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original article

Micro HTA as a tool for clinical governance: the experience of the Breast Unit in "Santa Maria" Terni Hospital

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SUMMARY: **Micro HTA as a tool for clinical governance: the experience of the Breast Unit in "Santa Maria" Terni Hospital.**

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The last decade has witnessed the affirmation of the paradigm Health Technology Assessment (HTA) as a tool for government innovation technology in health care. As is known, this is an approach of evaluation oriented policy making that, in addition to provide for the disclosure of its results, it is proposed to consider simultaneously the clinical, economic, organizational, ethical and social issues arising from the introduction or disposal of a health technology, understood in the broadest sense of the term. In order to reconstruct a realistic picture of its level of implementation we have reproduced a micro HTA which served to assess the Harmonic Focus® device usefulness in breast surgery.

KEY WORDS: Micro HTA - Implementation - Harmonic Focus® in breast surgery.

Introduction

Modern medicine relies increasingly on technological solutions to meet the health needs expressed by the population. Drugs, devices, medical equipment along with diagnostic and therapeutic procedures up to combined modern technologies and genomic ones imply an exceptionally broad and diverse concept of "health care technology" (1, 2). The advancement of the basic scientific knowledge, together with the development of proper skills in the field of medicine offer now the basis for a technological progress that seems to be unstoppable. Technological innovation in the biomedical field is realized according to very unique models compared to other industrial contexts. In the biomedical field it is characterized, *inter alia*, by the particular nature of the assets produced. These assets are adopted as part of a delicate human services as health care and, therefore, in the evaluation of the "innovation efficiency" not only technical and economic factors must be taken into account but also ethical and social factors (4). In particular, the term 'assessment' (rating) in medical technology is used to define a process of multidisciplinary analysis concerning a precise technology, whose characteristics include the effectiveness, safety, directions for use, costs, the relationship between costs and effectiveness, thus involving not only the merely medical area, but also the social, economic and ethical one.

Origins

The HTA was founded in the U.S. in the late 60s when the term Technology Assessment was introduced at the U.S. Congress by Congressman Emilio Q. Daddario, a member of the Committee on Science and Astronautics. It was born as an analysis tool to evaluate the economic, social and legal impact of the new technologies supporting policy-makers (3). In addition, the Cochrane Collaboration was born in 1970s with the aim to collect, evaluate and provide information on the effectiveness of health interventions. Even in this case everything aims at selecting technologies based on their effectiveness (capacity to make the patients benefit from them) and to make an efficient use of these resources. In 1985 the Health Technology Assessment International (HTAi) was born as an international scientific

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society that connects all those professionally concerned with health technology assessment in universities, health care systems, industries and in the voluntary sector. In 1993 the International Network of Agencies for Health Technology (INAHTA), which coordinates and promotes cooperation among the 52 international non-profit organizations belonging to it, was founded by thirteen founding members Amongst these, eleven were created before 1995 while the other thirty-two were born later; they all are non-profit organizations, almost exclusively financed from public resources; twenty-four reflect the government authorities (technical bodies) and they all carry out assessments on medical devices (6, 7).

The rationale

Health technology is the practical application of a certain knowledge to prevent, diagnose, cure a disease. This term does not refer only to devices and equipment, but also embraces clinical procedures, prevention programs, drug treatments, organization and management systems; precisely, the following aspects: **performance**: the sensitivity and specificity of diagnostic tests, the compliance with manufacturing, reliability, ease of use and maintenance specifications; **clinical safety**: acceptability of a risk associated with the use of a technology in particular situations; **effectiveness:** a benefit obtained by using a technology in relation to a specific problem both in 'ideal conditions' (clinical efficacy) and in general routine conditions (effectiveness of practice); **economicity:** at the microeconomic level, it deals with the incidence of the costs, fees and reimbursement methods, while at the macroeconomic level it considers the effects the new technologies can have on the costs of the Healthcare System or the effects a technology can have on the allocation of the resources between different health programs or between different Healthcare sectors. Therefore the process of Health Technology Assessment (HTA) represents the 'bridge' between the scientific and technical world and that of the decision makers (policy makers); its aim is to assist and advise within proper health policy choices those who have decision-making power in the health sector (8).

The choice can be made at all levels: micro (evidence-based health care practice), meso (evidence-based management), macro (evidence-based health policy). The evaluation process may therefore be useful in the decision support when a technology is quite complex and is characterized by many uncertainties; a treatment or a diagnostic test is innovative or controversial; a proven technology is involved in significant changes in usage and results; a technology is expensive (7, 9).

Patients and methods

The proposed study involved all patients who underwent radical mastectomy or quadrantectomy and axillary lymphadenectomy at the departmental structure of Senology in "Santa Maria" Terni Hospital in the first half of 2012, and it was conducted on the basis of parameters that formed the study checklist. Our objective was to evaluate the clinical and organizational impact with Harmonic Focus on the surgical treatment of breast cancer using the HTA methodology to assess and analyze the efficacy and safety in the surgical treatment of breast cancer (10); to describe the level of adoption and use in our medical facility assessing the economic impact in our clinical practice and in the organization; to assess the impact that the use of technology can have on the patient.

