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Extended Research Article

Cost-effectiveness of endoscopic treatments for obesity: a clinical evidence map and systematic review to inform a model-based cost-effectiveness analysis

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Scientific summary

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Scientific summary

Background

Obesity is a common disease associated with poorer quality of life (QoL), increased risk of multiple metabolic, vascular, physical and mental health complications and mortality, and significant economic impact. Bariatric surgery is currently the most effective obesity treatment for sustained long-term weight loss and improvements in obesity complications. Despite its effectiveness, access to bariatric surgery is limited due to multiple factors including lack of resources among others. Lifestyle behavioural interventions (LSIs) are known to have modest effectiveness that is difficult to sustain long term. Endoscopic obesity treatments are becoming increasingly available globally and in the UK. Compared to bariatric surgery, they are less invasive, require a shorter hospital stay and are potentially cheaper, while replicating some of the anatomical and physiological changes that occur after bariatric surgery. This makes them a potential alternative, or bridge to, bariatric surgery. It is important to determine whether endoscopic treatments are both clinically effective and cost-effective to inform decision-making from the UK NHS/Personal Social Services (PSS) perspective on their potential for treating people living with obesity.

Aims and objectives

What is the current evidence for the clinical and cost-effectiveness of endoscopic treatments compared to alternative weight management interventions for obesity?

The specific objectives were:

- To produce a map of the evidence on the effectiveness of endoscopic therapies for obesity based on randomised, non-randomised controlled and uncontrolled studies.
- To undertake one or more systematic reviews of the clinical effectiveness of different endoscopic treatments, with the potential for undertaking meta-analyses, subgroup analyses and a network meta-analysis to determine the relative effectiveness of different treatments. As this was not feasible due to the vast numbers of studies, interventions and comparators, greater emphasis was placed on the evidence map with more detailed analysis limited to evidence that could be used to inform the economic model.
- To undertake a systematic review of available economic evidence on the use of endoscopic treatments for obesity.
- To undertake a model-based cost-effectiveness analysis comparing endoscopic treatments with other alternative treatments from the UK NHS/PSS perspective; in consultation with the steering group, three separate economic models were developed to enable key endoscopic therapies to be compared to laparoscopic bariatric surgery or pharmacotherapy.

Methods

The review was registered on PROSPERO (CRD42022302942) and reporting followed the general principles of the Preferred Reporting Items for Systematic Reviews and Meta Analyses.

Evidence map

Searches and study selection

Databases [Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE] were searched from inception to January 2023. There were no restrictions by study design, language, date of publication or publication type. Two reviewers independently undertook title and abstract screening and full-text selection. Disagreements were resolved by a third reviewer or by consensus and reasons for exclusion were recorded.

Eligibility criteria

Studies of patients of any age with obesity (as defined by the study authors) who received any endoscopic treatment were eligible. Any randomised, non-randomised controlled or single-arm study design was eligible (with $n \geq 2$). Any, or no, comparators were eligible (e.g. bariatric surgery, LSI, pharmacotherapy, a different endoscopic treatment) and any obesity-related outcome was eligible (e.g. weight loss, change in diabetes status, adverse events, QoL).

Construction and reporting of evidence map

A searchable database map of all available evidence for endoscopic treatments for obesity was constructed in Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA). Details on the population, intervention(s), comparator(s) where relevant, study design, sample size and length of follow-up were extracted by a single reviewer based on the abstract. Information on randomised controlled trials (RCTs) was checked by a second reviewer. Key descriptors were added to the evidence map via drop-down menus to enable filtering. Summary tables were used to collate the evidence from the map into four overarching categories: (1) restrictive procedures, (2) space-occupying devices, (3) malabsorption devices and procedures and (4) other endoscopic procedures. For all RCTs and non-randomised controlled studies, a brief narrative description was also provided.

Use of the evidence map to inform the economic evaluation

A full systematic review of effectiveness of all endoscopic treatments was not possible, given the vast volume of evidence and the numerous interventions and comparators. The map was therefore used to identify relevant evidence to inform the economic models.

