GREENLIGHT XPS™ VAPORISATION OF THE PROSTATE HAS PROVEN COST-EFFECTIVE

***Gordon Muir,[1] Neil Barber,[2] James Andrew Thomas,[3] Simone Giona[1]**

1. King's College Hospital, London, UK
2. Frimley Park Hospital, London, UK
3. Princess of Wales Hospital, Bridgend, UK
**Correspondence to gordon@london-urology.co.uk*

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ABSTRACT

Benign prostatic hyperplasia (BPH) is common in men aged >60 years, affecting urinary and bladder function. Due to the progressive nature of the disease, many men initially treated with conservative therapies require surgical intervention for symptom relief. Less invasive techniques, such as transurethral microwave therapy, needle ablation, transurethral resection of the prostate (TURP), and laser treatment, have been developed with TURP being the standard of care for BPH in Europe in prostates <80 mL (volume).

For an increasingly ageing male population often receiving anticoagulants for cardiovascular comorbidities, TURP may not be suitable due to high risk of bleeding, requirement for bladder washouts, and blood transfusions. Owing to these requirements and potential complications associated with surgery, TURP is performed as inpatient surgery requiring a 2 to 4-day hospital stay.

In the GOLIATH study, the 180 W GreenLight XPS™ laser system demonstrated comparable efficacy with TURP at 6 and 12 months, while maintaining low rates of adverse events, retreatments, or postoperative interventions in low-risk patients. Recovery parameters significantly favoured GreenLight XPS over TURP, thus greatly supporting GreenLight XPS use for BPH treatment during short-term stay.

There is a requirement for healthcare services to minimise costs. Estimated on a day-case basis, GreenLight XPS was significantly more cost-effective than TURP with a 25% reduction in procedural cost, lower indirect costs, and lower financial burden based on efficacy and adverse-event outcomes. Therefore, GreenLight XPS represents an appropriate treatment option for day-case surgery and a treatment that can be tailored to individual patient needs.

Keywords: Benign prostatic hyperplasia (BPH), transurethral resection of the prostate (TURP), day-case surgery, GreenLight laser photoselective vaporisation, cost-effectiveness, anticoagulants.

INTRODUCTION

Benign prostatic hyperplasia (BPH) describes an increase in prostate size due to the proliferation of cells. The resulting bladder outflow obstruction may cause frequent or painful urination, incontinence, a poor stream with hesitancy, straining to void, and an increased risk of urinary tract infection. The incidence of BPH is 50–60% in men aged 60–70 years and increases to 80–90% by ages 70–80 years.[1] Due to the progressive nature of the disease, many men initially treated with conservative therapies require surgical intervention for symptom relief. Traditionally, treatment of BPH includes watchful waiting, pharmacological approaches, and open prostatectomy. However, with the

advent of minimally invasive techniques such as transurethral microwave therapy or needle ablation, transurethral resection of the prostate (TURP), and laser treatment, physicians have largely moved away from open prostatectomy.

TURP is the standard of care for BPH in Europe, with open prostatectomy and laser enucleation reserved for patients with larger glands (prostate >80 mL).[2] Most urologists have been trained in TURP; however, for an increasingly ageing male population, who to a large extent receive anticoagulants to treat cardiovascular comorbidities, TURP may not be suitable due to the high risk of bleeding,[3] and the need for bladder washouts and blood transfusions. Most complications are associated with a long operative time. Bipolar TURP may allow safer management of patients with cardiac comorbidities and larger prostate volumes[2] as the potentially fatal TUR syndrome is much less likely than with monopolar TURP. Both methods of TURP are performed as inpatient surgery usually requiring a hospital stay of 2–4 days.

Within any health service, there are drivers to create efficiencies to improve patient safety and minimise cost. In light of recent economic challenges, total healthcare spending across the Organisation for Economic Co-operation and Development (OECD) countries has fallen sharply since 2009.[4] Therefore, alternative procedures have been developed in an attempt to minimise invasiveness, reduce complications, and shorten recovery times.

