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Original Paper

A Cost Analysis of Nd:YAG Laser Ablation Versus Endoscopic Intubation for the Palliation of Malignant Dysphagia

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Although endoscopic intubation is the mainstay of non-surgical palliation of malignant dysphagia, Nd:YAG laser ablation has been shown to provide good palliation with few complications. The study reported here incorporates data from published and unpublished sources into a cost model which estimates the lifetime cost of palliation with the two therapies. It is estimated that, depending on the assumptions used, laser palliation costs between £153 and £710 more per patient than endoscopic intubation. Sensitivity analysis is used to assess whether variation in clinical practice and in the unit costs of resources will change the conclusions of the study. This indicates that, under most alternative sets of assumptions, intubation retains its cost advantage. However, factors that might reduce, or even eliminate, this cost differential include undertaking more laser procedures as day-cases, using more expensive expanding metal stents for intubation and reducing the need for follow-up laser procedures with palliative radiotherapy.

Key words: costs, palliation, laser therapy, endoscopy
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INTRODUCTION

THE ANNUAL incidence of cancer of the oesophagus or cardia has been estimated at 7.33 per 100 000 in one English region [1]. Although not one of the most common cancers, the number of deaths from oesophageal cancer in the U.K. has increased markedly in recent decades [2]. Patients frequently present with the disease relatively late in its natural history, when the disease is two-thirds or more circumferential [3]. This, and the advent of more sophisticated forms of diagnostic technology which has increased the recognition of extensive disease, have resulted in palliative treatment being considered the only course of action for between 60 and 80% of patients [4, 5]. On average, only 18% of patients are alive 1 year after diagnosis [4]. Obstruction from the tumour is the most common problem with cancer of the oesophagus and cardia [6]. The aim of palliation, therefore, is to maintain a reasonable quality of life until patients die of generalised disease.

Surgery may provide the best relief of dysphagia, but it has been argued that the associated levels of morbidity and mortality are too high for a palliative therapy [7]. This, and the frequency of tumour spread, associated medical problems and frailty due to age, have resulted in the widespread use of non-surgical palliative therapies [8]. In the U.K., the insertion of a prosthetic oesophageal tube has been the most common form of palliative therapy [5]. The high levels of operative mortality associated with surgical placement of a tube [9] has resulted in placement now largely being undertaken endoscopically [10].

In recent years, the Nd:YAG laser has provided an additional dimension to non-surgical palliative therapy for dysphagia. Nd:YAG laser ablation has been shown, in a number of clinical series, to provide high initial success rates with low rates of complication [11–13]. Some studies have attempted to compare patients receiving primary palliative therapy with the Nd:YAG laser with those for whom endoscopic intubation was the only available option. These comparator groups have been historical [14, 15], contemporaneous but non-randomised [16, 17] and randomised [18–20]. In general, these studies are likely to have recruited too few patients to identify any important clinical differences at conventional levels of statistical significance—total sample sizes have ranged from 20 to 144 patients. One study did show significantly better swallowing after laser treatment, but laser patients did require significantly more procedures [17].

As yet, there has been no attempt to assess rigorously the

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relative cost of the two therapies. This must be seen as an important gap in the literature as, increasingly, purchasers of health care have to make decisions about resource allocation using information on relative cost-effectiveness as well as health outcomes. Using data from a number of published and unpublished sources, this paper estimates the relative lifetime cost of Nd:YAG laser and endoscopic intubation as alternative forms of primary palliation for malignant dysphagia.

MATERIALS AND METHODS

The objective of the analysis was to estimate the additional cost (or saving) resulting from the use of the Nd:YAG laser as a form of primary palliation for malignant dysphagia, as compared to endoscopic intubation. The analysis considered the cost of the major health service resources used by patients undergoing the two forms of palliation over their lifetimes. It was assumed that patients survive, on average, for the same length of time whatever their primary palliative therapy [17]. The general approach of the analysis was to define a cost model which describes key clinical pathways along which patients undergoing palliation may pass. The probabilities in the model were taken from published studies. The health service resource use associated with the pathways was identified from two comparative studies involving University College London Hospitals (UCLH), U.K. Those resources were costed based on unit cost data taken from relevant suppliers or from UCLH financial records.