Indirect comparisons

Where direct evidence on relevant interventions being compared was not available from the evidence map, indirect comparisons were undertaken. This is where treatments are compared indirectly across different studies based on the fact that they have the same comparator in common and are also similar in other aspects. RCTs were sought from existing systematic reviews and targeted searches of Cochrane CENTRAL. Stata® (version 17) (StataCorp LP, College Station, TX, USA) was used to undertake random effects meta-analyses, and results from pair-wise meta-analyses were used to perform indirect comparisons.

Systematic review of cost effectiveness

The broad searches used to identify effectiveness studies for the evidence map were also used to identify any model-based economic evaluations for this review. Trial-based or model-based economic evaluations comparing the costs and outcomes from two or more obesity treatments where at least one was an endoscopic therapy were eligible for inclusion. Appropriate risk of bias tools were applied and a narrative synthesis was undertaken.

Economic evaluation

Model development was informed by evidence from the evidence map, the indirect comparisons, evidence found through purposive literature searches beyond endoscopic procedures and clinical assumptions. Three state transition cohort Markov models were designed in Microsoft Excel 2018 to estimate the cost-effectiveness of endoscopic therapies compared to alternative weight management interventions for adult patients with obesity (body mass index of > 30 kg/m^2). A cost–utility analysis was conducted based on the outcome of cost per quality-adjusted life-year (QALY). The base-case analysis was from the perspective of the NHS and PSS over a 5-year time horizon. Costs and benefits were subjected to an annual discount rate of 3.5%, following the recommendation of National Institute for Health and Care Excellence. The comparison of the following treatments was conducted within three separate economic models for a 5-year time horizon: model 1: endoscopic sleeve gastroplasty (ESG) versus laparoscopic sleeve gastrectomy (LSG); model 2: ESG versus semaglutide; model 3: intragastric balloon (IGB) versus semaglutide. Patients could transition between four obesity health states and cycle length was 6 months for the first cycle and 12 months thereafter. Uncertainty was explored via both deterministic and probabilistic sensitivity analyses.

Results

Evidence map

There were 1574 records of relevant studies included in the evidence map, with 90% of these published after 2009. Most of these records were related to single-arm studies (73%), 18% related to non-randomised controlled studies, and 9% related to RCTs. The most common endoscopic interventions were space-occupying devices (mainly IGB), restrictive procedures (mainly variations of ESG) and to a lesser extent malabsorption devices (such as duodenal–jejunal bypass liner). The most common comparators were a different endoscopic treatment (or variation of the same treatment), bariatric surgery (often LSG) and LSI, with sham procedures and pharmacotherapy less well represented. Most studies reported weight loss and/or safety outcomes but could also include changes in body composition, satiety and gastric emptying, and biomarkers of metabolic and glycaemic control. Duration of follow-up varied from 1 week to 5 years but was most frequently between 6 and 12 months. The vast majority of studies were in adults, with very few records relating to studies undertaken in children or adolescents. Patients were enrolled for weight loss prior to surgery ('bridge to surgery') or following weight regain after previous obesity treatment in a small proportion of studies. A limitation of the map is the reliance on abstracts only for data extraction.

In terms of informing the economic models, non-randomised studies comparing ESG with LSG as well as studies reporting weight loss in the longer-term were identified from the evidence map.

Indirect comparisons

Seven RCTs were included in the indirect comparison, two RCTs comparing ESG with LSI, three RCTs comparing IGB with LSI and two RCTS comparing semaglutide with LSI. The analysis found little evidence of a difference in mean per cent of total body weight loss (95% confidence interval) between ESG and semaglutide at 6 months [2.15 (−29.47 to 33.76)] and 12 months [0.54 (−2.05 to 3.14)]. There was also little evidence of a difference between IGB and semaglutide at 6 months [0.37 (−6.25 to 6.98)] but good statistical evidence of a difference in favour of greater weight loss with semaglutide at 12 months [−7.91 (−11.14 to −4.67)]. Limitations of the analysis include some uncertainty around the transitivity assumptions made such as similarity of comparators and populations.

