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Platinum Priority – Review – Benign Prostatic Hyperplasia  
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## Emerging Minimally Invasive Treatment Options for Male Lower Urinary Tract Symptoms

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### Abstract

**Context:** Lower urinary tract symptoms (LUTS) are one of the most common and troublesome nonmalignant conditions affecting quality of life in aging men. A spectrum of established medical and surgical options is available to provide relief of bothersome LUTS. Both the adverse events of medication and the morbidity with surgical treatment modalities have to be counterbalanced against efficacy. Novel minimally invasive treatment options aim to be effective, ideally to be performed in an ambulatory setting under local anaesthesia and to offer a more favourable safety profile than existing reference techniques.

**Objective:** A comprehensive, narrative review of novel minimally invasive treatment modalities for the management of male LUTS due to benign prostatic enlargement is presented.

**Evidence acquisition:** Medline, PubMed, Cochrane database, and Embase were screened for randomised controlled trials (RCTs), clinical trials, and reviews on novel minimally invasive treatment options for male LUTS due to benign prostatic enlargement.

**Evidence synthesis:** With regard to newly devised intraprostatic injectables (botulinum neurotoxin A, NX1207, PRX302), PRX302 is currently the only substance that was superior to placebo in a phase 3 RCT providing proof of efficacy and safety. The prostatic urethral lift technique has been evaluated in several phase 3 trials showing rapid and durable relief of LUTS without compromising sexual function in carefully selected patients without a prominent median lobe. The first clinical experience of the temporary implantable nitinol device demonstrated that implantation of this novel device is a safe procedure, easy, and fast to perform. Further studies are required to evaluate efficacy, durability, and to define appropriate patient selection. New ablative approaches like the image guided robotic waterjet ablation (AquaBeam) or procedures based on convective water vapour energy (Rezūm) are in the early stages of development. Prostatic artery embolization performed by interventional radiologists at specialised centres shows a high technical success rate in the treatment of bothersome LUTS. However, a substantial clinical failure rate and a particular spectrum of complications not commonly seen after urologic interventions do occur and need to be critically evaluated.

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**Conclusions:** Initial promising clinical results on novel minimally invasive treatment options indicate efficacy comparable to standard techniques, often associated with a more favourable safety profile, in particular with preservation of sexual function. Many of these techniques are in their infancy and based on experience of new developments in the past. Further RCTs are required to evaluate efficacy, safety, and durability of novel techniques with long-term follow-up and careful evaluation of the selection criteria, which have been applied in clinical trials. The prostatic urethral lift is the only procedure with Level 1 evidence data and that can therefore be recommended for treatment of male LUTS in clinical practice for selected patients.

**Patient summary:** Minimally invasive treatment options have been developed to provide relief of lower urinary tract symptoms comparable to standard surgical techniques with a more favourable safety profile. However, long-term clinical evaluation is still needed for most of these innovations before they can be recommended to be an effective replacement for standard surgical treatment.

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## 1. Introduction

Lower urinary tract symptoms (LUTS) considerably impair quality of life in men. LUTS represent one of the most common nonmalignant conditions with significant socio-economic importance to public health systems worldwide. Male LUTS due to benign prostatic enlargement (LUTS/BPE) is the most common reason next to urinary tract infections for urologic consultation in clinical practice [1]. Annual expenditures on the management of LUTS/BPE are reported to be approximately \$6 billion dollars in the USA [2]. In a population with increasing life expectancy, the economic burden is expected to follow an upward trend in the future [3].

The treatment of bothersome LUTS/BPE comprises conservative approaches, pharmacological options, and various surgical procedures [4,5]. Medical therapy has a therapeutic ceiling in terms of efficacy and in addition to the associated adverse effects including postural hypotension, dizziness, asthenia, and compromised sexual function are the main reasons for discontinuation.

Transurethral resection of the prostate (TURP) has stood the test of time and is justly considered the surgical reference method offering durable clinical improvement. Although refinements of the technique improved the safety profile of TURP over time, considerable morbidity of 20% and long-term complications including ejaculatory dysfunction (65%), erectile dysfunction (10%), urethral strictures (7%), urinary tract infection (4%), bleeding requiring transfusion (2%), urinary incontinence (2%), and a retreatment rate of 6% have still to be acknowledged [4,5]. The use of laser enucleation of the prostate has emerged as a very effective and potentially more efficacious approach comparable in terms of efficacy to open simple prostatectomy. Laser ablation techniques have also been widely explored in recent years [6–9].

The development of novel minimally invasive procedures strives for innovative approaches equally effective to standard techniques with a more favourable safety profile. A true minimally invasive treatment should be cost-effective and easy to perform. It should ensure rapid and durable relief of symptoms and ideally be performed in an ambulatory setting under local anaesthesia. A short recovery time and smooth return to normal activity are

important determinants for quality of life after surgery [10,11]. Sexual function including erectile and ejaculatory function is compromised after treatment with current standard techniques, but should be completely preserved by a successful minimally invasive approach unless tissue is ablated. In the past, a plethora of concepts have been abandoned owing to insufficient clinical outcomes or lack of reproducibility.

Novel innovative concepts have been introduced into the interventional spectrum for the management of LUTS and early clinical results seem to be promising. The development of intraprostatic injectables, medical devices, and innovative techniques of tissue ablation have attracted renewed interest in the field. The objective of the current review is to present the early clinical experiences with novel emerging minimally invasive treatment options for male LUTS due to BPE.

## 2. Evidence acquisition

Medline, PubMed, the Cochrane database, and Embase were screened for randomised controlled trials (RCTs), clinical trials, and reviews on novel minimally invasive treatment options for male LUTS due to BPE. The authors discussed emerging techniques that were considered novel concepts. Approaches like intraprostatic ethanol injections or prostatic stents have been investigated in the past with modifications over time and therefore these were excluded in this review. As clinical data on new treatment options are scarce the authors decided to provide a narrative review by presenting briefly the basic principles of each technique and the early available clinical data. The objective of this collaborative review is to inform the reader on new advances in the field in an informative and objective way based on published data, without making formal recommendations. We focus on intraprostatic injectables including botulinum neurotoxin A (BoNT/A), NX1207, and PRX302, mechanical devices like the prostatic urethral lift (PUL) and the temporary implantable nitinol device (TIND), new techniques for prostate ablation such as the image guided robotic waterjet ablation (AquaBeam) and procedures based on convective water vapour energy (Rezūm), and finally the prostatic artery embolization (PAE).

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