

GREENLIGHT™ LASER SYSTEM FOR DAY-CASE SURGERY

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Chairperson

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Speakers

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MEETING SUMMARY

In light of recent economic challenges, reductions in healthcare spending are vital to sustain the level of care in health services across the world. The British Association of Day Surgery (BADs) recommendations highlight the need to revise post-surgery care and consider short-stay surgery as a viable option in patients undergoing treatment for benign prostatic hyperplasia (BPH).

A comparative study of the GreenLight XPS™ laser system and transurethral resection of the prostate (TURP) reported significant benefits with GreenLight™ Laser Therapy across Europe, and specifically in the UK, in terms of duration of catheterisation, time to stable health, and duration of hospitalisation. In addition, fewer post-surgery complications and morbidity highlight the suitability of GreenLight for day-case treatment in 70% of patients. When based on day-case GreenLight surgery, the direct cost of the GreenLight system is significantly more cost-effective than TURP. Although GreenLight is suitable across the entire patient spectrum, with particular benefits to high-risk patients, a pragmatic approach to assessing the best treatment management for each individual patient is required to allow for adequate care and ultimately patient quality of life.

Introduction

Doctor Ian Jackson

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 the Organisation for Economic Co-operation and Development (OECD) countries have fallen sharply since 2009,¹ a trend that has been reported around the globe.² 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 translated into reduced funding as a result of health service inflation.³ 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.

The BADs Directory⁴ has been developed as a benchmark for day-case and short-stay surgical procedures and provides a focus for clinicians and managers involved in the planning and provision of short-stay elective surgery. Now in its fourth edition,

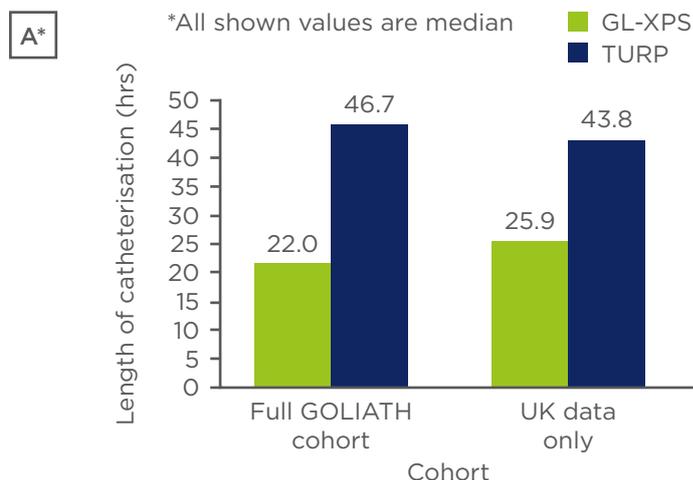
recent additions to recommendations highlight the viability of performing TURP by laser in a day-case surgery setting. Currently a limited number of patients are treated as day cases, but evidence suggests that up to 75% of patients who require this procedure could be managed on an ambulatory care basis.⁴

GreenLight Laser System for Day-Case Surgery

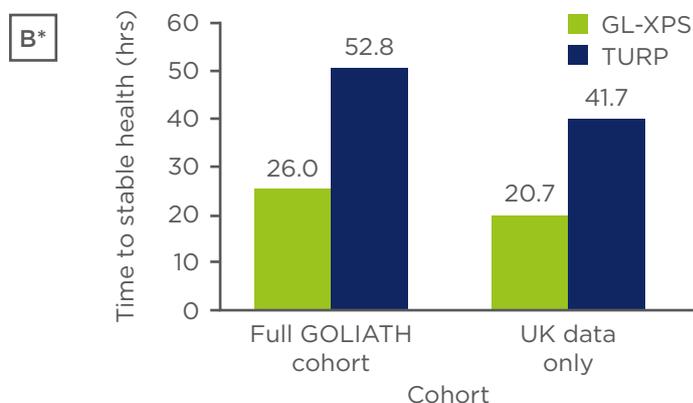
Professor Andrea Tubaro
and Mister Gordon Muir

TURP is the standard of care for BPH in Europe. However, the recent pan-European GOLIATH study has demonstrated non-inferiority of the GreenLight XPS laser system compared with TURP in terms of symptoms, flow rate, and residual urine. Furthermore, the study has demonstrated a significantly lower incidence of adverse events when using GreenLight.⁵⁻⁷ In addition, the GreenLight system demonstrated significant benefits with regard to length of catheterisation, time to stable health, and hospitalisation (Figure 1), factors that greatly support shorter-term stay of patients undergoing surgery for BPH.