Discussion

The comparison between the results and the studies analyzed has showed that the use of Harmonic produces a simplification of the surgical phase, bleeding reduction as well as a greater respect for human tissues thus reducing the operative time and hospitalization of the patient (11, 12, 17). As regards the specific organizational aspects, here considered in a broad sense, and referring to what emerged not only from the literature but in particular from the questionnaires, it can be said that the use of the new technology as analyzed in this study can provide remarkable improvements if it is used properly. In particular, there has been an increase in the dissection skill and in the accuracy of the surgical procedure which could provide more detailed information in terms of increased efficiency with a certain improvement of the organization, once quantified in greater depth. The completion of the surgeons' learning curve appears to be essential for this purpose: proper experience in the use of the instrument affects the reduction in the appearance of peri- and postoperative complications and consequently in the hospital length of stay (13-15). At the same time, the positive information concerning the length of the surgery, the multi functionality of the technology as well as the reduction in the use of other devices make affirm that all the organizational system, for example the individual operating rooms, could take considerable advantage of it. Moreover, the observed reduction of complications, such as seroma and hematoma, the reduction of surgical wound infections related to the reduction of the suction drainage of any postoperative collections, the reduction of involuntary muscle spasms, inevitable when the patient is operated with normal electrosurgical unit, may lead to an improvement in terms of organization and management of the structure providing the performance. Obviously, the impact in terms of cost reduction in favor of the structure should not be forgotten. Technology can be introduced immediately, since the generator is present in the surgery unit of the hospital. In particular, the code FCS9M has already been recorded and en-

coded by the Hospital therefore, it should not follow the paths involved in the introduction process of "new products". The reduced recovery time compared to the average duration with a standard technique will allow departments to increase hospital bed turnover rate (16, 18, 19). This could be a benefit to reduce waiting lists thus increasing profitability. At the same time, the patient can return to work earlier or resume normal activities in a much shorter time, reducing the impact on the costs of the Social and Health System. The lack of specific economical studies makes difficult a cost-efficacy evaluation on the use of the HF in the surgical interventions for breast carcinoma; therefore we decided to compare the estimate of costs of the single procedure in our structure with the DRG (Diagnosis Related Group) fares reported in the 2009 *TUC* (*Tariffa Unica Convenzionale*). In order to estimate the total cost per procedure we have considered: the cost of purchasing the technology, the cost of human resources involved, the cost of the operating room, the cost of hospitalization. In order to estimate the total cost per procedure we have considered: the cost of purchasing the technology, the cost of human resources involved, the cost of the operating room, the cost of hospitalization. An inner "survey" allowed to collect information concerning: the staff involved in the execution of the surgical procedure, the execution time of the surgical procedure (incision - suture), the total amount of operating-room time and the devices used in the procedure. To connect the cost of the time spent by all human resources involved, we have considered the National Collective Labor Agreement for the Medical and Veterinary management in the National Health Service and the average salary of the management staff in "S. Maria" Terni Hospital. The cost of the devices has been calculated on the basis of the prices applied by the supplier.

From the analysis of medical records of patients who had received surgery for breast cancer, it was possible to obtain information about the average days of hospitalization which, in turn was multiplied by the average cost for inpatient fund at our hospital (500 €). The cost of the operating room has been calculated by multiplying the time of occupation of the room to the cost per minute (Table 2).

The estimated total cost per procedure, obtained by adding all the cost elements previously calculated (Table 3), was subsequently linked to the value of the ordinary hospitalization in the DRG 258 and 260, respectively "Total mastectomy for malignancy without complica-

TABLE 1 - COST OF HUMAN RESOURCES INVOLVED IN THE PROCESS.

	Human resources involved per single procedure	Time needed per procedure (min)	Gross cost per year (€)	Minutes of work per year	Cost per min. (€)	Cost per procedure
Surgeon	1	63	77.633,40	118.560	0,65	€ 41,25
Associate surgeon	2	63	77.633,40	118.560	0,65	€ 82,51
Anesthesiologist	1	100	77.633,40	118.560	0,65	€ 65,48
Nurse	2	100	39.602,57	112.320	0,35	€ 70,52
Total						€ 259,76

TABLE 2 - AVERAGE COST FOR ROOM AND INPATIENT PROCEDURE.

Hospital stay cost				**Cost of the operating room**			
Hospitalization	Unit cost	Days	Total	Operating room cost per hour	Operating room cost per min	Room occupation time per procedure (min)	Total
Ordinary	€ 500	1,33	€ 655	€ 441,81	€ 8,27	100	€ 827,00

TABLE 3 - ESTIMATED COST PER PROCEDURE.

Devices cost	**Human resources cost**	**Operating room cost**	**Inpatient cost**	**Total**
€ 611,7	€ 259,8	€ 827,0	€ 655	€ 2.353,5

TABLE 4 - ESTIMATED COST PER PROCEDURE COMPARED WITH THE TUC DRG 258 AND 260 RATES (IN € 2009).

Procedure cost	DRG 258	DRG 260
€ 2.353.5	€ 5831	€ 4434

tions" and "Subtotal mastectomy for malignancy without complications" (Table 4).

Our cost analysis has showed that, despite the acquisition cost of the medical device, surgery for breast cancer has a value that is fully within the DRG rates associated with these procedures (respectively mastectomy and total/subtotal mastectomy). It should be considered, moreover, that it does not take into account the consumption of anti-inflammatory drugs and the management of the complications that could be reduced considering the benefits associated with a lower tissue damage induced by the use of the ultrasonic scalpel. On the basis of clinical experience so far with our attempt to estimate the costs of the procedure, we argue that the simplification of surgery and the reduction of the complications associated with it, can have a positive impact on the organization in terms of reduction of costs related to the reduction of days of hospitalization and the costs of the management of the complications. Our study has tried to assess the costs of the procedure derived from the observation of the cases treated in our hospital in the first half of 2012 and from the analysis of literature evidences. We recognize that the analysis carried out is an underestimation of the actual costs associated with the surgical procedure for the treatment of breast cancer, but it may equally provide a general vision desirable to happen in clinical practice.

Conflict of interest

The authors declare that they have no competing interests.

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