“...there is a beneficial effect regarding UTI when using hydrophilic-coated catheters.”

DeRidder et al, 2005

De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.

De Ridder, 2005

Study Hypothesis

To compare the performance of SpeediCath hydrophilic-coated catheters versus uncoated polyvinyl chloride (PVC) catheters

Study Type and Methods

Randomized, open label, multi-center trial over 12 months

Patient Population

Male SCI patients with injury <6mos; no urethral stenosis, fibrosis, and 0-6 months of IC use.

Catheters compared

Hydrophilic: SpeediCath® (n= 61); Uncoated: Conveen® (n= 62)

Outcomes Measured

1. UTI
2. Hematuria
3. Satisfaction (4-point Likert scale; presented dichotomously)

Strengths

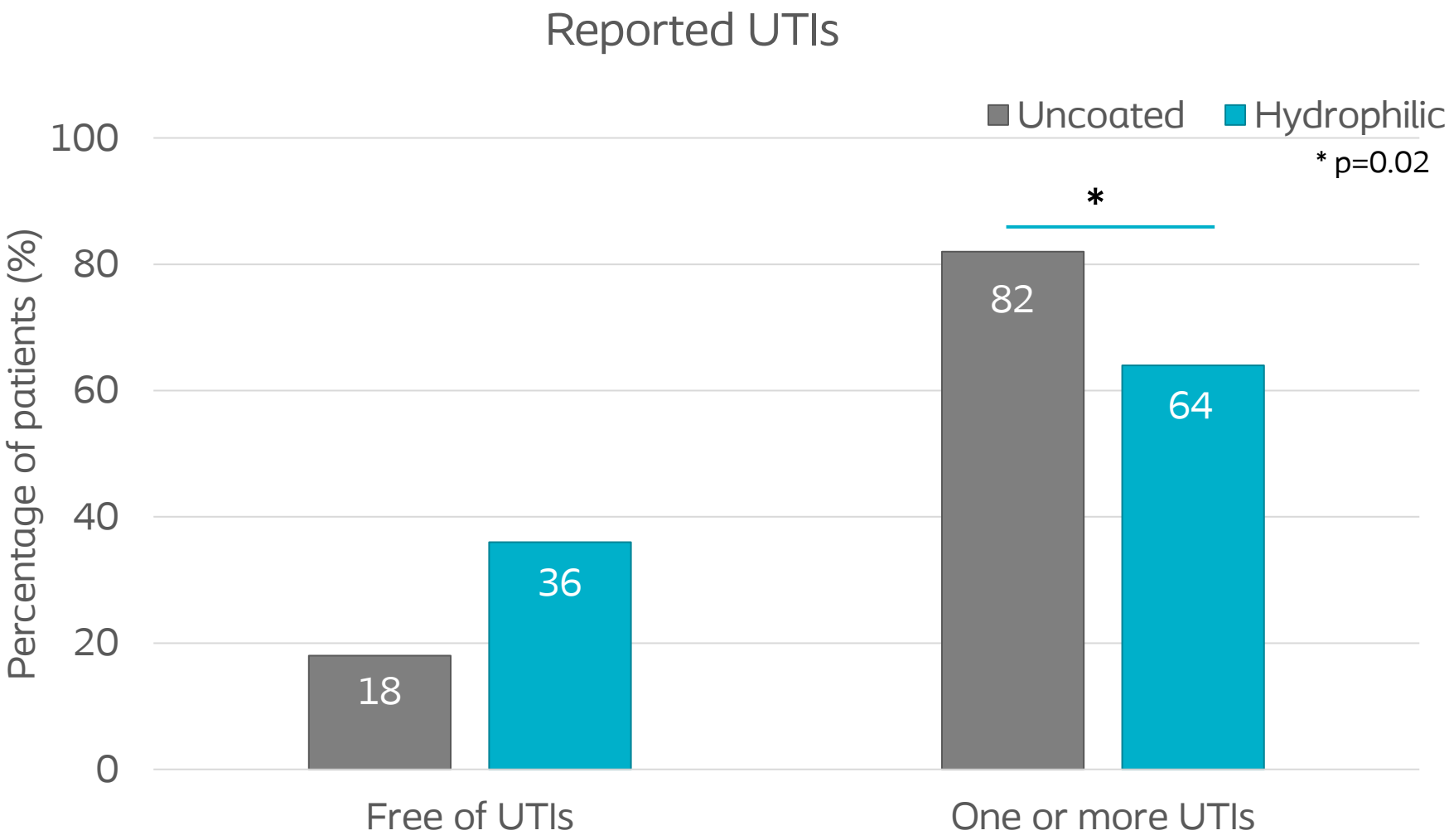
- IC naïve patients
- Randomized
- Duration of study was sufficient to allow for getting used to product

Limitations

- High drop out rate (due to switch to indwelling or no more catheters required
- Low power (stated need 50 in each group for 90% power but high drop out rate)
- Whether Conveen® was single use or reuse was not specified

