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PO Box 117
221 00 Lund
+46 46-222 00 00

The cost of feedback microwave thermotherapy compared with transurethral resection of the prostate for treating benign prostatic hyperplasia

G. KOBELT, A. SPÅNGBERG* and A. MATTIASSON†

Karolinska Institute, Stockholm, Sweden and European Health Economics, Spéracèdes, France; and Departments of Urology, *University Hospital Linköping, and †University Hospital Lund, Sweden

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OBJECTIVE

To compare the efficacy of a new microwave thermotherapy for treating benign prostatic hyperplasia (BPH), the ProstaLund Feedback Treatment (PLFT®, ProstaLund Operations AB, Lund, Sweden) and transurethral resection of the prostate (TURP) in a clinical trial to their effectiveness in clinical practice over 1 year, to estimate their cost over 1 year, and to evaluate the cost of re-interventions over a longer period (2–3 years).

PATIENTS AND METHODS

In a large randomized international 1-year clinical trial PLFT was as effective as TURP in improving symptoms of BPH and urinary flow. Because PLFT is an outpatient procedure it was less costly than TURP. However, the cost-effectiveness of the new procedure depends on its long-term effectiveness in clinical practice. All 146 patients in the randomized clinical trial were included in the present analysis. The outcome was based on the International Prostate Symptom Score (IPSS)

and the bother score, and costs were estimated from treatment-related adverse events and hospitalization. To validate the estimates based on the clinical trial 1-year data on effectiveness and complete resource use in clinical practice were collected in a retrospective observational study from hospital charts and patient questionnaires of 88 patients who had undergone either TURP or PLFT. To assess the number of re-interventions after TURP after the first year information was obtained from hospital and surgical procedure data in the Swedish inpatient registry. The 3-year data for a total of 52 010 patients who had an index hospitalization for TURP between 1990 and 1995 were available for the analysis. The estimate of long-term consequences of PLFT was based on complication and re-intervention data for 87 patients who had undergone PLFT between 1997 and 1999.

RESULTS

The mean 1-year costs in the clinical trial were estimated at €1763 for PLFT and €3209 for

TURP. When all treatment-related resource use in clinical practice for 88 patients was included the costs were estimated at €1924 and €3264 for PLFT and TURP, respectively. The IPSS and bother scores were not significantly different between the groups in both datasets. Using the registry data the cost of TURP including re-interventions (TURP and bladder neck incisions) was estimated at €3159 over 2 years and €3185 over 3 years; the respective costs for PLFT were €2121 and at €2151.

CONCLUSIONS

In the 1-year clinical trial PLFT was as effective but less costly than TURP, but long-term data are still lacking. However, the preliminary analysis over 3 years indicates that the average cost of the procedure remains lower than the total cost of TURP for the same period.

KEYWORDS

cost, PLFT, TURP, microwave therapy

INTRODUCTION

The conventional management of patients with BPH includes watchful waiting and drug therapy for those with mild to moderate symptoms and mildly to moderately impaired voiding, and surgery in more severe cases. There are several different surgical techniques and the 'reference standard' has been TURP. In the past decade several new surgical techniques have been introduced, e.g. transurethral microwave thermotherapy (TUMT), various laser operations, radiofrequency needle ablation and transurethral vaporization of the prostate [1–4]. Compared with TURP these techniques

are less invasive and require shorter hospitalization, or can be delivered as outpatient procedures, leading to lower resource use and hence lower costs of the primary procedure. However, TURP has remained the intervention of choice for patients with moderate to severe symptoms, as there are only limited data on the long-term effectiveness of the newer techniques.

Because of the resource constraints, several reviews comparing the costs of the different treatments have been published [5–10], but economic evaluations have been limited mostly to studies for drug treatment [11–15]. Very few studies have focused on the

economics of TUMT as an alternative to TURP [16,17].

Recently, a new microwave thermotherapy technique, ProstaLund Feedback Treatment (PLFT®, ProstaLund Operations AB, Lund, Sweden) was shown in a controlled 1-year trial to be as effective as TURP [18]. There was no significant difference in the number of successful treatments, defined by the IPSS and its bother score [19] and peak urinary flow rate (Q_{max}). PLFT is different from earlier techniques as it allows monitoring of the intraprostatic temperature during treatment. However, it is too early to know whether the long-term effectiveness of PLFT will be better

than earlier microwave techniques, thus avoiding frequent re-interventions.

