ORIGINAL ARTICLE

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).*

Introduction

Uterine myoma is the most common benign tumour of the uterus [1], affecting around 20-25% of women over 30 years old [2]. The incidence of this disease increases from age 40 to 50.

This disease is usually asymptomatic; sometimes, however, it may cause disorders such as dysmenorrhea, compromising women's health and quality of life. Symptoms may be severe enough to require treatment.

There are several options for the treatment of myomas, including both medication and surgical procedures, such as myomectomy and hysterectomy. Surgical and other invasive interventions still dominate treatment [3], while the medical therapy is currently limited to the preoperative reduction of symptoms [4].

Myomectomy is the only surgical option for women of childbearing age. With myomectomy, it is necessary to consider both laparoscopy and colpoceliotomy, which, in this paper, is defined as "innovative technology".

Laparoscopy was first described by Semns in 1980 [5]. It is a surgical procedure in which a small incision is made, through which a viewing tube (laparoscope) is inserted. Colpoceliotomy is a surgical procedure in which an opening of the pelvic cavity is made through the fornix of the vagina. The latter procedure is less invasive than the standard one; there is no need of any abdominal incision and the peritoneum is surgically opened via the vaginal fornix; furthermore colpoceliotomy can be useful even in case of large, numerous and intramural fibroids [6]. However, although the first description of this method dating from 1951, thanks to De Bedoya [7], it is an uncommon methodology as it requires a detailed knowledge of the vaginal apparatus and manual transvaginal skills. It is, therefore, a rarely used technique in the removal of uterine myomas. Over the last decades, this methodology has been studied by other authors [8-9], asserting that its surgical access to pelvis and, in general, its surgical time are more rapid if compared with laparoscopy one. However, despite these advantages, gynecologists do not often use vaginal myomectomy [10].

The aim of the present study is to compare laparoscopy with colpoceliotomy, focusing on the advantages and benefits of the innovative technology, based on their use in the Department of Obstetrics and Gynecology of the Health Authority Civil Hospital of Legnano. The final goal of the analysis conducted is the definition of the best procedure to be implemented and used in this specific setting, in accordance with a multidimensional and multi-disciplinary Health Technology Assessment (HTA) approach, considering the Health Authority point of view.

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 methodologies 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], with an evidence-based, more quantitative and objective approach.
The present paper compares laparoscopy with colpoceliotomy through the implementation of a Hospital-Based HTA, namely IMPAQHTA model (*Implementation of a quick Hospital-based HTA*), assuming the Health Authority Civil Hospital of Legnano perspective.
The proposed IMPAQHTA framework was redesigned, based on exiting models: 1) Core Model [13], because of the completeness of its dimensions; 2) Multi Criteria Decision Analysis [14], because of the quantitative scoring methods evaluation; 3) Lombardy Region Model [15], because of its alignment with policies, laws and country-oriented setting.
The IMPAQHTA framework [16] identified 8 dimensions to be used in the assessment phase: *i)* general relevance; *ii)* safety; *iii)* efficacy; *iv)* effectiveness; *v)* economic and financial impact; *vi)* equity; *vii)* legal, social and ethic impact; and *viii)* organizational impact. The above mentioned dimensions could be evaluated using 13 specific quantitative metrics.
The implemented framework is composed by three distinct logical phases:
i) prioritisation of the 8 dimensions of analysis;
ii) evaluation of the technologies, thanks to the support of 13 quantitative criteria for the complete quantitative assessment and the production of a final report;
iii) determination of a concise result, for the final appraisal of the evaluated innovations.
With regards to the first phase, the 8 dimensions composing the framework are prioritized by specific evaluators, in accordance with the VTS-HTA Lombardy Region model [15]. Thus, the dimensions are prioritised in order to show their relative importance through a numerical value, following a rating scale from 1 to 8 (1 = less important and 8 = more important), using the evaluators' judgment in order to define which is the most important dimension.
A clarification is needed. The chief of the Department of Obstetrics and Gynaecology (who was currently using the innovative technology) needed to evaluate all the impact related to the introduction of Colpoceliotomy in the ordinary clinical practice, thus requiring the judgement of the Strategic Board. The prioritization phase involved 5 members of the Hospital Authority, acting as evaluators.
The second phase consists of a detailed analysis of the dimensions; *i)* identification of different evaluation sub-dimensions; *ii)* attribution to each of them, a three level rating score with 1 (less performant), 2 (equal performant) and 3 (more performant) was applied, in accordance to the Mitton Model [17].
For the complete technology assessment, developing the IMPAQHTA framework, a multi-disciplinary HTA team was required: 6 volunteers, with a certified knowledge and skills on HTA, composed an evaluating team and produced an unabridged IMPAQHTA report, useful for the Strategic Board, to take evidence-based choices during the appraisal phase.
The third phase, according to evidence in the literature, regarding EVIDEM Core Model and Multi-Criteria Decision Analysis, leads to the final synthesis, in order to compare the technologies evaluated. The higher the final rating is, the more preferable the technology is. This final evaluation was conducted by the Strategic Board of the reference Hospital, with the inclusion of the Chief of Department of Obstetrics and Gynaecology.
Moving on from these premises, the evaluation of the above mentioned 8 dimensions was conducted by the multi-disciplinary team, with the development of 13 sub-dimensions using specific operative and quantitative tool (Tab. I).
It is important to clarify that the efficacy dimension was not taken into consideration in the present analysis, because the proposed evaluation was a specific need of the Health Authority of reference, thus grounding the assessment on real data referring to the year 2013.
Safety is a relevant dimension to be investigated, one that leads to the evaluation of adverse events, mortality or morbidity, related to the technologies under assess-