The basic cost model

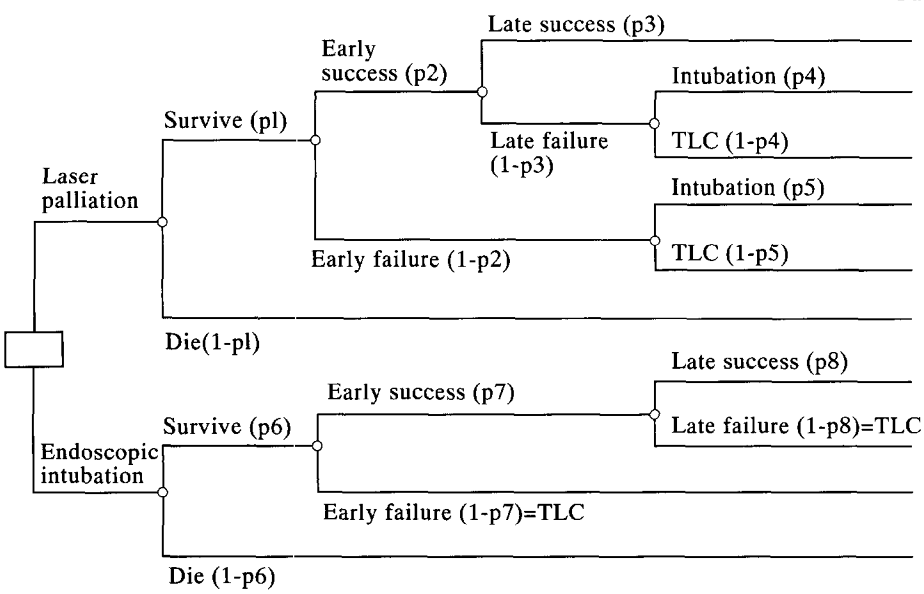
Depending upon which primary palliative therapy a patient receives for malignant dysphagia, they will undergo a different profile of endoscopic procedures. For example, a patient may initially receive endoscopic dilatation, then laser ablation and, in the terminal stage of their disease, endoscopic intubation. Figure 1 illustrates, using a decision tree, how the palliative therapies have been modelled for the purposes of cost analysis. The figure shows that, at the first and only decision node in the tree, a choice is taken regarding the primary endoscopic palliative therapy: laser or endoscopic intubation. It is possible that some patients will die during treatment. For patients surviving treatment, there is a risk of early failure; for patients for whom treatment is an early success, there is a probability of late failure; patients who are both early and late successes are considered to experience long-term palliation.

The definitions of early and late success employed in the cost model are those used by Loizou and associates [17]; early success is defined as an improvement in swallowing within 2 weeks of initial treatment; late (or long-term) success is defined as maintenance of improved swallowing—with or without repeat endoscopic therapy—until death. For patients whose primary therapy is laser ablation, early or late failure would be followed by one of two clinical decisions: intubation or no further intervention ("tender loving care"). For failures with primary intubation therapy where no laser is available, tender loving care represents the only management option. Thus Figure 1 shows that, for the primary palliative therapy of laser ablation, there are six pathways (A–F). For primary therapy using endoscopic intubation, there are four pathways (G–J):

Resource use

Health service resources are used when patients pass down any of the pathways in Figure 1. To estimate the resource use associated with each pathway, two data sources were used. The first data source is a prospective non-randomised comparison of 43 patients undergoing laser ablation with 30 patients receiving endoscopic intubation for malignant dysphagia [17]. Resource use data were available on 42 of the laser patients and 27 of the intubation patients.

The second data source is a randomised controlled trial



Pathway	Path probability	Dataset numbers*	Expected cost[ø]
A	0.46	42	£1773
B	0.23	18	£2561
C	0.05	0	£2029
D	0.18	4	£3041
E	0.08	4	£647
F	0.00	0.00	£0
G	0.81	24	£1116
H	0.09	3	£1616
I	0.06	0	£496
J	0.04	0	£298

□ = decision node o =chance node *=There were insufficient data to allocate two patients to a pathway

ø=Base-case estimates

Figure 1. Decision tree showing the structure of cost model for the two palliative therapies, and the dataset numbers, costs and probabilities for each pathway. The branch probabilities are shown in parentheses. TLC, "tender loving care".

comparing primary palliative therapies of laser alone and laser plus external radiotherapy for malignant dysphagia. When data were collected for the purposes of economic evaluation, the trial was not yet complete; but as of April 1992, data on numbers, types and timing of endoscopic procedures and on the length of any in-patient stay were collected for 28 patients receiving laser alone as their primary palliative therapy. Figure 1 provides details of the numbers of patients in the two trial datasets passing down each pathway.

