



RETROSPECTIVE ANALYSIS OF EFFICACY AND SAFETY OF BULKAMID IN WOMEN WITH SUI

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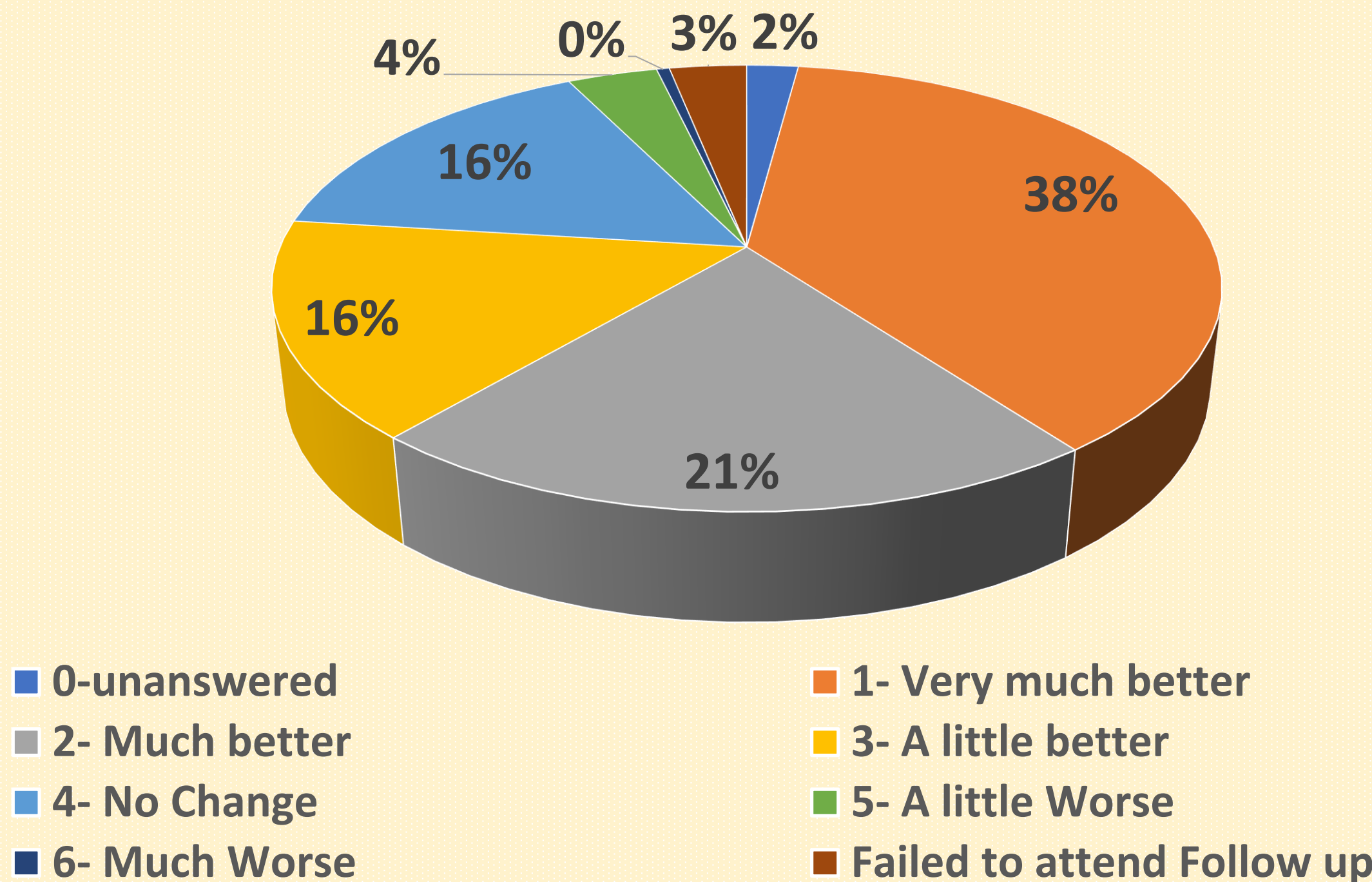