GreenLight laser photoselective vaporisation of the prostate (PVP) has evolved over the past 16 years from the 80 W photoselective vaporisation system to the current 180 W GreenLight XPS™ laser system.[5] During PVP, a fibre that conducts a high-power 532 nm wavelength laser is inserted into the urethra that vaporises prostatic tissue.[6] The efficacy and safety of GreenLight, as well as practice and treatment recommendations, will be reviewed here.

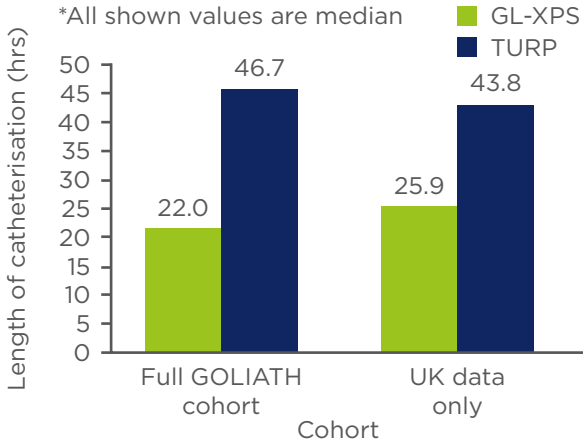
CLINICAL EVIDENCE AND SUITABILITY OF GREENLIGHT FOR DAY-CASE SURGERY

Currently, a limited number of patients are treated as day cases but evidence suggests that up to 75% of patients who require treatment for an enlarged prostate could be managed on an ambulatory care basis.[7] Randomised studies of GreenLight compared with TURP have definitively proven the effectiveness of PVP.[8-10] The GOLIATH study is a randomised, multicentre, non-inferiority study comparing 180 W GreenLight XPS and TURP.[8-10] Comparable efficacy in terms of International Prostate Symptom Score (IPSS), maximum urinary flow rate, and residual urine were demonstrated at 6 and 12 months.[8,9] In terms of safety, there were no significant differences in adverse events,[8-10] and very few adverse events or retreatments were reported in either arm.[10] Recovery parameters also significantly favoured GreenLight XPS over TURP, with shorter length of catheterisation and time to stable health (defined as the ability to void without an indwelling catheter, a post-void residual urine of <100 mL) and hospitalisation (Figure 1), factors that greatly support shorter-term stay of patients undergoing surgery for BPH with GreenLight XPS. Comparison of erectile function revealed that it was similar between the treatment arms at baseline and 12 months as measured by the International Index of Erectile Function,[9] confirming results from previous studies; although it must be noted that these studies used the 80 W system.[11] The early postoperative reintervention rate (within 30 days) was 3-times higher after TURP compared with GreenLight (9.8% versus 2.9%; p=0.025).[8] Overall, postoperative reintervention rates were not significantly different between treatment arms.[8]

The significant results observed for the GreenLight XPS Laser Therapy System in the main trial were reflected in a UK-based subanalysis of the GOLIATH study (Figure 1).[12] When comparing treatments, patients receiving surgery with the GreenLight XPS system reported reduction in hospital stay by 1 day and significant benefits in terms of stable health as well as a reduction in the duration of catheterisation.[8] Durability of treatment outcomes was demonstrated over 24 months with comparable efficacy and safety profiles or quality of life for GreenLight XPS compared with TURP.[10]

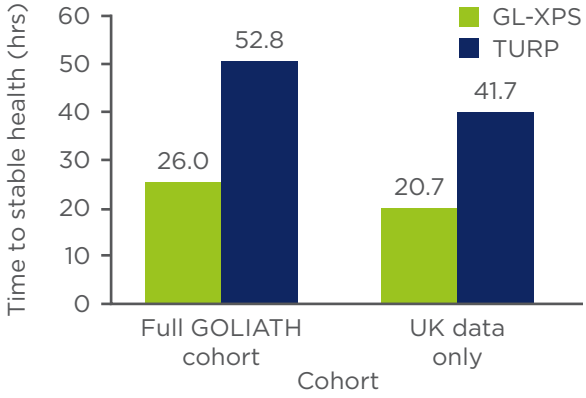
Early discharge of patients receiving treatment with the GreenLight XPS system has been demonstrated across Europe due to lower rates of complications/morbidity seen with this technique. The GOLIATH study had specific inclusion and exclusion criteria, excluding patients experiencing urinary retention or those with an enlarged prostate (>100 g), patients >80 years of age, or patients with bleeding disorders or cardiovascular comorbidities <180 days prior to consent.