For each patient in the two trial datasets, lifetime health service resource use was estimated. Four categories of hospital resource use were defined. The first category is diagnostic resource use. Diagnostic resource use as part of patients' initial assessment, prior to the choice of palliative therapy, was assumed to be equal in both groups and was not, therefore, included in the cost analysis. Resource use after initial assessment includes full blood counts which take place prior to every endoscopic procedure.

The second category of hospital resource use is endoscopic procedures. For patients whose primary palliative therapy was laser, possible endoscopic procedures included assessment, dilatation, laser alone, dilatation plus laser, dilatation plus laser plus intubation and dilatation plus intubation. For patients whose primary palliative therapy was intubation, possible endoscopic procedures included assessment, dilatation and dilatation plus intubation. The third category of hospital resource use is that related to any in-patient stay.

It is likely that patients will receive a similar form and intensity of hospital follow-up (e.g. visits to an out-patient clinic) whatever primary endoscopic palliative therapy they receive. Therefore, given the assumption of equal survival from initial assessment of palliation [17], hospital follow-up costs were assumed to be equal for the two primary therapies and were, therefore, excluded from the analysis. In the base-case analysis, the resource use implications of any complications of endoscopic treatment were assumed to be fully reflected in the trial data. The impact of this assumption was assessed using sensitivity analysis.

In addition to the hospital cost of palliative therapy, it is likely that patients will require further health care support in the community, especially in the terminal stage of their illness. In practice, this support is likely to involve a mix of inputs from patients' general practitioners (GPs), district nurses, cancer specialist nurses and hospice care, as well as from friends and relatives. Few data are available on this mix of care. The important issue is whether there is any *difference* between patients undergoing laser ablation and those receiving intubation in terms of this support. In the base-case analysis, it was assumed that patients receive, on average, the same community health care support whatever their primary palliative therapy, so these costs were excluded from the analysis. The implications of this assumption were explored using sensitive analysis.

Valuing resource use

Using mean resource use data taken from the two comparative trials, the mean health service cost of each of the pathways in Figure 1 was estimated. Resource use was valued using a set of unit costs based on supplier prices or derived from the financial accounts of UCLH. All unit costs relate to the 1991–1992 financial year. The unit costs of endoscopic procedures include the costs of staff, consumables such as gloves and tubes, drugs such as sedation and reverse sedation and an allocation of hospital overheads. The cost of equipment was also included, such as the cost of the laser and of the endoscopes which has been amortised to an equivalent annual cost using a 6% discount rate, and estimates of expected useful life and annual utilisation. In the case of the laser, an annual utilisation of 620 patient-treatment sessions was used, based on UCLH data; variation in this rate was explored using sensitivity analysis. The expected lengths of endoscopic procedures were based on clinical judgement.

The cost of patients passing down the pathways in Figure 1 was estimated by multiplying their average resource use by the relevant unit costs. As indicated in Figure 1, no patient from the two trial datasets passed down four of the pathways. The cost estimates for these pathways were, therefore, generated by adjusting the cost of similar pathways. The procedure cost of pathway C was taken as being equivalent to that of a late success with laser; the in-patient care cost was assumed equivalent to that of a late failure with intubation. The procedure cost of pathway I was based on that of late success with intubation; in-patient care cost was assumed to be equivalent to that of early laser failures managed with tender loving care. As regards the two operative mortality groups, because the probability of such mortality is taken as zero for the laser, the expected hospital cost of the mortality group for the laser (pathway F) was not estimated; the expected cost of the mortality group for intubation (pathway J) was based on one intubation procedure plus one night in hospital.

To calculate the total expected cost of the two primary palliative therapies, the mean cost associated with each pathway was multiplied by the probability of a given patient passing down that pathway, and these products were summed. In order to derive these total expected costs, it was necessary to estimate the probabilities p_1 to p_8 in Figure 1. These estimates were generated by pooling the results of six clinical studies comparing laser palliation with endoscopic intubation published before April 1992 [14–19]. In the case of the probability of late failure, only one study provided results [17]; this study too is the only one which provided data on the clinical management decisions taken as a consequence of early or late failure.