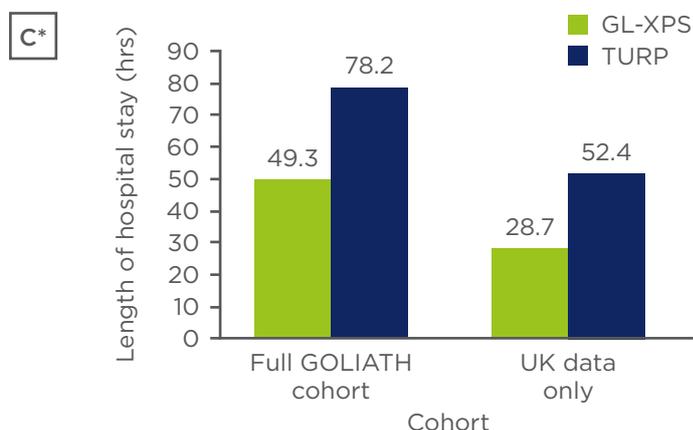
Current regulations in some European countries do not mandate early discharge of patients after surgery, which may lead to resistance against short-stay management by clinicians and to unnecessarily extended hospitalisation. However, practical influences and economic incentives allow UK-based clinicians to discharge patients within the first day of surgery if regarded safe. This behaviour and the significant results observed for the GreenLight system in the main trial were reflected in a UK-based sub-analysis of the GOLIATH study (Figure 1) (data on file, Boston Scientific). All patients were released from hospital earlier than their counterparts in the main trial. When comparing treatments, patients receiving surgery with the GreenLight system reported reduction in hospital stay by 1 day and significant benefits in terms of stable health, defined as the ability to void without an indwelling catheter, a post-void residual urine of <100 mL, as well as a reduction in the duration of catheterisation.⁵ Early discharge of patients receiving treatment with the GreenLight system has been demonstrated across Europe due to lower rates of complications/morbidity seen with his technique.



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



Local reimbursement may have skewed overall data.



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™ (GL-XPS) system with transurethral resection of the prostate (TURP) for the treatment of benign prostatic hyperplasia: (A) duration of catheterisation following surgery, (B) time to stable health, and (C) duration of hospitalisation.⁵

TWOC: trial without catheter.

Despite the fact that the GreenLight system has been used primarily in patients with severe comorbidities, in the UK up to 70% of patients had recovered to an acceptable level for discharge the morning after surgery⁸ 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.⁹ 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,⁸ a practice that is incentivised in the UK healthcare service.

It is worth noting that the GOLIATH study was based on the average patient seen in clinical practice, excluding patients experiencing urinary retention or with an enlarged prostate (>100 g), patients over 80 years of age, or patients with bleeding disorders or cardiovascular comorbidities <180 days prior to consent. Therefore, the suitability of short-stay management requires careful consideration of individual patient background and needs.

The degree of debulking of the prostate required to claim successful treatment has remained undefined and, although a larger debulking ratio can lead to a longer-lasting treatment effect, the risk of developing complications may increase proportionally. In clinical practice, GreenLight provides a tool to achieve effective and reproducible debulking of the prostate comparable to TURP even in large prostates. Additional benefits of GreenLight include low rates of bleeding and a lack of TURP syndrome, erectile dysfunction, stress urinary incontinence, and death.¹⁰ Another study assessing higher-risk patients previously excluded from the GOLIATH study treated with or without anticoagulants and antiaggregants demonstrated comparable outcomes for patients receiving GreenLight or TURP in terms of flow rate, International Prostate Symptom Score, and residual urine, thus supporting the case for day-case surgery with GreenLight.¹⁰

Consideration of patient background plays a vital role when deciding the length of patient stay

following surgery. Patients, especially elderly patients, may feel more comfortable and safer in their home environment. Home-stays potentially reduce the risk of delirium in elderly patients and the risk of contracting infections in a hospital setting.

Short-stay procedures with GreenLight have been performed in a multitude of high-risk patients, and a pragmatic approach to assessing patient comorbidities, assessing a patient's social environment, reaffirming treatment safety, and adjusting the timing of the procedure to allow monitoring if required, contributes to a prompt discharge within the first 24 hours following surgery.

Q&A Session

All questions were answered by Mr Muir.

What was the degree of irritative symptoms reported and are there studies assessing these effects?

Two clinical trials comparing GreenLight and TURP demonstrated slightly lower levels of dysuria with GreenLight, based on patients reporting pain and the use of pain medication. Dysuria may have occurred more frequently in the past when treatment methods were new and there was little standardisation of technique. Initial marginal differences in storage symptoms disappeared shortly after surgery. It is important to reassure patients undergoing bladder/urethral surgery and raise awareness that symptoms may worsen before any improvements become apparent. Reoperation rates were low for both GreenLight and TURP.

Given the constraints of transport in busy commuter regions, would you recommend a geographical and/or time cut-off in terms of how long it takes for a patient to get to your hospital?