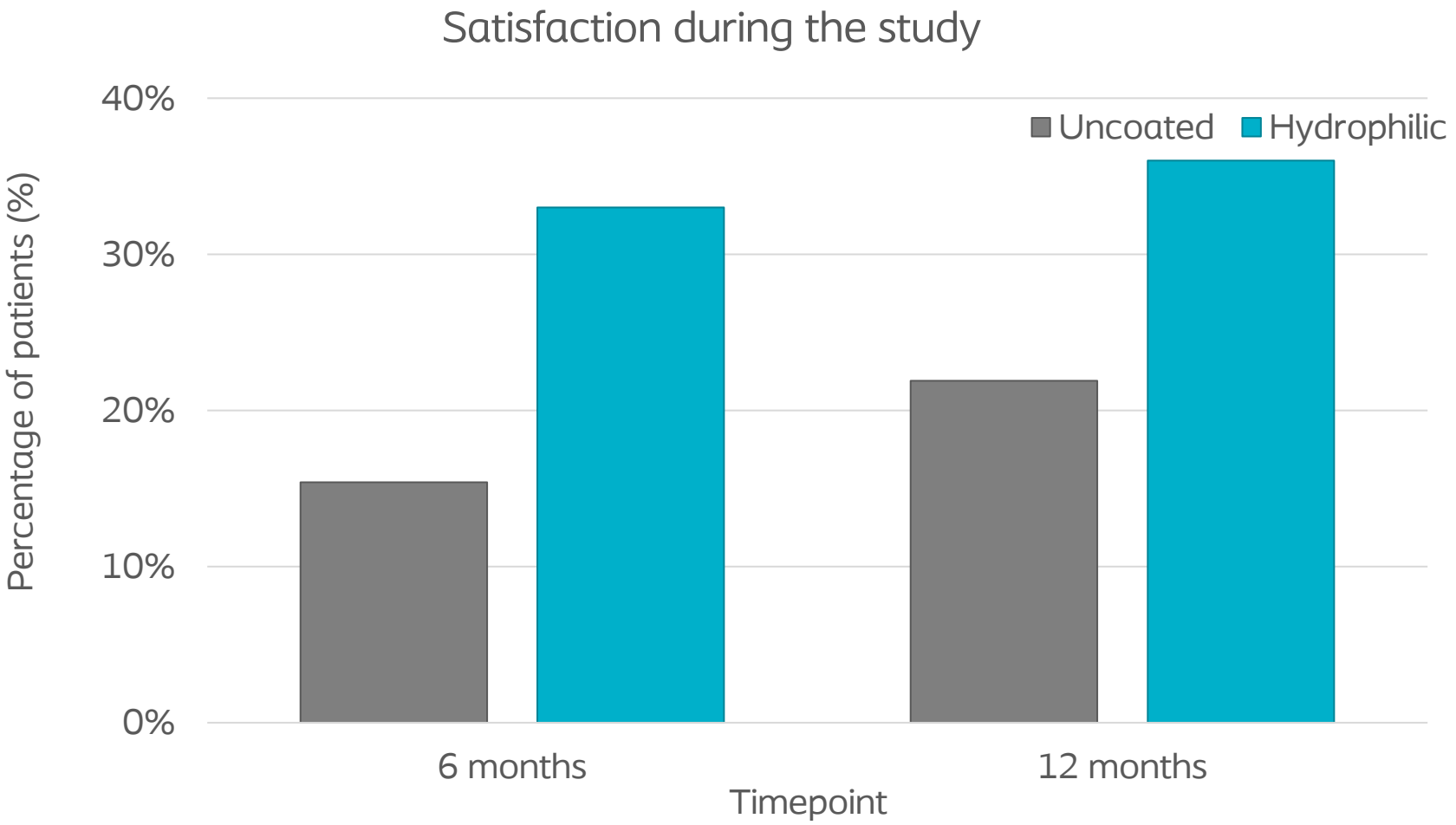
De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.

Fewer patients reported UTIs after using a hydrophilic-coated catheter as compared to uncoated catheters



De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.

A greater percentage of patients reported being very satisfied after 6 and 12 months in the hydrophilic group compared to the uncoated group



No statistical difference was reported in overall satisfaction, at 6 or 12 months.

De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.

Data reported, but not shown:

- There was no significant difference between hydrophilic and uncoated catheters in:
  - Occurrence of bacteriuria, leukocyturia, hematuria

- More patients/caregivers reported hydrophilic-coated catheters were easy or very easy to introduce and withdraw the catheter and overall catheterization

- Time needed to catheterize was the same in both groups

De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.

Conclusions:

- Hydrophilic catheter users experiences fewer clinical UTIs than those using uncoated catheters

- Twice the number of patients who used hydrophilic catheters reported no UTIs than those using uncoated catheters

De Ridder DJ, Everaert K, Fernandez LG, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. *Eur Urol.* 2005;48(6):991-995.