The objective of the current analysis was to compare the efficacy of PLFT and TURP as shown in the clinical trial with their effectiveness in clinical practice over a year, and to estimate their 1-year costs and those of re-interventions for up to 3 years. As there was no statistically significant difference in the 1-year effectiveness between the treatments in the trial, cost-effectiveness was not analysed.

PATIENTS AND METHODS

Several different datasets were used in the current analysis, covering the clinical trial and observational data for the short-term (1 year), and follow-up studies and patient registries for the long-term analysis. PLFT has been used in Sweden since 1998 and 3-year follow-up data were available from two centres. The long-term analysis was therefore limited to 3 years.

At the time of the study hospitalization data for the years up to 1998 were available in the Swedish Inpatient Registry from the Epidemiological Center of the National Board of Health and Welfare. A complete dataset including all patients with a first hospitalization for a main diagnosis of BPH (ICD9600X, ICD10 N409) in combination with the surgical procedure TURP (operation code 6620 or KED22) for the years 1990–98 was obtained. The threshold of 1990 was chosen to ensure that the average length of stay (LOS) was representative of current practice. To examine re-admissions during the 3 years after the primary intervention, only patients who underwent the primary procedure in the years 1990–95 were included in the study. A total of 52 010 initial discharges were thus available for the analysis. The cost of re-admissions was based on the percentage of second or third major procedures (TURP, bladder neck incision) and the average LOS for the remainder of the admissions.

CLINICAL TRIAL DATA

In this multicentre study in Scandinavia and the USA, 146 patients were randomized 2 : 1 to PLFT (100) and TURP (46) [18], and followed at 3, 6 and 12 months. A response was defined as an IPSS of ≤ 7 or a decrease of $\leq 50\%$ from baseline and/or a Q_{max} of ≥ 15 mL/s or an increase of $\geq 50\%$ from

baseline. There was no difference in responders in the two groups after a year, with 82% of patients in the PLFT and 86% in the TURP arm fulfilling the response criteria, and only cost-minimization was therefore analysed. Figure 1 shows the response in the clinical trial over 1 year.

Within the trial no resource use data were collected but information on moderate/severe adverse events was used to estimate the cost of follow-up. Only events that were probably or possibly related to the primary intervention and had led to a hospital admission were included. In the absence of detailed information on the hospital stays, the cost of re-admissions was estimated using the mean LOS for re-admissions after TURP found in the Swedish inpatient registry. Outpatient visits were excluded as they were protocol-driven and hence not different in the two groups.

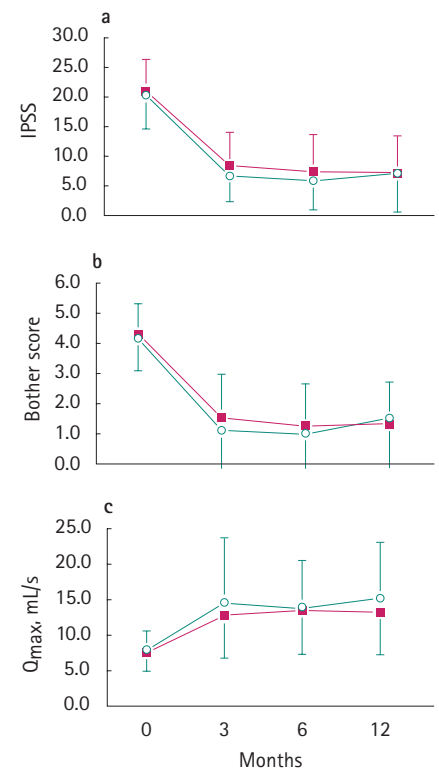
OBSERVATIONAL STUDY

The observational study had two main objectives. First, as no detailed resource use data were collected during the clinical trial, the 1-year costs for the two procedures were to be established in a retrospective study. Second, the outcome in the clinical trial was to be compared to effectiveness in clinical practice.