A*



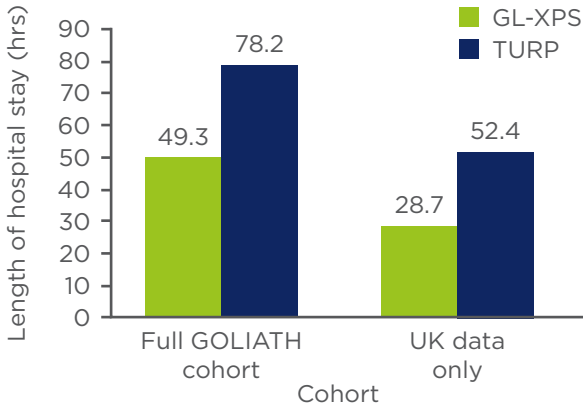
King's Practice - "fast" TWOC at 2 hours for majority of patients 70% void on day of surgery, others take small catheter home.

B*



Local reimbursement may have skewed overall data.

C*



Some centres limited in ability to discharge patients.

Figure 1: Secondary outcomes of the GOLIATH trial and the GOLIATH UK-specific sub-analysis comparing the GreenLight XPS™ system with transurethral resection of the prostate for the treatment of benign prostatic hyperplasia.

A) duration of catheterisation following surgery; B) time to stable health; and C) duration of hospitalisation.

GL XPS: GreenLight XPS™ system; TURP: transurethral resection of the prostate; TWOC: trial without catheter.

Therefore, the population of men seen in the study represent an average patient seen in clinical practice. It was not believed to be ethical to subject men with an increased risk of bleeding to randomisation between GreenLight XPS and TURP.

Further studies assessing high-risk patients previously excluded from the GOLIATH study treated with or without anticoagulants/antiaggregants, or those with large prostate volumes, demonstrated comparable outcomes for patients receiving GreenLight or TURP in terms of flow rate, IPSS, and residual urine but with very low rates of bleeding or other complications; thus supporting the case for day-case surgery with GreenLight.[13,14] Similar outcomes were observed when comparing efficacy and safety of bipolar TURP and PVP, with significantly shorter recovery time for PVP, again suggesting PVP is more suited for day-case surgery than bipolar TURP.[15]

As with any other treatment, short-stay management requires careful consideration of individual patient background and needs; however, GreenLight XPS represents a suitable treatment option for day-case surgery, high-risk, and elderly patients for whom TURP may represent a potentially unacceptably morbid procedure.

ASSESSMENT OF GREENLIGHT COST-EFFECTIVENESS

In light of recent economic challenges, there has been a global requirement for healthcare services to minimise costs. As the economic crisis continues to have an impact, both public and total healthcare spending across OECD countries have fallen sharply since 2009;[4] a trend that has been reported around the globe.[16] In many regions, this drop has been primarily driven by a collapse in the growth of government health spending; whereas in some countries, such as the UK, a level health spending or a slight increase in health spending may translate into real-time reduced funding as a result of health-service inflation.[17] Therefore, it is vital for health-service economies to minimise costs in the acute hospital setting by maximising the use of day-case surgery and short-stay surgery with enhanced recovery.

In the UK, the British Association of Day Surgery (BADS) has collaborated with commissioning bodies to incentivise the move of procedures into the day-surgery arena, which has resulted in 70–75% of elective surgery being performed as day cases.

