

TEN MINUTES TO CURE MIXED URINARY INCONTINENCE? – RESULTS OF THE BOTOX®-BULKAMID® STUDY



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Introduction

In this **prospective investigator-initiated study** a combination of surgical therapies was applied to treat **mixed urinary incontinence (MUI)**. In a single operation, Botulinum toxin (**Botox®**) and bulking agent (polyacrylamide hydrogel, PAHG, **Bulkamid®**) were injected against the urgency (UUI) and stress (SUI) components of MUI. An elderly and frail population group may benefit from the short intervention that – in contrast to conservative and medical treatments – does not require a long-term therapy adherence. Conversely, such a **combination therapy** may carry the risk of potentiating adverse events, e.g. postoperative voiding dysfunction, urinary tract infection or de novo urgency. To find out, we investigated safety, efficacy and sustainability of this novel combination approach in a small study population.

Objectives

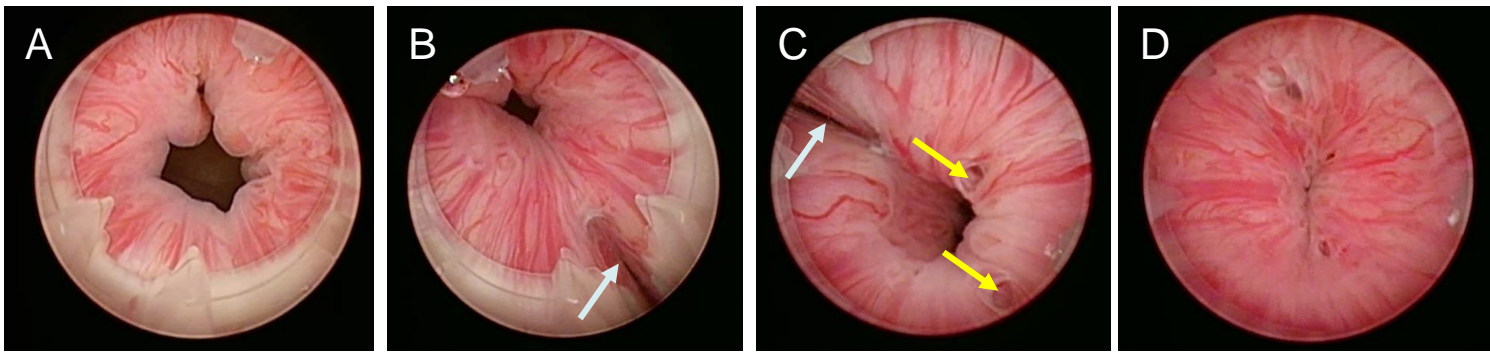
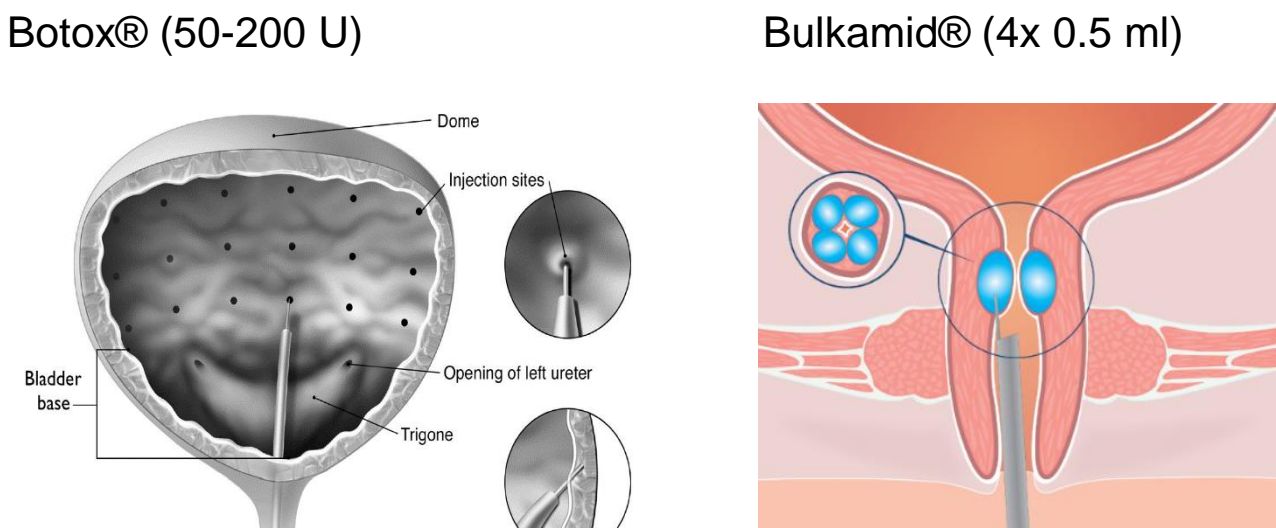
- Can MUI be treated by Botox® and Bulkamid® therapy?
- Can an elderly and frail population benefit from this intervention?
- Safety, efficacy and sustainability of this therapy?

