A Health Technology Assessment: laparoscopy versus colpoceliotomy

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Key words
Colpoceliotomy • Laparoscopy • HTA

Summary

Introduction. The objective of this paper is the comparison between two different technologies used for the removal of a uterine myoma, a frequent benign tumor: the standard technology currently used, laparoscopy, and an innovative one, colpoceliotomy. It was considered relevant to evaluate the real and the potential effects of the two technologies implementation and, in addition, the consequences that the introduction or exclusion of the innovative technology would have for both the National Health System (NHS) and the entire community.

Methods. The comparison between these two different technologies, the standard and the innovative one, was conducted using a Health Technology Assessment (HTA). In particular, in order to analyse their differences, a multi-dimensional approach was considered: effectiveness, costs and budget impact analysis data were collected, applying different instruments, such as the Activity Based Costing methodology (ABC), the Cost-Effectiveness Analysis (CEA) and the Budget Impact Analysis (BIA). Organisational, equity and social impact were also evaluated.

Results. The results showed that the introduction of colpoceliotomy would provide significant economic savings to the Regional and National Health Service; in particular, a saving of € 453.27 for each surgical procedure.

Discussion. The introduction of the innovative technology, colpoceliotomy, could be considered a valuable tool; one offering many advantages related to less invasiveness and a shorter surgical procedure than the standard technology currently used (laparoscopy).
Materials and methods

In order to achieve the above mentioned objective, HTA was considered the most acknowledged tool for being adopted in the decision-making phase, in professional and knowledge-intensive settings, such as hospitals. HTA is a multi-disciplinary tool, one that aims at evaluating both the real and the potential effects of technologies, and the consequences that the introduction or the exclusion of a procedure has for the health system, the economy and society.

The present approach is able to analyse different technologies, by examining their economic, social, clinical, ethical and organizational implications [11], thus identifying technologies that offer a greater benefit to the population. The primary objective of HTA, is not to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly influence the decision making process [12], to increase specialists and evaluators’ knowledge, but to directly 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HTA: LAPAROSCOPY VS COLPOCELIOTOMY

Cost-effectiveness analysis (CEA) is necessary to have suitable measures of effectiveness, because this technique expresses health benefits in simple terms, such as years of life gained [23]. This method is often implemented in an HTA report in order to obtain a specific effectiveness with minimum costs.

Whereas a CEA evaluates both costs and outcomes of alternative technologies over a specified time horizon in order to estimate their economic efficiency, a Budget Impact Analysis (BIA) is based on their affordability. In fact, its main purpose is to predict the final consequences of the adoption and diffusion of a new technology into a healthcare system with finite resources [24].

Results

The Sample
The analysis was conducted in accordance with the real data performed by the Department of Obstetrics and Gynaecology of the Health Authority Civil Hospital of Legnano, during the year 2013.

In particular, it emerged that 166 women were treated for the removal of uterine myomas (Tab. II). The table above shows that the two populations under analysis (118 patients in the arm of colpoceliotomy and 48 patients in the arm of laparoscopy) were comparable from both the dimensions and the diameters of the myomas. It could be considered a relevant feature, allowing the comparability of the two population and the related technologies used in this category of procedure.

Results from the IMPAQHTA Model Implementation
The first step of the HTA is the prioritisation of the dimensions, by the chief of the Department and the Strategic Board of the Hospital of reference, involving a total of 5 individuals as evaluators. The table below shows that the most important variable for the experts is the patient’s safety (Tab. III).

The second most relevant dimension is the economic and financial impact. When the ABC analysis is implemented, the technologies are perfectly superposable in terms of the process’ description; however, the specification of net costs; iii) computation of net health effects; iv) application of decision rules; v) sensitivity analysis [23]. This method is often implemented in an HTA report in order to obtain a specific effectiveness with minimum costs.

| N. of patients | Colpoceliotomy | Laparoscopy | P-value |
|----------------|----------------|-------------|---------|
| 118            | 48             |             |         |

| Mean age (years) | 41 | 39 | >0.005 |
|------------------|----|----|--------|
| Length of procedure (min) | 85 | 80 | >0.005 |
| Myoma diameters (cm) | 7  | 6  | >0.005 |
| Myoma dimensions (gr) | 100 | 200 | 0.01   |
| Length of hospitalization | 3  | 5  | 0.000  |
| Adverse events | 1.60% | 6% | 0.000  |

Tab. II. Description of the sample under assessment.
specific and related operative phases of the intervention are different (Tab. IV).
The table above shows the differences, between each phase, in terms of costs and impact. It emerges that laparoscopy absorbs economic resources for a total of €1,789.42, whereas colpoceliotomy a total of €1,336.15, allowing a €453.72 saving for each surgery. This difference may be explained by the expensive instruments used for laparoscopy.