The expected cost of the two primary palliative therapies is, to some extent, influenced by the survival of patients: for laser patients in particular, the longer they live the more palliative endoscopic procedures they are likely to require. An assumption of the analysis is that the average period of survival, from assessment for palliation, is equal for the two primary palliative therapies [17]. The expected cost of laser palliation was, therefore, adjusted, on a *pro rata* basis, to a level reflecting equal survival in both groups.

Sensitivity analysis

Sensitivity analysis is used in economic evaluation to assess whether changing the assumptions and parameters in a model alters the conclusions of the analysis. In this study, sensitivity analysis was used in particular to assess the generalisability of the cost estimates to patterns of clinical practice other than those at UCLH, U.K. As alternatives to the base-case analysis, a resource sparing analysis re-estimated the cost differential between the two primary palliative therapies assuming rather lower levels of resource use. Instead of using the mean levels of resource use related to each pathway observed in the two trial datasets, lower 95% confidence intervals were incorporated into the model.

A resource intensive analysis was also undertaken which assumes that resource use is somewhat higher than in the base-case. Three components of the cost analysis were altered for the

Table 1. The unit cost estimates of endoscopic procedures used as part of the primary palliative therapies

Endoscopic	Staff	Consumables	Equipment	Drugs	Tests	Overheads	Total
Laser	£56	£1	£28	£13	—	£18	£116*
Dilatation	£25	£1	£6	£13	—	£18	£63
Assessment	£19	£1	£3	£13	—	£18	£54
Dilatation plus laser	£75	£1	£34	£13	—	£18	£141*
Dilatation plus intubation	£75	£33†	£6	£13	£69‡	£18	£214
Dilatation plus laser plus intubation	£93	£33†	£34	£13	£69‡	£18	£260*

*Cost of fibre of £57.00 added per patient (i.e. one fibre no matter how many laser procedures); † Includes cost of Celestin tube; ‡ Barium swallow.

resource intensive analysis. Firstly, instead of mean estimates of resource use from the trial datasets, upper 95% confidence intervals were used. Secondly, instead of assuming that the cost of caring for patients in the community during the "tender loving care" phase of their disease is zero, it was assumed that 100% of the period between their last endoscopic procedure and death is spent in a hospice. Thirdly, instead of assuming that the costs of any complications with endoscopic therapy are already reflected in the resource use estimates in the trial data (in terms, for example, of additional endoscopic procedures or in-patient stay), a specific analysis of the costs of complications was added. This analysis involved pooling the probabilities of complications for laser and intubation procedures from the six comparative studies [14–19] and costing each complication (which reaches a pooled incidence of 1% or more) using clinical judgement on their typical resource use implications. Thus, an expected total cost of complications for the two palliative therapies was estimated.

RESULTS

The unit cost estimates for each type of endoscopic procedure received by patients are detailed in Table 1. Other key unit costs include the "hotel" cost of a night in hospital at £83 (based on UCLH data) and a day in a hospice at £210 (Eden Hall Hospice, London, U.K., used in the sensitivity analysis only). Table 2 provides details of the number of endoscopic procedures undertaken on patients in the two trial datasets according to primary palliative therapy and pathway. The table indicates that patients undergoing laser palliation received more endoscopic procedures.

Table 3 shows the probability of a given patient passing along each of the pathways, based on data pooled from the six comparative studies. Table 3 also presents the mean procedure, in-patient and total costs of each pathway for the base-case analysis; the total cost estimates of each pathway are also shown in Figure 1. Table 4 details the total expected cost of the two primary palliative therapies for the base-case analysis, as well as the expected survival. In the case of laser palliation, an adjusted cost shows the expected cost when survival is equal to that of patients undergoing intubation. Table 4 shows that, for the base-case analysis, a typical course of palliative therapy using the laser costs £710 more per patient than a therapy based on endoscopic intubation.

Table 4 shows the cost estimates from the resource sparing and resource intensive analyses. The assumptions underlying the estimates of the cost of complications associated with laser and intubation procedures, which have been incorporated into the resource intensive analysis, are detailed in Table 5. The changes incorporated into these alternative analyses reduce the lifetime cost of laser palliation relative to endoscopic intubation by between £148 and £557 per patient, but the laser remains more costly.

