



EXECUTIVE SUMMARY (Adapted from the report by ERNI ZURINA ROMLI)

#### **Authors:**

Dr. Erni Zurina Romli Dr. Izzuna Mudla Mohamed Ghazali

### **External Reviewers:**

Dato' Dr. Rohan Malek b. Dato' Dr. Johan Thambu Consultant Urologist Hospital Selayang

Dr. Noor Ashani bin Md. Yusoff Consultant Urologist Hospital Kuala Lumpur

### **Disclaimer:**

This technology review (mini-HTA) is prepared to assist health care decisionmakers and health care professionals in making well-informed decisions related to the use of health technology in health care system, which draws on restricted review from analysis of best pertinent literature available at the time of development. This technology review has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Other relevant scientific findings may have been reported since the completion of this technology review. MaHTAS is not responsible for any errors, injury, loss or damage arising or relating to the use (or misuse) of any information, statement or content of this document or any of the source materials.

For further information, please contact:

Malaysian Health Technology Assessment Section (MaHTAS) Medical Development Division Ministry of Health Malaysia Level 4, Block E1, Precinct 1 Government Office Complex 62590 Putrajaya.

htamalaysia@moh.gov.my Tel: 603 8883 1229

Available at the following website: http://www.moh.gov.my

2022

# Background

Benign prostatic hyperplasia is a urological condition characterised by enlargement of the prostate gland, which results in bladder outlet obstruction. The obstruction gives rise to voiding symptoms (poor urine stream, straining to urinate, hesitancy, incomplete emptying after urinating, interrupted stream) and storage symptoms (frequency, urgency, nocturia, urge incontinence). The prevalence of BPH is more than 50% at age 60 years old and 90% in men over 85 years old. Similarly, the local prevalence of BPH was reported to be increased 8% per decade from 41.7% for men aged 50 to 59 to 65.4% for men aged 70 or more. Hence, LUTS related to BPH represents a significant socio-economic burden to the public health care system, especially in the ageing population. Management of LUTS comprises conservative approaches (reassurance and advice/ watchful waiting), medical therapies and surgical treatments. An innovative method of minimally invasive surgical treatments (MIST) of the prostate provides a potential treatment option aiming to relieve the symptoms with less perioperative risks and morbidity, as well as less sexual dysfunction. A MIST is a procedure with the potential to be performed on a day case basis, avoiding general anaesthetic boasting a potentially lower side effect profile than invasive treatments. Rezūm is a novel MIST that has gained increasing attention with an appealing outcome using a convective thermal ablation therapy, also known as water vapour thermal therapy (WVTT).

## Objective

The objective of this systematic review was to assess the effectiveness, safety, economic and organisational implications of Rezūm therapy for the treatment of LUTS in men with BPH.

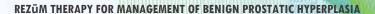
### **Methods**

A comprehensive search was conducted on the following databases without any restriction on publication language and publication status. The Ovid interface: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non- Indexed Citations and Daily 1946 to September 28, 2021; Cochrane Library 2021 Issue 8 - Cochrane Database of Systematic Reviews — Cochrane Central Register of Controlled Trials (CENTRAL). Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 30 September 2021.

## Results and conclusion:

A total of 220 titles were identified through the Ovid interface and PubMed, and five were identified from references of retrieved articles. Following duplicate removal, appraising and applying the inclusion and exclusion criteria, 15 full text articles were eligible to be included for qualitative synthesis. The selected full text articles comprised one network meta- analysis, one randomised control trial (RCT), three before and after studies, eight cohort studies and two economic evaluation studies.

Based on retrievable evidence, Rezūm therapy had shown to improve urologic symptoms and quality of life as early as six months post procedure and remained durable through five years follow-up. In comparison to medical monotherapy, Rezūm demonstrated more significant improvement in lower urinary tract symptoms and a slower





EXECUTIVE SUMMARY (Adapted from the report by ERNI ZURINA ROMLI)

rate of clinical progression among BPH patients. Through an indirect comparison between MIST procedures, Rezūm therapy displayed comparable effectiveness outcomes to UroLift, but was inferior to Aquablation at two years follow- up. The TURP procedure (gold standard) was found to cause a more significant improvement in urologic symptoms and quality of life compared to Rezūm therapy at different time intervals up to two years of follow up periods. Application of Rezūm therapy for large-sized prostates (≥ 80mls) showed comparable improvement with small-sized prostates (<80mls).

The occurrence rate of adverse events was high. Most reported adverse events were minor adverse events (CDC I-II) with transient effects. Commonly reported adverse events include dysuria (17%-22%), UTI (11%-17%), urinary retention (4%-34%) and haematuria (11%-18%). Rezūm therapy was associated with minimal sexual dysfunction, contrary to medical treatment and TURP procedure. No de novo erectile dysfunction was reported. The reported retrograde ejaculation (RE) rate was less than 12%. Rezūm therapy had a surgical retreatment rate of 4% at two years follow-up and 4.4% at five years follow-up. However, it was reported to have a higher retreatment rate than TURP (4% versus 1.5% at two years post-procedure). The medical retreatment rate with alpha-blockers following Rezūm therapy at one, two, three, four and five years were 0.7%, 2.2%, 3.7%, 5.2% and 11.1%, respectively.

Rezūm therapy was shown to be a cost-saving procedure in comparison to other MISTs and invasive BPH surgeries (HoLEP and TURP). The net cost saving was significantly associated with its lower procedural cost (inclusive of preoperative assessment and follow-up visits), reduction in bed days and operation theatre hours spared. Patient's satisfaction level with the experience and outcome of Rezūm therapy was good.

There was a high level of satisfaction with the Rezūm procedure among the patients, either with the experience or the procedure's outcome. Most patients would recommend the procedure to a friend in similar circumstances. However, when a comparison was made with the UroLift procedure, patients seemed to be more satisfied with the experience and the outcome of UroLift treatment.