EFFECTS OF SILICONE HYDROCOATED DOUBLE LOOP URETERAL STENT ON SYMPTOMS AND QUALITY OF LIFE IN PATIENTS UNDERGOING FLEXIBLE URETEROSCOPY FOR KIDNEY STONE: A RANDOMIZED MULTICENTRE CLINICAL STUDY

ABSTRACT

Introduction and Objectives: Silicone was one of the first materials to be used for DJ ureteral stents. Due to its softness, it is purported to be associated with less patient discomfort. However, this had not been evidenced through clinical trials.

Purpose: To compare the hydrocoated silicone stent (Coloplast Imajin® hydro) to Percuflex™ Plus stent (Boston Scientific) in terms of patient comfort and quality of life after flexible ureteroscopy (fURS) for stone disease over a 5-week prospective follow-up.

Materials and Methods: This is a multicenter, single-blind, prospective, randomized trial of 141 patients treated with fURS for renal stones. Primary outcome was USSQ Body Pain Index recorded before DJ removal at day 20 (D20). Secondary endpoints were USSQ scores at intermediate dates (D2, D7, D20) and 2 weeks after stent withdrawal (D35), occurrence of adverse events and stent encrustation.

Results: The trial was completed by 113 (80.1%) patients. Mean (SD) USSQ body pain scores were 25% lower at D20 for the silicone stent: 18.7 (11.4) vs 25.1 (14.2), p=0.015. No difference in term of adverse events and safety profile was observed. USSQ urinary symptoms scores at D2, D7 and D20 were lower in the silicone stent group: 26.4 (7.7) vs 31.8 (8.1) at D20 p<0.001. The use of USSQ self-questionnaires was associated with a limited number of missing or incomplete answers.

Conclusions: The primary results of this large sample prospective randomized controlled study comparing the silicone Imajin® hydro stents to the Percuflex™ Plus stent show that silicone stents are associated with significantly less patient discomfort. We would recommend their use in patients who require stenting for stone disease.

Patient Summary: In this randomized prospective trial, silicone DJ stents Imajin® hydro result in lower pain and discomfort following flexible ureteroscopy as compared to Percuflex™ Plus.

Indications for Use:
Drainage of the upper urinary tract over fistulas or ureteral obstacles.

Contraindications:
Untreated progressive infection of the upper urinary tract.

Warnings:
Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

Adverse Events:
The following events have been reported although their occurrence greatly depends on medical conditions of patient: infection, encrustation, obstruction, rupture, migration, bladder irritation symptoms, pain, hematuria, erosion.

See Instructions for Use for detailed information regarding warnings/precautions, adverse events prior to using this product. For further information contact Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

COLOPLAST KEY TAKEWAYS

- This study demonstrates that patients implanted with a silicone Imajin Hydro ureteral stent had a normalized body pain index score of 19.2 compared to 26.0 for patients implanted with the Percuflex™ plus stent from Boston Scientific according to the USSQ body pain index. This represents a difference of 6.8 points or 26% in favor of the Imajin Hydro ureteral stent from Coloplast.
- This study demonstrates that patients implanted with a silicone Imajin Hydro ureteral stent scored their day 20 urinary symptoms at 26.4 compared to 31.8 for patients implanted with the Percuflex™ plus stent from Boston Scientific according to the USSQ body pain index. This represents a difference of 5.4 points or 17% in favor of the Imajin Hydro ureteral stent from Coloplast.
- No significant difference was noticed between the two groups regarding demographic characteristics, clinical history, size and treatment of stone or initial pain.
- Silicone stents are associated with significantly less patient discomfort and the authors of this clinical study would recommend the use of silicone stents in patients who require stenting for stone disease.