Table 2. Number of endoscopic procedures undertaken on patients in the trial datasets according to pathway

Pathway	Mean	Standard deviation	Number of patients*
Laser:late success (A)	5.6	2.6	42
Laser:late failure, tube (B)	8.2	2.9	18
Laser:late failure, TLC (C)	—	—	0
Laser:early failure, tube (D)	5.0	2.5	4
Laser:early failure, TLC (E)	3.3	0.9	4
Laser:procedure-related death (F)	—	—	0
Intubation:late success (G)	1.5	0.9	24
Intubation:late failure, TLC (H)	2.3	0.6	3
Intubation:early failure, TLC (I)	—	—	0
Intubation:procedure-related death (J)	—	—	0

TLC, Tender loving care.
* Insufficient data to allocate two patients to a pathway.

Table 3. Estimated cost per patient of each pathway and associated probabilities for the base-case analysis

Pathway	Probability	Procedure	In-patient care	Total
Laser				
Group A	0.46	£701	£1072	£1773
Group B	0.23	£1067	£1494	£2561
Group C	0.05	£701	£1328	£2029
Group D	0.18	£634	£2407	£3041
Group E	0.08	£398	£249	£647
Group F	0.00	—	—	—
Intubation				
Group G	0.81	£247	£869	£1116
Group H	0.09	£288	£1328	£1616
Group I	0.06	£247	£249	£496
Group J	0.04	£215	£83	£298

Table 4. Total expected costs per patient and survival periods of the two primary palliative therapies for the base-case and two alternative analyses

Primary palliative therapy	Base-case	Resource sparing	Resource intensive
Laser			
- Procedure	£751	£599	£991
- In-patient care	£1353	£834	£1879
- Community support	£0	£0	£866
-Total	£2104	£1433	£3736
- Survival (days)	161	161	161
- Adjusted total*	£1802	£1227	£3202
Intubation			
- Procedure	£249	£211	£398
- In-patient care	£843	£454	£1237
- Community support	£0	£0	£1414
- Total	£1092	£665	£3049
- Survival (days)	138	138	138
Adjusted laser intubation	£710	£562	£153

* Adjusted to a level consistent with equal survival.

DISCUSSION

Differential cost

The analysis described in this paper indicates that, over the short period that patients with malignant dysphagia are likely to live, palliation of their symptoms using Nd:YAG laser ablation will cost between £153 and £710 more than endoscopic intubation, based on data from UCLH, U.K. An important issue is the extent to which these cost results are generalisable: a number of parameters in the model might vary from centre to centre.

Table 5. Estimates of the expected cost of complications associated with laser and intubation procedures used in resource intensive analysis

Complication	Probability per procedure	Resource implications	Expected cost*
Laser			
- Perforation	1.6%	Placement of cuffed tube and antibiotics	£8
Total laser			£8
Intubation			
-Perforation	7.7%	Extra barium swallow, antibiotics, 5 extra nights in hospital	£46
- Haemorrhage	3.0%	Two units of blood	£3
- Aspiration pneumonia	1.8%	Antibiotics, 3 extra nights in hospital	£6
- Tube migration	13.0%	New tube	£28
- Food impaction	6.0%	Endoscopy to clear	£3
- Peptic oesophagitis	1.0%	Omeprazole	£1
- Tumour overgrowth	2.0%	New tube	£4
- Tube dislocation	2.0%	New tube	£4
Total intubation			£95

* Cost weighted by probability of complication occurring.

The first of these parameters is the length of in-patient stay associated with the two forms of palliation. It is possible that, in some centres, more of the endoscopic therapies might be undertaken on a day-case basis than at UCLH, U.K. If neither form of primary palliation required any in-patient care, intubation would lose its cost advantage for the resource intensive analysis. If more laser procedures could be carried out on a day-case basis than intubation procedures, intubation may lose its cost advantage for the base-case and alternative analyses. Although these scenarios are possible, the fact that laser palliation is likely to take place in specialist centres rather than in general units will probably result in a need for at least some patients to stay overnight in hospital because of distance. Another parameter to consider is the unit cost of a night in hospital. The £83 per night used in this analysis may be lower that that in other centres. Given the greater use of in-patient stay amongst laser patients shown here, any increase in this unit cost would increase the cost advantage of intubation.

A further parameter in the cost model that may vary between clinical centres is the annual utilisation of the laser equipment. If utilisation is high, there is a greater number of patient-treatment sessions over which to divide the capital and maintenance costs of the laser equipment. It is unlikely, however, that annual utilisation would reach sufficiently high levels to remove the cost advantage of endoscopic intubation. If annual utilisation were to increase from the 620 in this analysis to 2000 patient-treatment sessions as a result, for example, of greater multi-specialty use of the equipment, expected cost differences would only fall by between £58 and £91.