Methods

55 women were included with:

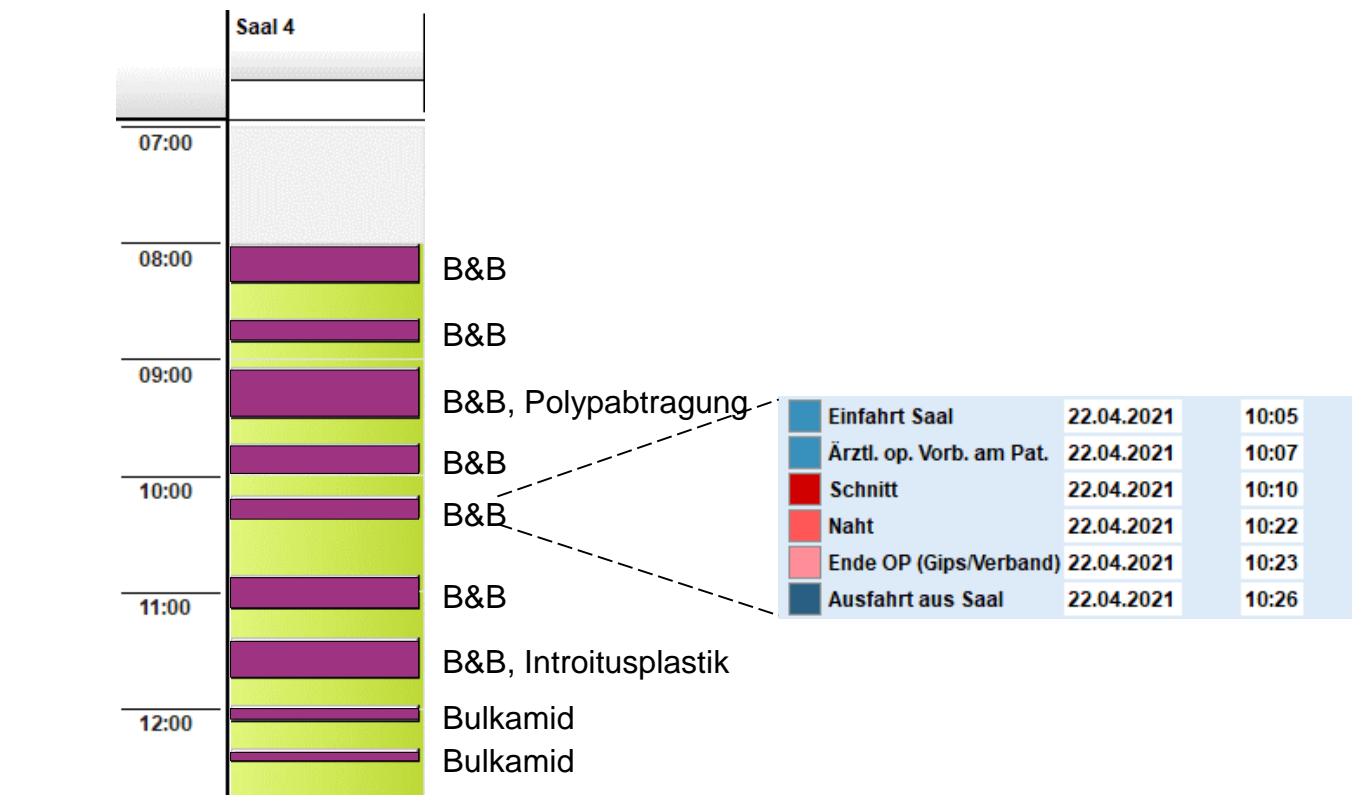
- Stress-dominant MUI
- Positive cough test
- ≥8 micturitions per day