The CEA was calculated as the “ratio” between the unit cost per patient related to the two compared technologies (derived from the previously conducted ABC Analysis) and the effectiveness data. The effectiveness data is defined as the percentage of “non-complications surgery”. It emerges that in the colpoceliotomy arm only 1.60% of patients reported problems during surgery. On the contrary, in the laparoscopy arm 4% of patients reported the onset of mild and moderate adverse events. As previously mentioned, the effectiveness data used for the CEA have been collected from an observational study involving 166 patients in total (see Table II).

In accordance with the real data related to the year 2013, Table V shows that the innovative procedure achieved a higher cost-effectiveness value if compared with the gold standard technology. Colpoceliotomy, on the basis of an increase in the effectiveness data, leads to a decrease of total costs, thus being defined as the dominant strategy.

In the BIA, two scenarios are considered: the first one calculates the annual cost of 118 laparoscopy surgeries and 48 standard procedures, taking into account what actually happened in the year 2013 within the reference Health Authorities; the second one estimates the annual cost of 166 surgeries, if done with the standard technology (it could be considered as the “baseline” scenario). According to this scenario, the BIA, with the inclusion of both the results deriving from the activity based costing approach, and the organisational investment needed, leads to an overall significant financial and economic saving for the Health Authority of reference, in case of implementation of colpoceliotomy procedure in the clinical practice (with regards to the year 2013).

An economic saving of €48,955.06 emerged from the evidence, in the first scenario: the data confirmed that colpoceliotomy could be introduced in the clinical practice of the referred hospital. This difference takes into account also the training costs required by the introduction of colpoceliotomy.

This analysis was implemented over a 12-month period due to the fact that the present health technology evaluation was requested by the Strategic Management Board of the Health Authority of reference.

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**Tab. III. Prioritisation.**

| Dimensions                      | Evaluators | Total | Normalisation |
|--------------------------------|------------|-------|---------------|
|                                | #1 | #2 | #3 | #4 | #5 |
| Safety                         | 5 | 1 | 1 | 1 | 2 |
| Economic and financial impact  | 1 | 2 | 3 | 3 | 1 |
| Effectiveness                  | 2 | 5 | 4 | 5 | 3 |
| Organisational impact          | 5 | 3 | 5 | 2 | 5 |
| Efficacy                       | 7 | 7 | 2 | 4 | 4 |
| General relevance              | 6 | 6 | 6 | 6 | 6 |
| Equity                         | 4 | 8 | 7 | 7 | 7 |
| Social and ethical impact      | 8 | 4 | 8 | 8 | 8 |

| Phases                        | Laparoscopy | Colpoceliotomy |
|-------------------------------|-------------|----------------|
| Pre-Hospitalisation           | 305.08 €    | 305.08 €       |
| Admission                     | 65.62 €     | 65.62 €        |
| Pre-Surgery Recovery          | 38.93 €     | 38.93 €        |
| Surgery                       | 1,089.64 €  | 636.37 €       |
| Post-Surgery                  | 201.83 €    | 201.83 €       |
| Discharge                     | 88.83 €     | 88.83 €        |
| Total                         | 1,789.42 €  | 1,336.15 €     |

**Tab. IV. ABC analysis.**

| Phases                        | CCT       | STD       |
|-------------------------------|-----------|-----------|
| ABC Analysis                  | €1,336.15 | €1,789.42 |
| Effectiveness data            | 98.40%    | 94%       |
| CEV                           | 1,357.87  | 1,903.64  |
| Budget Impact Analysis        |           |           |
| ABC Analysis                  | €1,336.15 | €1,789.42 |
| # surgery per year            | 118       | 48        |
| Surgery cost per year         | €243,557.30 | €297,043.55 |
| Further Training cost         | €3,870.00 | €660.80   |
| Total Training cost           | €64,530.80 |           |
| BIA                           | €248,088.10 | €297,043.55 |
| Δ BIA                         | -€48,955.45 | €/year    |

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of the Hospital Authority, and the financial period of reference for the budget was equal to 12 months.

Additional training courses are relevant from an organizational point of view. In fact, clinicians have to be trained in order to implement the innovative procedure. The figure shows that colpoceliotomy is preferable from an organizational point of view. A clarification is needed: for a proper reading of the picture, it is important to take into consideration the two areas (the wider the area is, the more preferable the technology is).

However, specific training courses are needed for clinicians, scrub nurses and support staff for learning the correct procedure for colpoceliotomy, in terms of (i) adequate preparation of the women undergoing the intervention, (ii) proper provision of all the instruments required and (iii) correct implementation of the innovative technology.

In particular, it emerged that in the specific setting under assessment, 2 surgeons, 3 scrub nurses and 5 health professionals needed to attend a 20-hours training course. With respect to the last phase of the IMPAQHTA framework implementation, it is important to determine a final score, both for laparoscopy and colpoceliotomy, useful for an evidence-based decision-making appraisal phase.