This issue needs to be assessed on an individual basis for each patient and depends on age, the level of social support, homecare service availability, familiarity with GPs, and comorbidities. Patients living independently are generally suited for short-stay surgery. Patients usually live within a 1-hour journey time from the hospital, but rules may vary between day care units.

If you think that GreenLight is such a wonderful treatment, why it is not more widely adopted, for example, in the UK?

Although GreenLight is now widely adopted in the UK, acceptance of the method when it was first marketed may have been slow due to lack of

training and bad experiences using other lasers in the past. In addition, the National Institute for Health and Care Excellence (NICE) required clinical evidence, which carries some difficulty in urology, bearing in mind the patient numbers required for a randomised clinical trial and the exclusion of high-risk patients. Currently, GreenLight represents the safest method of laser surgery for the average BPH patient and is straightforward for clinicians to learn and teach.

Do you think NICE is going to change its opinion?

Mr Muir commented, in his opinion, that the GOLIATH study was the best randomised study assessing patients with lower urinary tract symptoms and/or BPH, but has not been included in the most recent NICE assessment.

If patients with large glands had been included in the GOLIATH study, outcomes would have demonstrated more of a separation between TURP versus GreenLight. Are any studies in this patient population planned?

The exclusion of patients with large glands (>100 g) in the GOLIATH study was mandated by

the external safety committee, as well as current guidelines which recommend treatment with TURP in prostates 30-80 mL in size.¹¹ In addition, a rigid approach towards clinical trials by NICE further complicated the comparison of GreenLight and TURP in patients on blood thinning medication, in patients with severe cardiovascular problems, and in elderly patients. While many cases of laser surgery in these patient groups have been reported, it appears that no recommendations will be made by NICE without evidence from randomised clinical trials, which may never be performed.

The limitation for the gland size in the GOLIATH study was based on the use of TURP. The trial design was based on that of Peter Gilling, which is similar to the GOLIATH trial design. However, NICE did not accept the resulting publication as it was published outside the UK.

Mr Muir agreed and highlighted that, traditionally, clinicians in the UK will treat BPH in larger prostates with TURP, whereas this is not the case in the majority of other countries, where clinicians will use TURP for debulking in prostates up to a weight of 80 g but resort to prostatectomy in larger glands.

Click below to view the following videos:

- **Q&A Session - Impact of the GreenLight™ Laser System for Day-Case Surgery Mr Gordon Muir**
- **Results of the GOLIATH Study Prof Andrea Tubaro**
- **The Importance of Day-Case Surgery Dr Ian Jackson**

REFERENCES

1. OECD. Health spending continues to stagnate, says OECD. Available at: <http://info-oecd.blogspot.co.uk/2013/06/health-spending-continues-to-stagnate.html>. Last accessed: 14 January 2016.
2. OECD. Health Statistics 2015. Available at: <http://www.oecd.org/els/health-systems/health-data.htm>. Last accessed: 14 January 2016.
3. Nuffield Trust. The funding pressures facing the NHS from 2010/11 to 2021/22: A decade of austerity? Available at: http://www.nuffieldtrust.org.uk/sites/files/nuffield/121203_a_decade_of_austerity_full_report_1.pdf. Last accessed: 14 January 2016.
4. British Association of Day Surgery. BADS Directory of Procedures 4th Edition. 2006.
5. Bachmann A et al. 180-W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European Multicentre Randomised Trial--the GOLIATH study. *Eur Urol.* 2014;65(5):931-42.
6. Thomas JA et al. A multicenter randomized noninferiority trial comparing greenlight-XPS laser vaporization of the prostate and transurethral resection of the prostate for the treatment of benign prostatic obstruction: two-yr outcomes of the GOLIATH Study. *Eur Urol.* 2016;69(1):94-102.
7. Bachmann A et al. A European multicenter randomized noninferiority trial comparing 180 W GreenLight XPS laser vaporization and transurethral resection of the prostate for the treatment of benign prostatic obstruction: 12-month results of the GOLIATH study. *J Urol.* 2015;193(2):570-8.
8. Thomas JA et al. Cost effectiveness of XPS vs TURP, a UK analysis. *Eur Urol Suppl.* 2014;13:e129.
9. Thomas JA et al. The continuing story of the cost-effectiveness of photoselective vaporization of the prostate versus transurethral resection of the prostate for the treatment of symptomatic benign prostatic obstruction. *Value Health.* 2015;18(4):376-86.
10. Bachmann A et al. 180-W XPS GreenLight laser therapy for benign prostate hyperplasia: early safety, efficacy, and perioperative outcome after 201 procedures. *Eur Urol.* 2012;61(3):600-7.
11. Gratzke C et al. EAU Guidelines on the treatment and follow-up of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. *Eur Urol.* 2013;64(1):118-40.