However, this trend still needs to be established in the field of urology. Newer technologies, such as GreenLight XPS, allow hospitals to shift a large number of patients from 2–3 day inpatient procedures to an outpatient procedure thus increasing potential savings from overnight stays and relieving pressure on the small number of beds available throughout UK hospitals. Furthermore, scheduling patients as day cases supports completion of procedures, as patients are not likely to experience treatment delays as a consequence of discharge prior to surgery owing to shortage of beds.

Current regulations in some European countries do not mandate early discharge of patients after surgery which may lead to resistance against short-stay management by clinicians and to unnecessarily extended hospitalisation, as the procedure itself and patient management is very labour-intensive. However, practice set-up and economic incentives allow UK-based clinicians to discharge patients within 1 day of surgery if deemed safe.

It has recently been shown that although the mean duration of hospitalisation was statistically lower with PVP compared with TURP (1.2 versus 4.9 days, respectively; $p<0.001$), rates of short-term complications and reinterventions were comparable.[18] Sensitivity analyses estimated cost savings of approximately €400 (£305) per procedure in favour of PVP when taking into account cost of equipment, consumables, anaesthesia, medications, inpatient hospitalisation, and cost to treat complications,[19] despite the shorter operating time with TURP (mean of 10 minutes). GOLIATH results resonate with clinician experience in that most patients can be discharged shortly after GreenLight treatment without the need for catheterisation, compared with patients treated with TURP, which reduced the risk of urethral infections and hospital-related complications.

In our experience, the GreenLight XPS system has been widely used to treat men with comorbidities; despite this, up to 70% of patients recovered to an acceptable level for discharge the morning after surgery,[20] and although the direct cost of the GreenLight system is slightly higher compared with the cost of TURP, cost-effectiveness studies have demonstrated that a discharge rate of 32% establishes GreenLight as economically viable.[21] There are no advantages with GreenLight from a cost point of view when treatments are performed as inpatient procedures. However, when estimated on a day-case basis, the GreenLight system is significantly more cost-effective than TURP based on a 25% reduction in procedural cost, overall lower indirect costs to treat complications and reoperate, and lower financial burden as a result of efficacy and adverse-event outcomes. These values could be further improved upon with increasing rates of day-case surgery,[20] a practice that is incentivised in the UK healthcare service.

IMPLICATIONS ON CLINICAL PRACTICE AND GUIDELINES

Monopolar TURP has long been seen as the treatment standard for men with lower urinary tract symptoms secondary to prostatic enlargement. Newer treatment choices, which are as effective as TURP in reducing patients' symptoms, can now be offered. TURP and GreenLight form part of a treatment offering that can be tailored to a patient's individual circumstances and choices. Men should be offered the opportunity of treatment on a day-case basis with therapies such as GreenLight XPS, which can reduce risks of complications.

In the past, communication between physicians and patients has lacked adequate disclosure of the effects of treatment on everyday life such as chance of dry orgasm or sexual dysfunction. As needs differ between older and younger, or low-risk and high-risk patients, an in-depth conversation on the meaning of quality of life post-procedure is vital in choosing an adequate treatment option; particularly in patients who are concerned with certain aspects of sexual health.

GreenLight is effective in both symptomatic and elderly high-risk patients on anticoagulants or antiaggregants, and although elderly patients may not be treated as day cases, GreenLight allows treatment without withdrawal of their medication.[22-26] Furthermore, although many clinicians would limit vaporisation to prostates less than 80–100 g, experience has shown that any prostate size can safely be treated with GreenLight.[27,28]

The provision of quality day-case surgery is a key objective for surgeons treating BPH. The application of the GreenLight system in the context of a multidisciplinary team setting allows successful day-case surgery while continuously

reinforcing patient and carer confidence through reaffirmation of the procedure by the preoperative assessment team, ambulatory care nurses, the surgeon, anaesthetist, and postoperative teams.

CONCLUSIONS

GreenLight XPS provides equivalent clinical outcomes with fewer adverse events and shorter recovery time in a more cost-effective manner compared with TURP. The application of this new technology is suitable for the management of patients at high surgical risk. Maximal control of intra and postoperative bleeding and management of BPH surgery as a day-case is required.

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