The cost associated with operative mortality related to intubation may also differ from that used in this analysis. In the model, this cost was assumed to be equivalent to one endoscopic intubation procedure plus one night in hospital. In practice, this cost might be higher: a patient might spend time in intensive care, for example. This additional cost might cancel out the cost advantage of intubation over laser. However, to cancel out fully this cost advantage, given the probability of operative death with intubation of 4%, this cost would need to be very high at £17 750, in the base-case analysis, and £14 050 and £3825 in the resource sparing and resource intensive analyses, respectively. It is unlikely, therefore, that the assumption regarding the cost of operative mortality with intubation is of key importance to the conclusions of the analysis.

Another parameter that may vary in clinical practice is the experience of the centres undertaking these procedures. In general, lasers are only available in specialist centres where large numbers of patients will undergo palliation for malignant dysphagia. For smaller centres, intubation is likely to be the only treatment option and, when fewer patients are treated, the complication rate (and hence the cost) is likely to be higher.

A final parameter in the model that may vary between centres is the cost of the tube used for intubation. Recently, new self-expanding stents have become available [21] at an approximate cost of £500–£700 compared to the cost of the standard tube of £32 used in this analysis. If this new type of tube became widely used, it would remove most of the cost advantage of intubation in the base-case analysis, and produce a cost advantage to the laser in the resource sparing and resource intensive analyses.

Some small studies have considered the effect of combining the laser with either external or intracavitary radiotherapy. A tentative finding of the limited comparative clinical evaluation to date is that adding radiotherapy to laser may increase the period between endoscopies [22, 23], although this finding has not been replicated in other studies [24, 25]. A recent pilot study has indicated that brachytherapy, provided on a day-case basis as an additional therapy to laser palliation, can reduce the number of endoscopic procedures by approximately half [26]. If these findings are confirmed by prospective studies, the cost advantage of intubation would fall to approximately £188 in the base-case analysis and £432 in the resource sparing analysis; and it would lead to a cost advantage for the laser of £697 in the resource intensive analysis, given a unit cost of day-case brachytherapy of £380.

Cost-effectiveness

Although the results of this analysis indicate that primary palliation with the Nd:YAG laser is likely, under most assumptions, to cost more than that with endoscopic intubation, it cannot be assumed that intubation is the more cost-effective form of palliation. This depends crucially on the health outcomes generated by the two therapies. Given the short period that patients with incurable malignant dysphagia are likely to live and that there appears to be no difference in survival with the two forms of palliation [17], the key outcome is the impact on patients' health-related quality of life (HRQL). There have been no studies with a sufficiently large sample size to identify statistically significant overall differences between the primary therapies in HRQL.

Inevitably, HRQL deteriorates in the terminal phase as weakness and anorexia, rather than dysphagia, become the overriding features, regardless of the endoscopic technique used. In assessing the relative impact of laser and intubation on HRQL, an important consideration is the higher number of procedures, and hence hospital visits, required with the laser. This might be a burden to patients during their last few months of life, but it might provide a source of counselling and support through the close relationship that a patient is allowed to develop with the specialist palliative care team. Clearly the quality of swallowing facilitated by the two forms of endoscopic therapy will influence their relative impacts on HRQL.

To estimate the relative cost-effectiveness of the two primary therapies, it is necessary for further research to assess the value patients attach to both the process and the outcomes of the two primary palliative therapies. If these values are measured on a 0–1 scale where 0 represents death and 1 good health [27], they can be used to estimate the quality-adjusted life years (QALYs) generated by the two therapies [28]. If laser palliation is to prove cost-effective, it needs to generate sufficiently more QALYs than intubation to justify its additional cost.

It has been suggested, in the context of the Canadian health care system, that if a new intervention can generate more QALYs than conventional therapy at an incremental cost per additional QALY of less than (Canadian) $20 000 (approximately £10 500), there is strong evidence that its cost-effectiveness justifies adoption [29]. If that threshold were to be used in the U.K., the cost results in this paper suggest that the process and outcomes of laser palliation would need to be valued, on the 0–1 valuation scale, at least 18% more highly by patients than those of intubation in the base-case analysis, and at least 14% and 3% more highly for the resource sparing and resource intensive analyses, respectively. Further research is required to test whether patients do indeed value the outcomes of the laser more highly than those of endoscopic intubation, and whether, if they do, those values reach these crucial thresholds.

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