Background : Stress/ Mixed Urinary incontinence is a debilitating condition, culminating in a negative impact on the physical and the mental quality of life, with high morbidity rates and unsustainable financial burden. The pause on vaginal tapes has rejuvenated the interest in less invasive procedures like the use of Urethral Bulking Agents (UBA) in the times of the current pandemic era. The aim of this study was to measure the efficacy and safety evaluation of Bulkamid injection in women with Stress urinary incontinence (SUI) or stress predominant Mixed urinary incontinence (MUI).

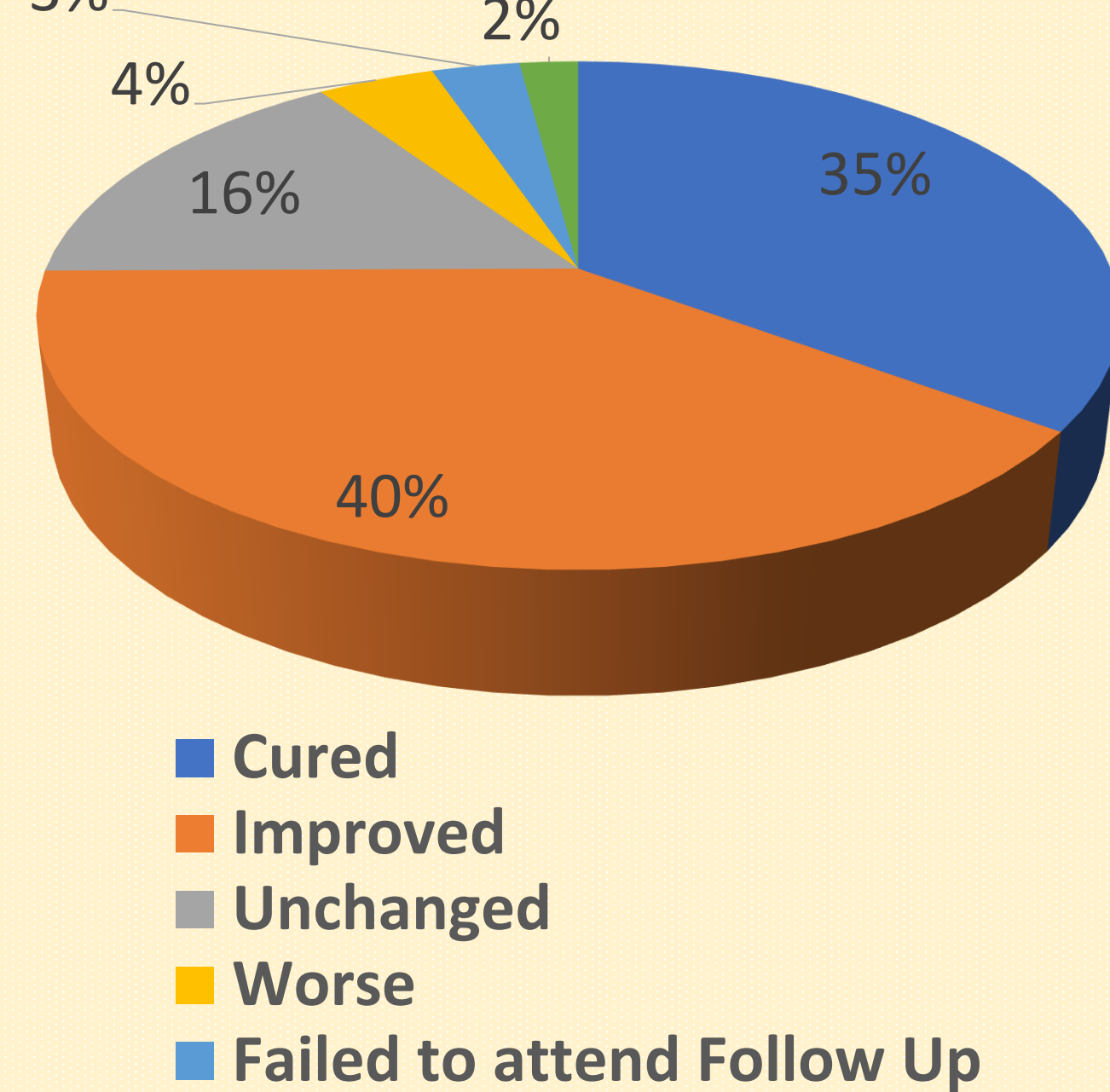
Methods :