The study combined retrospective data collection from medical charts for the first 3 months after the primary procedure with a patient questionnaire collecting information about complications and other resource use at least 1 year after the intervention. Three specialized urological centres participated in the study: University Hospital Lund, University Hospital Linköping and the Regional Hospital in Kalmar. A fourth centre was excluded from the analysis (University Hospital Uppsala), because there were too few TURPs during the enrolment period.

Each centre included 30 consecutive patients who had undergone either TURP or PLFT between July 2000 and June 2001. Patients were identified from the hospital database, and detailed resource consumption for 1 month before the intervention and 3 months afterward was collected by medical personnel. Data collection stopped with a routine follow-up visit within a maximum of 4 months after the primary procedure. For patients with complications during the first 3 months, data abstraction continued until

FIG. 1. The outcome in the clinical trial for the IPSS (a), bother score (b) and Q_{max} (c) for TURP (green open circles) and PLFT (red squares). Adapted from [18].



the problem had resolved and patients had a routine visit. Resource consumption included all surgical interventions, initial hospitalization and re-admissions, pre-surgical visits and diagnostic tests, and follow-up and medication after surgery. In addition, when available in the medical charts, the pre-surgical IPSS with its bother score was noted.

Subsequently, between May and July 2002, patients were asked by mail to complete a questionnaire about complications and hospital admissions in the period since the initial operation, and medical visits and medication related to prostate symptoms during the preceding 3 months. In addition, they were asked about their current symptoms and bother (IPSS) and their overall quality of life (QoL) using the EQ-5D [20,21]; this is a well-validated generic instrument with five questions addressing five domains of QoL from which an overall QoL weight (utility) on a scale between 0 (death) and 1 (full health) can be estimated. The instrument also contains a visual analogue scale where respondents indicate how they rate their

TABLE 1 The mean 1-year costs per patient in the different datasets; costs in the inpatient registry and the clinical trial represent costs of the primary procedure and re-admissions, and second procedures during the first year after intervention. Costs in the observational study include all related follow-up costs. The mean cost per patient over 2 and 3 years after intervention includes costs of re-interventions and re-admissions for complications. In the Uppsala sample, 26 patients had a follow-up of ≥ 2 years and 48 of ≥ 3 years; in the Lund sample the respective numbers were 28 and 39. The inpatient registry includes 52 010 patients with an admission for TURP

Dataset	Costs, Euro	
	TURP	PLFT
1 year		
Inpatient registry	3100	
Clinical trial	3200	1760
Observational study	3260	1920
2 years		
Uppsala		2020
Lund		2120
Registry	3160	
3 years		
Uppsala		2140
Lund		2150
Registry	3190	

current health on a scale between 0 (worst possible) and 100 (best possible). The EQ-5D has been used in many studies and standardized population values developed, allowing the comparison of results across different diseases or with the general population.

The information on complications and hospitalization was matched with the data from the medical charts, to avoid double-counting. All outpatient visits to a department of urology were included. Visits to GPs were included if the patient had no comorbidity and had had a complication after the intervention. Consultations related to other disease were excluded. Similarly, only urological drugs were included in the analysis.

For the long-term follow-up after PLFT the charts were specially reviewed at the Lund University Hospital. All patients who had undergone PLFT between April 1999 (when the procedure was introduced in Lund) and December 2000 were included in the study,

and all complications and re-interventions up to December 2002 collected from the medical charts. A similar dataset was available from the Uppsala University Hospital where PLFT has been used since February 1997. All patients treated up to December 2000 were included in the dataset and information on re-interventions was made available.

COSTS

Unit costs for inpatient days, outpatient visits and diagnostic procedures were calculated as the average of three official hospital price lists (Lund and Malmö University Hospitals, regional prices 2002, <http://www.srvn.org/pris02/lund/pdf>; County Council, Kostnad per intagen patient, varddag, läkarbesök. Stockholm Landstingsförbundet, 1999; Linköping, University Hospital price list 2002, <http://www.e.lio.se/Svn/Prislista/avschnitt1/index/pdf>). Drug costs were taken from the Swedish drug tariff (FASS, Lakemedel i Sverige, Pharmaceutical Lexicon, Stockholm Lakemedelsinformation AB, 2001, <http://www.fas.nu/forms/ffassw/htm>) while diagnosis-related group (DRG) values were used for the different inpatient procedures. All costs are for the year 2002, and costs for the second and third year were discounted with 3%.