Systematic review of cost-effectiveness

Three cost–utility analyses were identified, conducted within a UK, USA, or Canadian setting. The studies explored three endoscopic therapies, ESG, swallowable IGB and aspiration therapy, compared against LSI or bariatric surgery. A lifetime horizon was used in models and primary outcomes were reported in terms of cost per QALY. Study findings could not be directly compared, given the differences in treatments compared and methods used, but overall findings suggested that endoscopic therapies were cost-effective when compared to LSI or no treatment but were dominated when compared to bariatric surgery. A common and significant limitation across all the studies was the scarcity of long-term data on the effectiveness of endoscopic therapies, and the lack of data on direct comparisons of different treatments. The UK cost–utility analysis was considered the most useful to inform the development of the new economic models because of the relevance of the setting (UK) and patient population.

Economic evaluation

Model 1 found that LSG is likely to be cost-effective compared with ESG, for the treatment of patients with obesity class II and III (£10,593 per additional QALY with LSG when compared with ESG in base case). This finding was robust to deterministic and probabilistic sensitivity analyses. Only the most pessimistic scenario regarding long-term efficacy with LSG led to an incremental cost-effectiveness ratio (ICER) approaching an upper threshold limit of £30,000/QALY.

Model 2 found that ESG is likely to be cost-effective compared with semaglutide for the treatment of patients with obesity class I and II (£7267 per additional QALY with ESG when compared with semaglutide in base case). This finding was more sensitive to deterministic sensitivity analyses, particularly cost, with a reduction in ESG costs by 10–20% resulting in ESG becoming dominant. The results were also sensitive to a reduction in assumed weight regain with semaglutide, resulting in an increased ICER for ESG.

Model 3 found that semaglutide is the dominant (cheaper and more effective) treatment option in the base case compared with IGB in patients with obesity class I and II, but the effect differences are very small. Semaglutide loses its dominance with a decrease of IGB costs by around 20%.

While the probabilistic sensitivity analysis (PSA) found a degree of confidence in the base-case estimates, there remains some uncertainty relating to the comparability of the included studies evaluating the different therapies. There were no RCTs directly comparing the interventions and it is possible the PSA could have overestimated certainty in the results. Other limitations include basing utility values and comorbidity costs on obesity health states rather than being directly associated with history of weight loss. Also, the 5-year time horizon may not capture longer-term benefits from ESG or LSG but was felt to be appropriate due to the lack of evidence on long-term weight trajectory following treatment. Weight loss beyond 12 months is based solely on clinical assumption for semaglutide and, as such, base-case estimates for models 2 and 3 should only be considered in the context of the sensitivity analyses.

Conclusions

A vast amount of research has been undertaken on a range of endoscopic therapies for obesity. The searchable evidence map provides a useful repository of evidence which can be used for planning and informing future research, including economic models. There were few economic evaluations of endoscopic therapies, and the models developed for this report will therefore add early evidence to the cost-effectiveness of endoscopic therapies. The three Markov models respectively found that over a 5-year time horizon, LSG was likely to be cost-effective compared with ESG (for obesity class II and III), and for obesity class I and II, ESG was likely to be cost-effective compared with semaglutide, and IGB was dominated by semaglutide. The model comparing ESG and LSG was robust to sensitivity analyses, while the other models were somewhat sensitive to intervention costs. There was substantial uncertainty around long-term weight loss for both semaglutide and IGB.

Future research

Future research should focus on longer-term studies evaluating effectiveness of endoscopic treatments, studies directly comparing endoscopic therapies against semaglutide and other emerging weight loss drugs, and studies which better reflect the complex treatment pathways of obesity. It could also explore the effectiveness of endoscopic therapies for patients in different obesity classes. Such studies could provide more robust evidence for informing future cost-effectiveness models beyond a 5-year time horizon.

Study registration

This study is registered as PROSPERO CRD42022302942.

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