Injection of Botox® and Bulkamid® **in one surgical procedure**

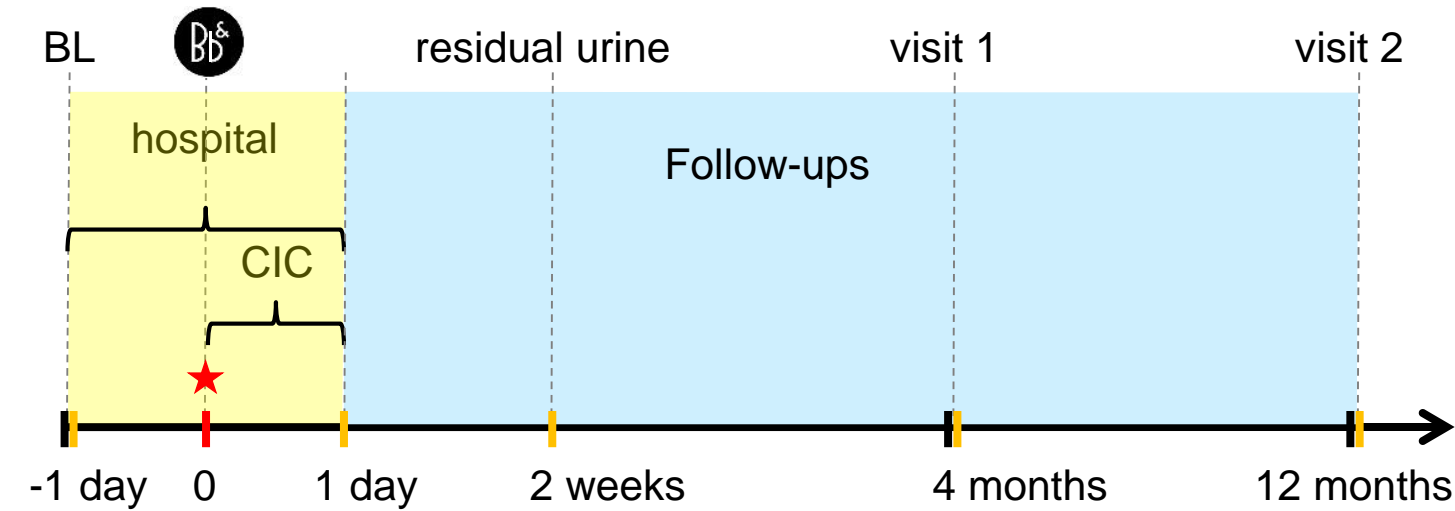


(A) Open urethra before injection; (B) 1st Bulkamid injection; (C) three further depots injected in one plane; (D) closed urethral lumen (coaptation) blue arrow: metal injection needle, yellow arrow: previous injection sites

Ten minutes to cure mixed urinary incontinence



Study design
Evaluation at baseline, and at postoperative 4 and 12 months

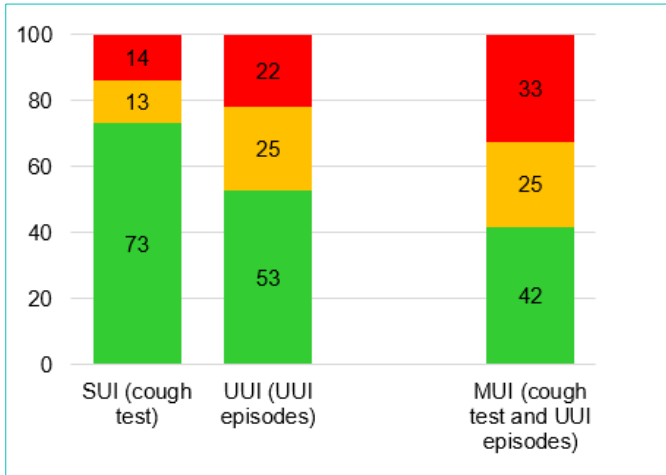


- Objective outcome: UUI episodes/day and cough test (SUI)
- Subjective outcome: impact of UUI and SUI on quality of life, ICIQ-UI SF
- Calculation of MUI outcome: combination of UUI and SUI outcomes
- Complications: post void residual urine and urinary tract infections

