

“There was no significant difference in the number of patients experiencing macroscopic bleeding episodes and no overall difference in the occurrence of hematuria, leukocyturia, and bacteriuria.”

DeRidder et al, 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)

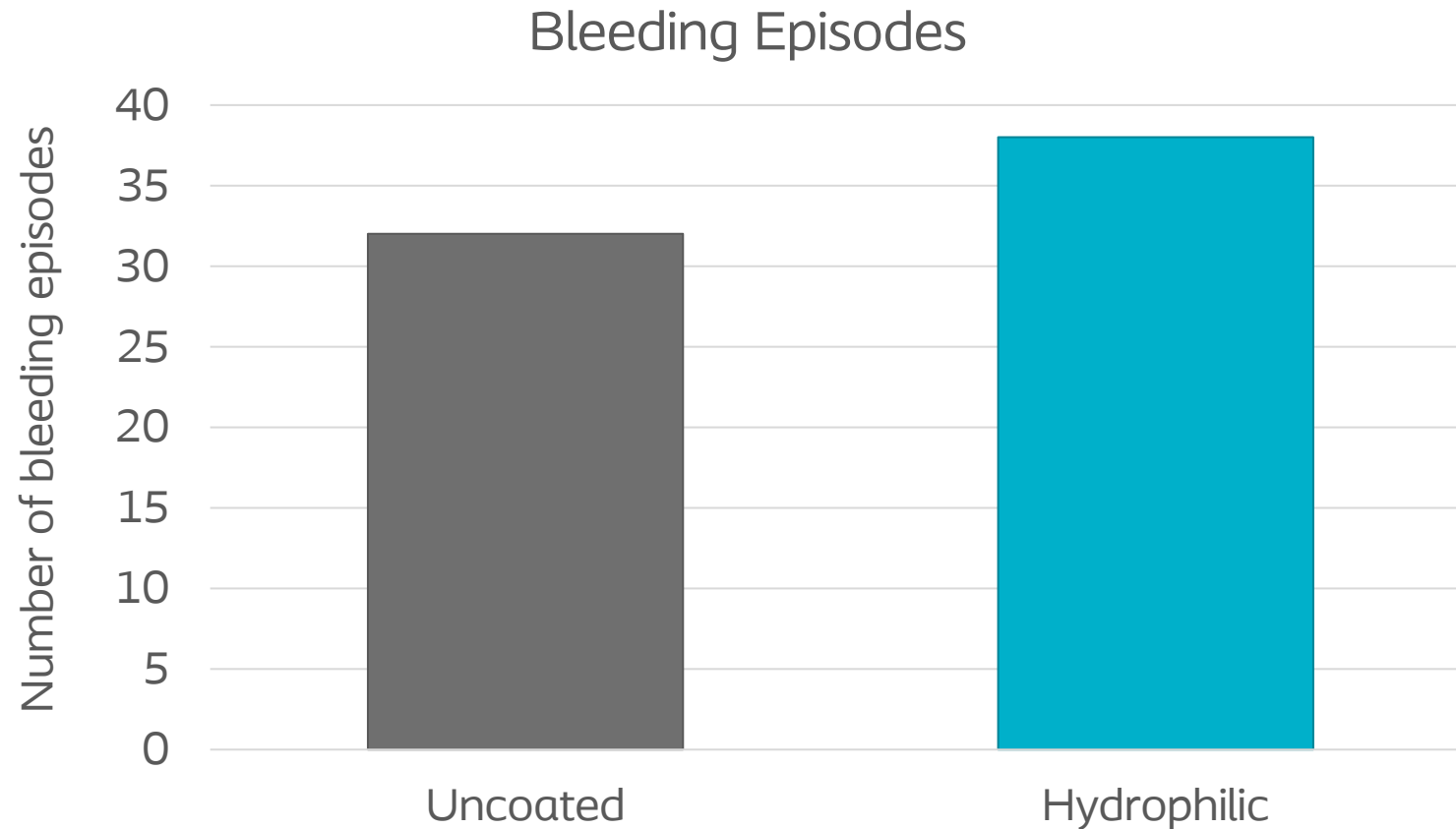
Strengths

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

Limitations

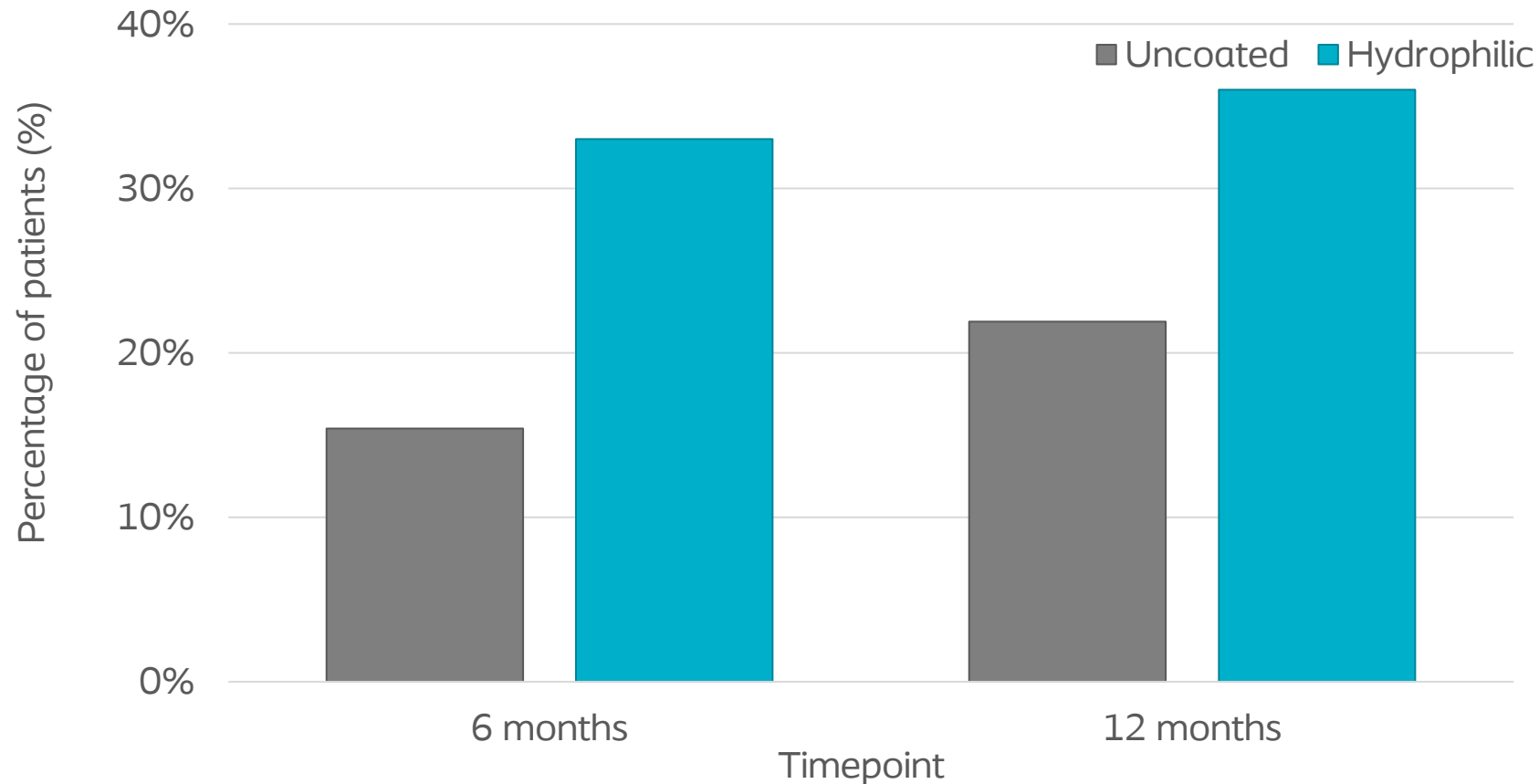
- High drop out rate (due to switch to indwelling or no more catheters required)
- Low power (stated need 50 in each group for 90% power but high drop out rate)
- Whether Conveen[®] was single use or reuse was not specified

No difference in bleeding episodes were reported between the two catheter types



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

Satisfaction during the study



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

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 and overall catheterization
- Time needed to catheterize was the same in both groups

Conclusions:

- No difference was reported between groups in the number of bleeding episodes, hematuria, bacteriuria, leukocyturia
- Ease of use was reported for hydrophilic-coated catheters by patients and caregivers