The cost of the major procedures was Swedish krona (SEK) 27122 (€2980, €1 = SEK 9.1) for TURP (based on the DRG for uncomplicated procedures), SEK 15620 (€1716) for PLFT and SEK 18913 (€2078) for uncomplicated bladder neck incision. For re-admissions, the cost for inpatient days in the respective departments was used. For the registry and long-term analyses the cost of inpatient days was calculated as a weighted average of a day in the urological and the general surgical ward, resulting in SEK 3830 (€421) per day.

RESULTS

Table 1 shows the 1-year cost estimates for the different datasets. In the inpatient registry, 5.7% of the patients were re-admitted during the 3 years after the index admission for TURP. Most re-admissions occurred during the first year after surgery; 2201 patients were re-hospitalized during the first year, with a total of 2559 re-admissions to the general surgical ward (58.3%) and to urological surgery (33.6%). In 51.7% of the

cases a second TURP was performed and in 2.3% a bladder neck incision. The procedures were minor, e.g. transurethral excision, lithotripsy or elimination of blood clots, in 13.2% of the cases, or diagnostic procedures (predominantly cystoscopy) in 21.5%, and 11.3% had undefined procedures. The mean (median, SD) LOS for the primary procedure was 5.0 (4.0, 3.6) days, and for re-admissions 4.9 (3.0, 3.6) days. Total costs for the first year after TURP were estimated at SEK 28264 (€3106) per patient.

In the clinical trial, seven patients in the TURP arm (15%) and four in the PLFT arm were hospitalized for moderate/severe adverse events (haematuria, haemorrhage and sepsis) related to the primary intervention. Including these events, total 1-year costs were estimated at SEK 29204 (€3209) per patient in the group undergoing TURP and SEK 16041 (€1763) per patient having had PLFT.

The chart review in the observational study included 48 patients in the TURP and 46 in the PLFT group, and the questionnaire was returned by 43 and 45 patients, respectively. Missing answers in the questionnaires were minimal and all patients could be included in the analysis. The mean (SD) age at the intervention was 69.1 (9.5) and 72.8 (7.1) years, respectively. The mean (SD) costs related to the primary procedures were SEK 28757 (5800) or €3160 (637) for TURP and SEK 15960 (2303) or €1754 (253) for PLFT. In both groups, 24 patients had one complication at the first visit after surgery, predominantly with urge, burning urination or difficulties of urination. In the PLFT group five patients had infections and five presented with urinary retention, compared with three and two, respectively, in the TURP group. Bleeding was more frequent after TURP than after PLFT (three and one, respectively). Symptoms of urge and burning lasted longer after PLFT, and more patients presented with infections at the second or third follow-up visit. Including the costs of complications and follow-up costs gives a total cost per patient of SEK 29700 (6993) or €3264 (768) in the TURP group and SEK 17505 (2901) or €1924 (319) in the PLFT group.

Table 1 also shows the 3-year costs for the special follow-up studies after PLFT and those for TURP estimated from the inpatient registry. In the second year after TURP 568 patients were re-admitted, with a total of 617 re-admissions. The mean (median, SD) LOS was

4.7 (4.0, 3.15) days and during 53.6% of the admissions patients underwent a second TURP. There were 555 re-admissions in the third year for 500 patients, 54.2% of them for a second TURP. The total costs per patient for 2 and 3 years are estimated at SEK 28748 (€3159) and SEK 28985 (€3185), respectively.

Thirty-nine patients were included in the special follow-up study on PLFT in Lund. The mean follow-up in this group was 2.7 years, with a total of 104 patient-years. Of these patients, 28 had a follow-up of ≥ 3 years. Re-interventions were necessary in eight patients (20%), seven of them within the first 2 years. Four patients had a second PLFT while three had a TURP and one a bladder neck incision. The total mean costs per patient for the first 2 years are estimated at SEK 19299 (€2121), and for 3 years at SEK 19579 (€2151).