This was a Trust-approved observational retrospective single-centre study of women attending a District General Hospital (DGHS) who underwent treatment with Bulkamid since 2013 to 2022, for the symptoms of SUI or Stress predominant MUI. The consented data has been extracted from the British Society of Urogynaecology Database for the following research purpose. The primary endpoint was a four-point scale of patient satisfaction as worse, unchanged, improved or cured. The secondary end points included re-injection rates, peri-procedural and post-procedural complications. All data are shown as means $\pm$ SD.

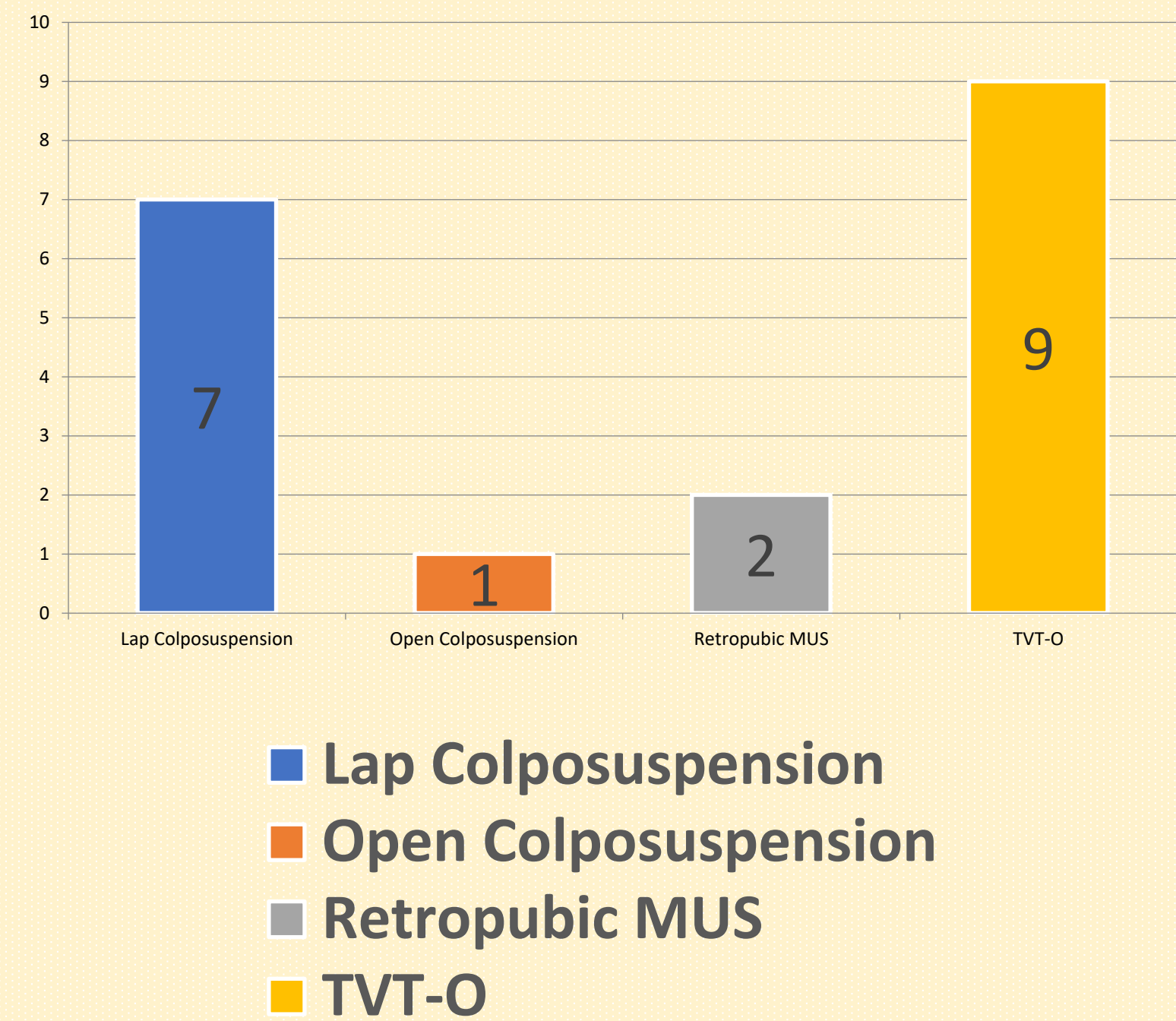
Global Impression of Improvement scale- 1st Dose