Tab. I. Details of the dimensions and the related sub-dimension of the IMPAQHTA model.

Dimensions	Sub-dimensions
General relevance	Quality of scientific evidences
	Description of the pathology and the related technologies
Safety	Seriousness of Adverse Events (mild, moderate or severe adverse events)
Efficacy	Efficacy data
Effectiveness	Effectiveness data
Economic financial Impact	ABC
	Health Economic Evaluation
	Budget Impact Analysis
Equity	Equity data
Legal, social and ethic impact	Legal aspects
	Social and ethical impact
Organizational Impact	Quantitative impact
	Qualitative impact

ment. In particular, it allows the identification of mild/moderate/severe adverse events, considering the population treated with the technology. Since the lack in literature of this specific information, safety data were collecting through specific interviews to clinicians, in relation to their own clinical experience. In particular, safety information refer to all the possible consequences on the patient, related to the use of the innovative technology, in terms of *a)* seriousness of adverse events; *b)* invasiveness of the procedure; *c)* safety in its implementation.
Equity, legal and organizational impacts were investigated using specific questionnaires, completed by both clinicians and patients, in accordance with the items composing the EUnetHTA Core Model. For instance, the equity impact aimed at investigating *a)* access to care on a local level; *b)* access to care for person of a legally protected status; *c)* hospital waiting list improvement and *d)* the invasiveness of the innovative technology.
The legal and the social impact aimed at evaluating both the patients' satisfaction and the related productivity loss.
Furthermore, the organizational impact had the objective to define the perception of the clinicians involved in the innovative procedure and to quantify all the investments needed if organizational changes occurred: *a)* additional people; *b)* additional room; *c)* training course; *d)* meeting and *e)* learning time of the implementation of the innovation, *f)* investment in equipment; *g)* update of the existing equipment; *h)* impact on the internal and the purchasing processes. According to this, all the items composing the above mentioned dimensions have been evaluated by the multi-disciplinary team (with the support of clinicians), with the rating scale proposed by Mitton and colleagues in 2011, as previously mentioned.
With regard to the economic and financial dimension, the method used for the enhancement of the average cost of the two technologies was the *Activity Based Costing analysis* (ABC), which measured the costs and performances of each activity. The concept of ABC was first defined in 1980 by Cooper and Kaplan [18] and it focused on the activity useful for the final output of the offered service; in particular, it gives the cost of a specific product (in this case, a specific technology), according to the activities through the use of cost drivers [19]. The process consists of the following stages [18, 20-21]: *i)* activities' identification; *ii)* definition of the activities' cost; *iii)* definition of the activities' cost drivers; *iv)* definition of the cost drivers' volume; *v)* definition of a unit cost, per cost driver, for each activity and *vi)* calculation of the unit cost per procedure.
Another methodology applied to compare the two technologies is the *Cost-effectiveness analysis* (CEA), an economic evaluation in which the costs of alternative procedures are compared using outcomes measures expressed in natural units [22]. In order to implement the CEA it is necessary to have suitable measures of effectiveness, because this technique expresses health benefits in simple terms, such as years of life gained [23]. From a methodological point of view, CEA is divided into five stages: *i)* definition of the program; *ii)* computation 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.
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 laparascopy) 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 super-imposable in terms of the process' description; however, the spe-

Tab. II. Description of the sample under assessment.

	Colpoceliotomy	Laparoscopy	P-value
N. of patients	118	48	
Mean age [years]	41	39	> 0.005
Length of the 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. III. Prioritisation.