The follow-up study in Uppsala included 48 patients with a mean follow-up of 3.5 years (167 patient-years), and 26 had a follow-up of ≥ 3 years; 5% needed a second PLFT and 7.7% underwent a TURP. Except for one TURP, all re-interventions were during the first year after the primary procedure. In this sample, total mean costs per patient for the first 2 years are estimated at SEK 18378 (€2020), and for 3 years at SEK 19453 (€2138).

EFFECTIVENESS AND QOL

Table 2 shows IPSS and bother scores before surgery and after ≥ 1 year in the observational study. The IPSS and bother scores after surgery were available for all patients who returned the questionnaires; the mean scores were not significantly different and comparable with those found in the clinical trial. The mean (range) time from the primary intervention was 16.3 (12–20) months. However, the IPSS before surgery was only available for 22 patients who had TURP and 33 who had PLFT. In this small sample the mean change from baseline was not significantly different in the two groups (12.2 and 10.1 for TURP and PLFT, respectively). The EQ-5D was completed by 35 and 36 patients in the TURP and PLFT group, respectively. Patients in the PLFT group had significantly higher utility scores (Table 2).

DISCUSSION

Over the past decade there have been important changes in the therapeutic

TABLE 2 Outcome and IPSS QoL, and the utility and other QoL measures, 12–20 months after the intervention in the observational study and the clinical trial

Variable	TURP			PLFT		
	No	Age	Mean (SD)	No	Age	Mean (SD)
Observational study (all answers)						
IPSS	43	70.6	6.4 (6.4)	45	74.3	7.7 (7.4)
Bother score			1.4 (1.3)			1.4 (1.1)
Patients with pre-surgical and 1-year scores						
Initial IPSS	22	68.8	21.7 (6.4)	33	73.5	19.6 (6.8)
IPSS			9.5 (6.4)			9.5 (7.3)
Initial bother score			3.9 (1.2)			3.7 (1.2)
Bother score			1.4 (1.3)			1.4 (1.1)
Clinical trial results						
Baseline IPSS			20.4 (5.9)			21.0 (5.4)
1-year IPSS			7.1 (6.6)			7.2 (6.2)
Baseline bother score			4.2 (1.1)			4.3 (1.0)
1 year bother score			1.5 (1.7)			1.4 (1.3)
Utility and QoL						
Patients with complete EQ-5D						
Utility*	35	71.1	0.79 (0.26)	36	73.2	0.92 (0.12) [†]
VAS			71.1 (22.3)			79.4 (13.7)
IPSS			7.7 (6.5)			8.8 (7.8)

*Scores of <zero (i.e. worse than death) were set to zero; [†]P < 0.01, with all other comparisons not significant.

management of BPH. The increase in the number of treatment options has considerably altered clinical practice. The availability of pharmacological treatment and less invasive surgical interventions has broadened the indications for treatment to include patients with less severe symptoms. Although invasive surgery is still considered the most effective treatment, it has become the second or third choice or been limited to patients with severe symptoms. In Sweden the annual number of interventions has decreased steadily from $\approx 15\ 000$ in our analysis for the early 1990s to 5000 in 1999 and 4400 in 2001 [22]. This indicates a better targeting of treatment for different patient groups, but might also be a change to less costly interventions as a consequence of the scarcity of resources. Noninvasive surgical techniques like TUMT can be given as outpatient procedures and will thus be less costly. TUMT is as effective in the short term as TURP [23] but its long-term effectiveness was originally questioned because of the high re-treatment rates [24–28]. However, as longer term data have become available [29–31], microwave treatment has been regarded as an effective treatment, as stated in [32]: 'microwave treatment has

undoubtedly turned the period of adolescence, without the descending slope that other, initially promising modalities, have shown!'

PLFT is also as effective at 1 year as TURP and the 3-year follow-up in the clinical study showed no statistical difference between PLFT and TURP [33]. The first long-term follow-up data available in clinical practice indicate a re-treatment rate of 12–20% over 3 years, compared with 5.7% for TURP. However, the vast majority of the re-treatments in the two samples used in this analysis were during the first year and might therefore partly be because PLFT is a new procedure. Indeed, re-interventions were more frequent in patients who had undergone the procedure during the first 6 months after its introduction.