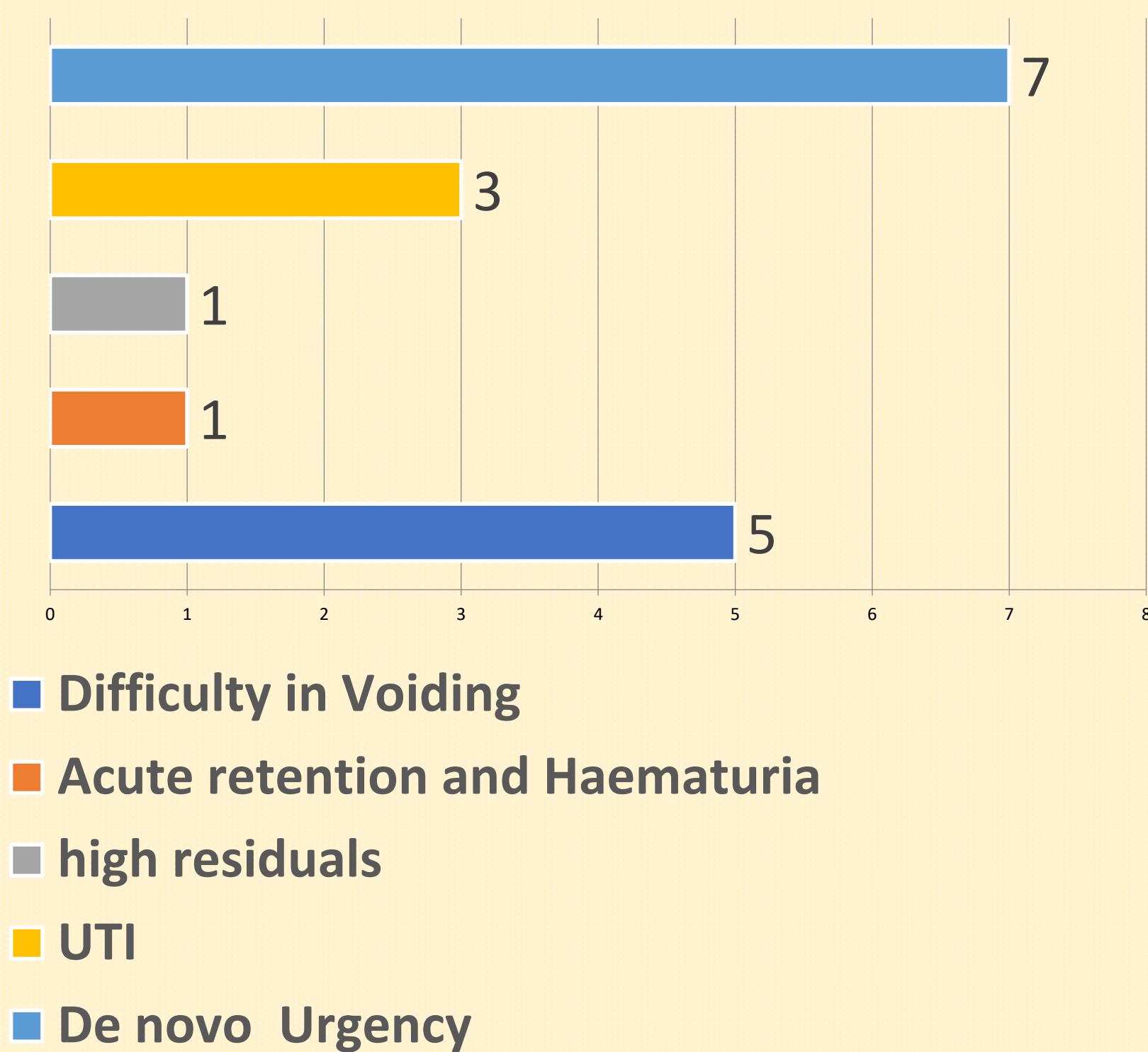
4 Point scale- 1st dose



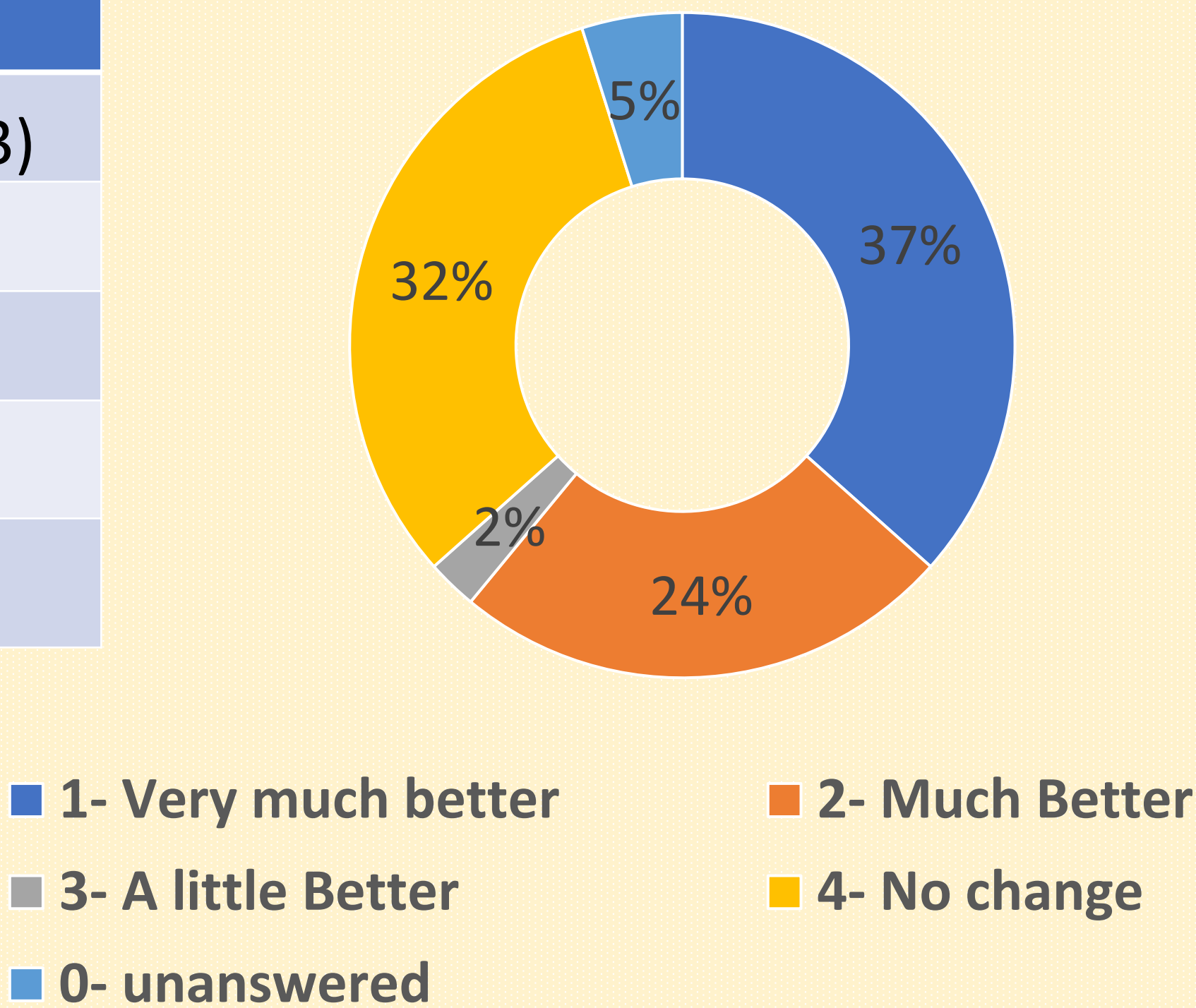
Surgeries post Bulkamid



Complications



Response to Top Up on 7 point scale



Results :

- Data of women who underwent treatment with Bulkamid **between April 2013 and May 2022** was extracted from the BSUG database. After a thorough screening, **192** of these women were included in the study.
- The ICIQ scores of moderate, severe, and very severe groups had **86%, 77% and 39%** response rates, respectively. The primary outcome, evaluating the efficacy of Bulkamid at 6 weeks follow up, revealed a significant improvement of **79.01% (p value <0.0001)**.
- On the Global Impression of Improvement scale, **72 women (37.69%)** felt very much better. On the 4-point Likert scale, 67 women (35%) felt subjectively cured of their symptoms and 76 women (39.79%) felt significant improvement in their symptoms, after treatment with Bulkamid.