It is relevant to specify the sub-criteria of each evaluated dimension, starting from the prioritisation shown in Table I. Sub-criteria are detailed in order to appoint a basis score for each of them.

The following table shows the final score of the present comparative study, assigned by all the 5 evaluators that have been involved in the prioritization phase (Tab. VI).

In this view, the chief of the Department of Obstetrics and Gynaecology and the Strategic Board assigned (in columns three and four) a rating score for each sub-criteria, taking into account all the possible differences related to the two technologies under assessment. In column five and in the final row defining each dimension, the maximum total achievable score is reported.

These data allow the calculation of the effect of each sub-dimension through a ratio between the maximum achievable total score and the established total score. Finally, it is useful to show the sum of the normalised scores per each technology (normalized score x normalized prioritization), resulting in a total score for colpoceliotomy and a total score for the standard procedure. The table shows that colpoceliotomy achieves a higher score than laparoscopy (0.56 vs 0.44).

Discussion

As shown in Table VI, colpoceliotomy achieves a higher score than laparoscopy. The innovative technology presents a lower annual cost and it brings significant economic savings for health care organisations. It is relevant to note the importance of an appropriate and rational implementation of the available technologies, in order to achieve maximum benefits with minimal costs. However, the introduction of a new technology affects the Health Authority of reference from an organizational point of view, requiring coaching and training courses for the persons involved in the procedure (as mentioned in the previous section). Then, it is necessary to have frequent meetings aimed at communicating the changes introduced by the new technical surgery in the whole organization.

The adoption of colpoceliotomy does not, however, require a purchase of new surgical instruments or equipment. Therefore, the innovative technology could lead to an economic saving due to the lack of need for expensive instruments, such as Trocar. The new procedure also allows a saving of time with some activities, such as the purchase or the maintenance of equipment; this may result in a positive impact on the internal process of gynaecology units and on health workers’ safety.

If colpoceliotomy were inserted in the clinical setting, it would have a positive impact also on the access to care, thus positively affecting the equity dimension (average score equal to 2.2). In fact, the innovative procedure would enlarge the treated “target” population, including persons of a legally protected status; thanks to the use of natural orifices, colpoceliotomy is less invasive and specific physical conditions of eligibility are not required.

In addition, colpoceliotomy has a relevant social impact on a patient’s life due to a shorter hospitalisation; this means that patients may return to their daily life and work sooner, thus reducing productivity loss. From the present analysis, it emerged that the average score declared by the expert for the social dimension is equal to 2.5 for colpoceliotomy; the innovative technology could improve the patient’s autonomy after the procedure.

However, there is a disadvantage in the implementation of colpoceliotomy: it requires an accurate manual ability, which implies a longer learning time of the new surgical procedure, thus needing coaching and training periods. This has been reflected in the evaluation of the
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organizational impact (see Fig. 1): the items related to training course needed for colpoceliotomy achieved a lower score than the standard procedure. The present feature has a substantial impact only on a short term period, because training courses required only 20 hours for person. In general, it emerges that the introduction of colpoceliotomy has a positive organizational impact, achieving an average score equal to 2.50.

Although an HTA study is a useful tool for decision makers, who are involved every day in many different strategic and tactical decisions [25], it is not the only one. In fact, the results and evaluation of an HTA are relevant to decision making only if they are aligned with the mission of the health care organization.

Conclusions

Colpoceliotomy is an alternative technique to laparoscopy, the latter being the standard method used for the treatment and removal of uterine myomas. At present, colpoceliotomy is still uncommon because it requires a high knowledge of the anatomy of female genitalia (in particular the vaginal canal), high experience and manual ability. Furthermore, the innovative procedure meets institutional constraints that limit its implementation. In the present study, an HTA evaluation was made, which compared the use of traditional laparoscopy and colpoceliotomy for the removal of uterine myomas. The results showed that the innovative technology is more advanta-
geous in terms of invasiveness and shorter surgery time; thus, this procedure is low-time consuming [26]. The study highlights both the social and the financial impact of colpoceliotomy, considering also the organisational impact on health care companies, represented by the introduction of coaching and training courses both for the medical staff and the support personnel involved in the surgery.

Data show that the new procedure is safe, and that it provides both short and long term benefits in terms of the savings in the purchase and maintenance of machinery. The innovative technology leads to a significant reduction in adverse events, invasiveness, duration of surgery and post-operative hospitalization.

Considering the economic and financial perspective, the new procedure would lead to a substantial reduction of costs related to the absence of sophisticated equipment, as required by laparoscopy, and to a smaller number of personnel involved.

Therefore, colpoceliotomy may be considered a valuable tool in reducing costs regarding the surgical treatment for uterine myomas.

In conclusion, although the present study highlights its technical superiority; that is, the advantages it ensures over prior or existing technologies [27], a further randomised study is suggested in order to confirm colpoceliotomy’s benefits achieved in the present study.

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