Dimensions	Evaluators					Total	Normalisation
	# 1	# 2	# 3	# 4	# 5		
Safety	3	1	1	1	2	1	0.222
Economic and financial impact	1	2	3	3	1	2	0.194
Effectiveness	2	5	4	5	3	3	0.167
Organisational impact	5	3	5	2	5	4	0.139
Efficacy	7	7	2	4	4	5	0.111
General relevance	6	6	6	6	6	6	0.083
Equity	4	8	7	7	7	7	0.056
Social and ethical impact	8	4	8	8	8	8	0.028

cific 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

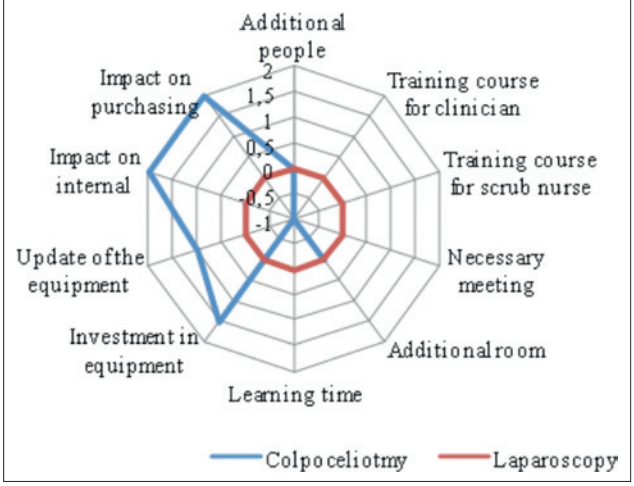
Tab. IV. ABC analysis.

Phases	Laparoscopy		Colpoceliotomy	
Pre-Hospitalisation	305.08 €	17%	305.08 €	23%
Admission	65.62 €	4%	65.62 €	5%
Pre-Surgery Recovery	38.93 €	2%	38.93 €	3%
Surgery	1,089.64 €	61%	636.37 €	48%
Post-Surgery	201.83 €	11%	201.83 €	15%
Discharge	88.33 €	5%	88.83 €	7%
Total	1,789.42 €	100%	1,336.15 €	100%

Tab. V. Cost-effectiveness and Budget Impact Analysis.

Cost-Effectiveness Value	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	CCT	STD
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	€4,530.80	
BIA	€248,088.10	€297,043.55
Δ BIA	-€48,955.45	€/year

Fig. 1. Organizational impact.



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 need: 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 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

Tab. VI. HTA comparative study.

		Basis score				Normalsed score			Final score	
Dimensions	**Sub – dimensions**	**CCT**	**STD**	**TOT**	**Incidence**	**CCT**	**STD**	**Normalized prioritization**	**CCT**	**STD**
Safety		2	2	6	1.5	0.5	0.5			
		4				0.5	0.5	0.22	0.11	0.11
Economic and financial impact	Activity Bases Costing Analysis	2	1	6	0.7	0.2	0.1			
	Cost-effectiveness Analysis	2	1	6	0.7	0.2	0.1			
	Budget Impact Analysis	2	1	6	0.7	0.2	0.1			
		9				0.7	0.3	0.19	0.13	0.06
Effectiveness		2	1	6	2.0	0.7	0.3			
		3				0.7	0.3	0.17	0.11	0.06
Organisational impact	Quantitative Impact	2	1	6	0.9	0.3	0.1			
	Qualitative Impact	2	2	6	0.9	0.3	0.3			
		7				0.6	0.4	0.14	0.08	0.06
Efficacy		2	2	6	1.5	0.5	0.5			
		4				0.5	0.5	0.11	0.06	0.06
General relevance	Consistency of evidence	1	3	6	0.3	0.0	0.1			
	Description of technology and comparator	1	2	6	0.3	0.0	0.1			
	Safety of the new technology and comparator	2	2	6	0.3	0.1	0.1			
	Target Population	2	1	6	0.3	0.1	0.0			
	Consistency of the objectives with the adopted strategy	2	2	6	0.3	0.1	0.1			
	Potential advantaged areas	2	2	6	0.3	0.1	0.1			
		22				0.5	0.5	0.08	0.04	0.05
Equity		2	3	6	1.2	0.4	0.6			
		5				0.4	0.6	0.06	0.02	0.03
Social and ethical impact	Ethical Impact	3	2	6	0.6	0.3	0.2			
	Social Impact	3	2	6	0.6	0.3	0.2			
		10				0.6	0.4	0.03	0.02	0.01
								Results	**0.56**	**0.44**

organizational impact (see Fig. 1): the items related to training course needed for colpoceliotmy 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 colpoceliotmy 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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