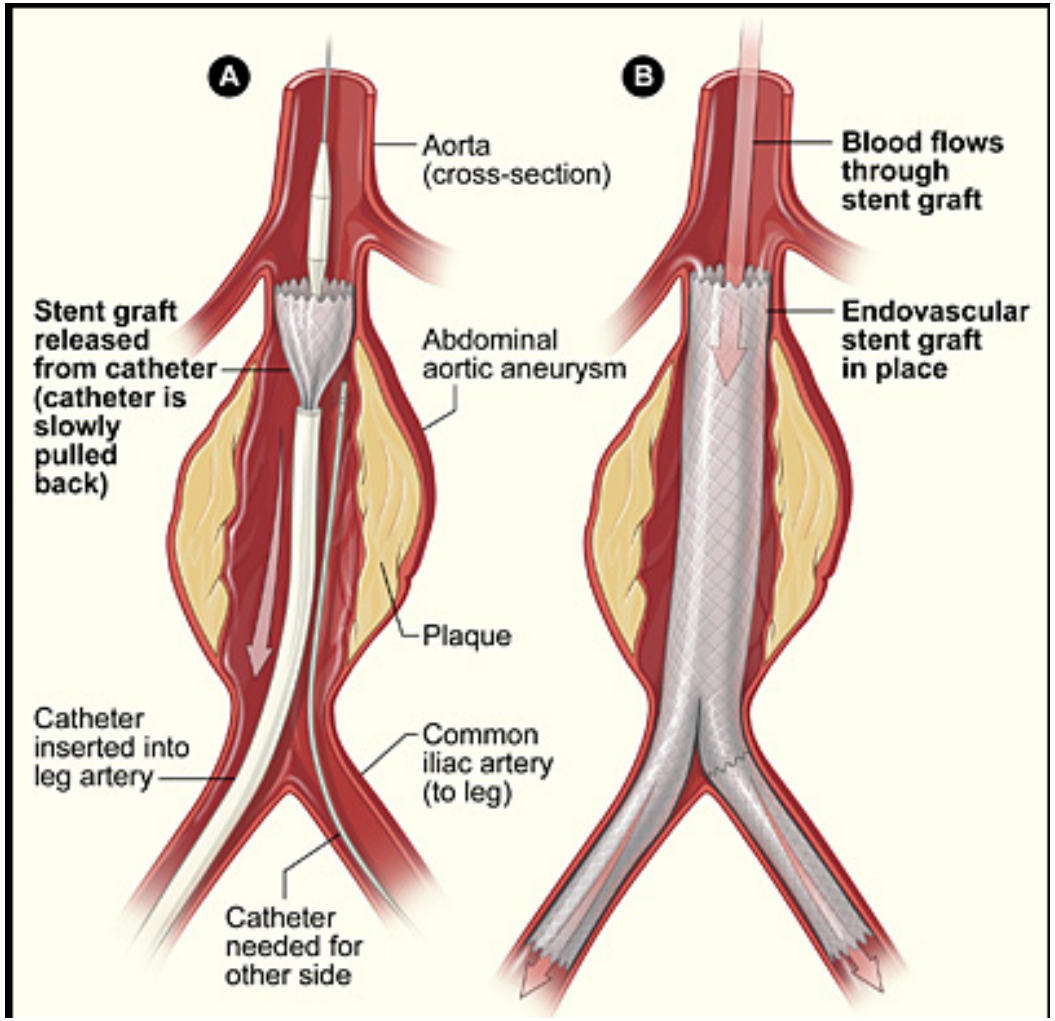

Schematic illustration of preparation, structure and antitumor effect of a nanoparticles-based drug-eluting BUS

# Stents

**Stent graft or covered stent**

Vascular stent with a **fabric coating** that creates a contained tube but is expandable like a bare metal stent.

**Covered stents** are used in endovascular surgical procedures such as endovascular aneurysm repair



# Stents

Colon and Esophageal stents

Pancreatic and biliary stents