Thus, a full assessment of the long-term effectiveness of PLFT will only be possible when larger samples become available. However, interestingly the costs were similar in the different datasets, both in the short- and in the longer term analyses in both the TURP and PLFT groups. In part this is because DRG costs were used for the main procedures,

eliminating differences within the groups. However, in view of the small samples in the clinical and observational studies, and that resource use in general is highly skewed, this approach is more appropriate. Nevertheless, it might be surprising that costs over a year in the observational study, where all follow-up costs were included, were no different from those estimated in the clinical and registry data, where only major complications were available. One reason may be that there is indeed very little follow-up necessary after either of these procedures, when no complications occur.

The results of this analysis indicate that PLFT remains considerably less costly than TURP even when complications and re-treatments are included. This is contrary to the results of a recent study in Denmark [17] that found the costs of TURP and TUMT to be very similar. However, the two studies cannot be compared, as different costing methods were used. Our analysis is based on DRG costs for the main procedures and daily costs for hospitalization for complications, while the Danish study used itemized costing. From the data available it appears that different costing criteria have been applied to TURP and TUMT (no capital cost for the use of the operating theatre for TURP, but amortization costs for TUMT equipment) and that the hourly cost of physician time has been underestimated. Lastly, the cost of TUMT depends on the cost of the disposable material, and thus different studies in different settings and countries may find different costs.

The present study has some limitations that need to be addressed. First, the analysis includes five different datasets and it is difficult to assert that patients in the different samples are fully comparable. However, the objective of the observational study was to collect resource consumption for a population similar to the clinical trial population, and there was no major difference in the age distribution and comorbidity of the two samples. The mean age in the observational study was 70 years and 28% of patients reported some comorbidity (diabetes, cardiac diseases, allergies, bronchitis), compared to 68 years and 29% (moderate/severe) in the clinical study. Second, except for the observational study, only major complications and re-interventions were included in the analysis. While this allowed comparison of the data with the national inpatient registry, costs may be underestimated. However, from the

observational data it appears that complications and re-interventions represent the vast majority of postsurgical costs, but it cannot be excluded that long-term costs may be higher than indicated in this analysis. Third, the long-term data on PLFT represent the first patients undergoing the procedure and re-interventions are overestimated. Lastly, our analysis is based on small samples (except for the registry data) and the results should therefore be interpreted with caution.

The change in IPSS was not significantly different between the two groups in the observational study, but slightly lower in both groups than in the clinical study. This is often the case when well-controlled clinical trial efficacy is compared to effectiveness in clinical practice. Also, again the observational sample is very small, as pre-surgical scores were not available in the charts for some patients. If all responses are included, increasing the sample size, the mean scores after surgery were lower in both groups (Table 2).

From the observational study it appears that PLFT is used in slightly older patients, probably because the procedure is less invasive. Despite this the mean utility score in this group was significantly higher than in the TURP group. It was also higher than the standardized general population score, which in the age group 70–75 years is 0.77. In the absence of utility values at baseline, it cannot be excluded that patients in this group were overall healthier, as the procedure was new. However, it might also be possible that an invasive procedure such as TURP takes a larger toll on patients' overall well-being and that patients take longer to recover. However, again the limited size of the sample does not allow firm conclusions.

The similarity of both the outcomes and the costs in the different datasets, in particular in the clinical trial and the observational study, indicate that PLFT in clinical practice can be expected to have a similar outcome as in the clinical trial, and preliminary long-term data indicate that costs will remain lower than for TURP, despite more re-interventions.

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CONFLICT OF INTEREST

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Correspondence: G. Kobelt, President, European Health Economics, 492 Chemin des Laurens, F-06530 Spéracèdes, France. e-mail: kobelt.gisela@he-europe.com

Abbreviations: TUMT, transurethral microwave thermotherapy; PLFT, ProstaLund Feedback Treatment; Q_{max} , peak urinary flow rate; LOS, length of stay; QoL, quality of life; DRG, diagnosis-related group; SEK, Swedish krona.