- There were very few complications (**n=18, 9.42%**) noted in the study, with the development of de novo urgency being the commonest.
- Additional Top-up of Bulkamid was required only for the **42 women (21.87%)**, with a median interval of 4 months.
- On further follow-up, **21 women** felt the need for secondary surgery following their initial Bulkamid treatment.

Conclusions :

- Our study established Bulkamid as an effective treatment for SUI or MUI with minimal adversities and reasonable durability.
- Advantages of being an out-patient procedure, with decreased waiting time, minimal invasiveness, reasonable side effect profile, and cost-effectiveness
- Nevertheless, a need for further qualitative research studies on the quest for an ideal bulking agent with better efficacy and safety rates, considering the factors influencing the patient choice.

Behandlungskonzepte, A. *et al.* (2017) 'Current Treatment Concepts for Stress Urinary Incontinence', *Praxis*, 106, pp. 1–8. doi: 10.1024/1661-8157/a002843.
Brosche, T. *et al.* (2021) 'Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence', *Neurourology and Urodynamics*. John Wiley and Sons Inc, 40(1), pp. 502–508. doi: 10.1002/NAU.24589.
Chow, P.-M. *et al.* (2022) 'Impact of Female Stress Urinary Incontinence on Quality of Life, Mental Health, Work Limitation, and Healthcare Seeking in China, Taiwan, and South Korea (LUTS Asia): Results from a Cross-Sectional, Population-Based Study', *International Journal of Women's Health*. Dove Press, 14, p. 1871. doi: 10.2147/IJWH.S383651.