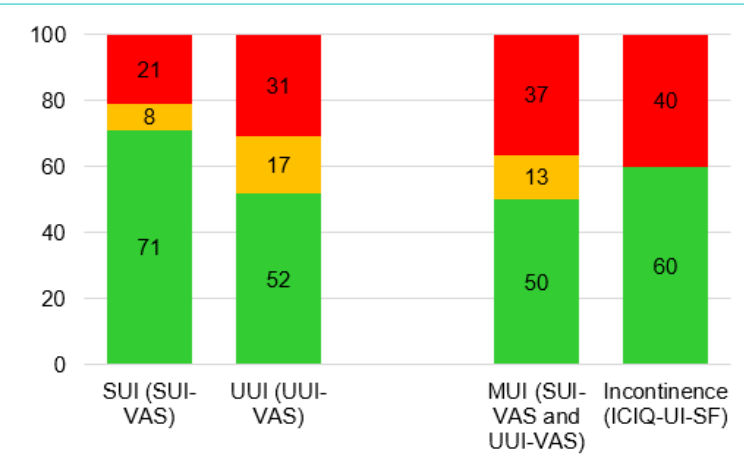
Results

- Median age: 75 years
- Median BMI: 28.5 kg/m²
- With severe comorbidities: 86%

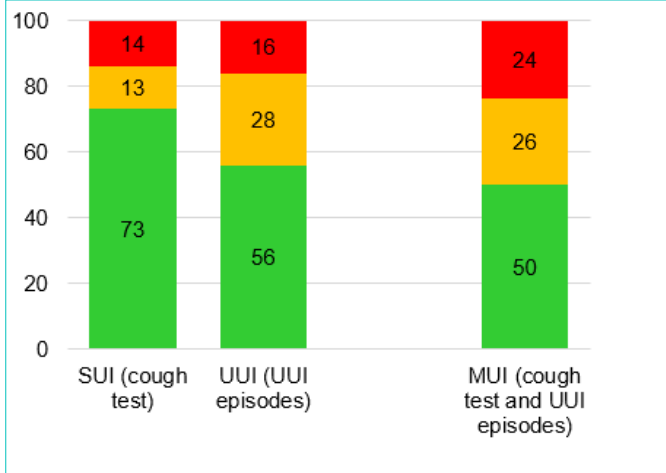
Objective outcome after 4 months



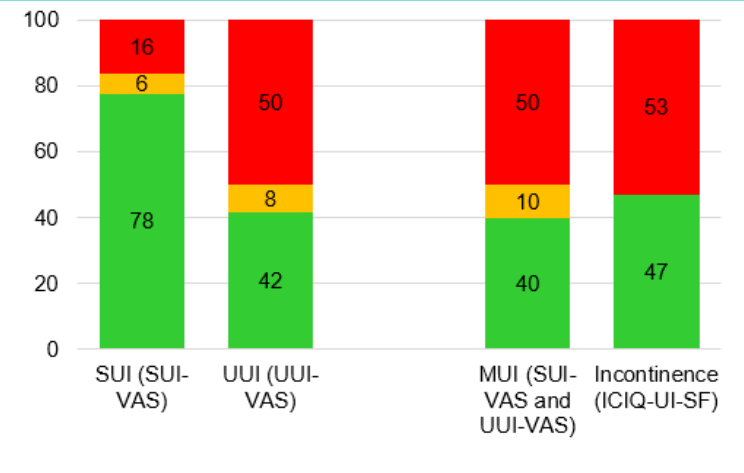
Subjective outcome after 4 months



Objective outcome after 12 months



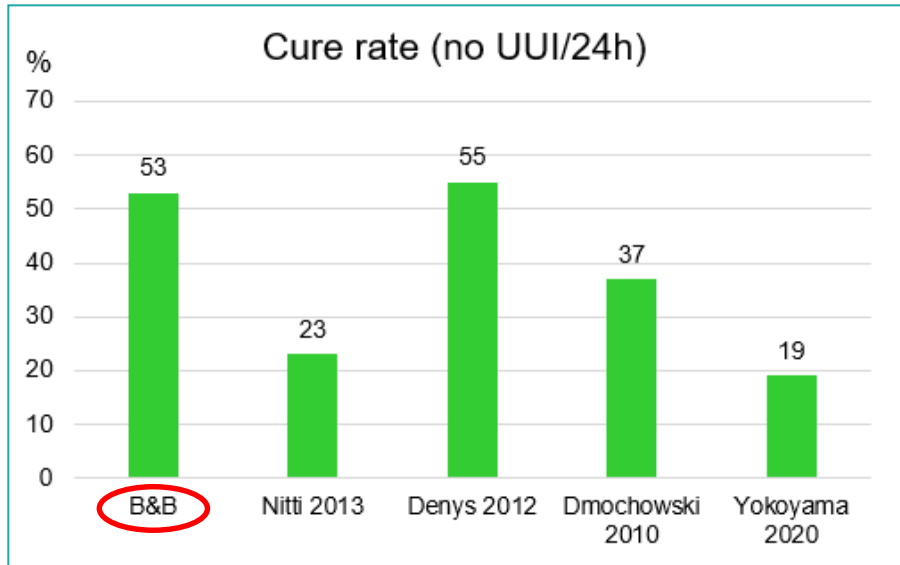
Subjective outcome after 12 months



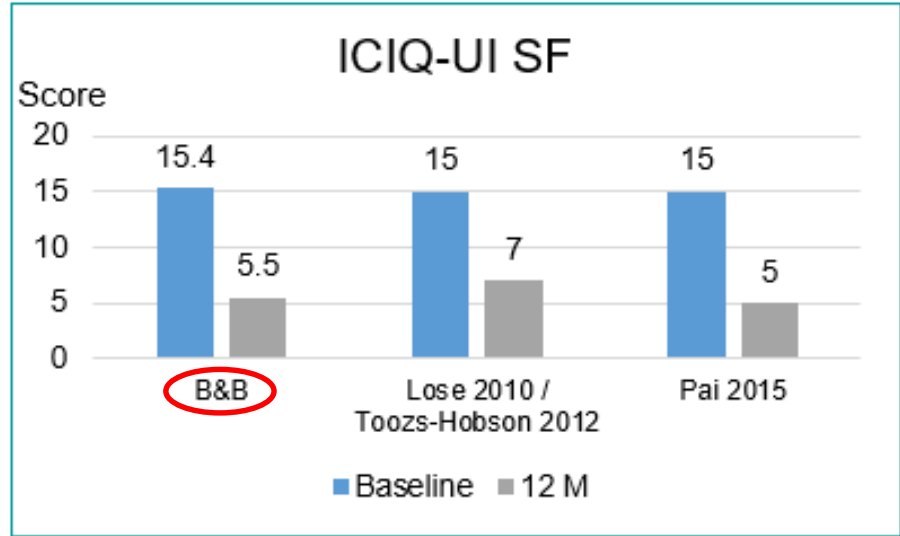
■ cured ■ improved ■ not cured

- **Well tolerated and safe therapy**
- Cure/improvement after 4 months: 67% objective, 63% subjective
- Cure/improvement after 12 months: 76% objective, 50% subjective
- **Lasting effect: 1 year or more**

Comparison with Botox® or Bulkamid® monotherapy
After Botox®, 4 months follow-up



After Bulkamid®, 1 year follow-up



→ B&B: **Similar or better than monotherapy**

Efficient → **low re-injection rates** for Botox® and Bulkamid®

Complications

- All complications were **transient**
- 22% clean intermittent catheterization immediately after the surgery
- 33% post-void residual volumes >100 ml at 14 days
- 13% symptomatic urinary tract infections within the first postoperative month

Conclusions

- Safe, only minor and transient complications
- Cure/improvement rates >60%
- Lasting effect: 1 year or more
- Also **suitable for frail, elderly and multimorbid patients**
- Also successful after previous incontinence surgery (salvage population)
- No general anesthesia necessary
- No discontinuation of anticoagulation necessary

References

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