Breath tests sustainability in hospital settings: cost analysis and reimbursement in the Italian National Health System

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Abstract. The high demand of Breath Tests (BT) in many gastroenterological conditions in time of limited resources for health care systems, generates increased interest in cost analysis from the point of view of the delivery of services to better understand how use the money to generate value. This study aims to measure the cost of C13 Urea and other most utilized breath tests in order to describe key aspects of costs and reimbursements looking at the economic sustainability for the hospital.

A hospital based cost-analysis of the main breath tests commonly delivery in an ambulatory setting is performed. Mean salary for professional nurses and gastroenterologists, drugs/preparation used and disposable materials, purchase and depreciation of the instrument and the testing time was used to estimate the cost, while reimbursements are based on the 2013 Italian National Health System ambulatory pricelist. Variables that could influence the model are considered in the sensitivity analyses.

The mean cost for C13 - Urea, Lactulose and Lactose BT are, respectively, Euros 30,59; 45,20 and 30,29. National reimbursement often doesn't cover the cost of the analysis, especially considering the scenario with lower number of exam. On the contrary, in high performance scenario all the reimbursement could cover the cost, except for the C13 Urea BT that is high influenced by the drugs cost. However, consideration about the difference between Italian Regional Health System ambulatory pricelist are done.

Our analysis shows that while national reimbursement rates cover the costs of H2 breath testing, they do not cover sufficiently C13 BT, particularly urea breath test. The real economic strength of these non invasive tests should be considered in the overall organization of inpatient and outpatient clinic, accounting for complete diagnostic pathway for each gastrointestinal disease.

Introduzione

Breath tests (BT) provide a valid non-invasive diagnostic method with high patient acceptance in many gastroenterological conditions. The 13C-urea breath test[1] detecting gastric Helicobacter Pylori infection is probably the best known, best standardized and most widely used breath test[2]. Other breath tests are widely used to diagnose carbohydrate malabsorption, intestinal motility disturbances and bacterial overgrowth in the small intestine by lactose, lactulose or glucose hydrogen-breath tests[3]. Finally, several breath tests have been proposed for different settings and they gather increasing interest, both in research and in clinical care. Among those, particularly important seem to be breath tests for gastric emptying, pancreatic function and liver function.

The great burden of gastroenterological diseases explains the increasing demand of these diagnostic tools: it has been estimated in 20% - 40% the prevalence of dyspepsia in the general population (12-15% of them has functional dyspepsia), with an incidence up to 2.8% per year[4]. Furthermore, infection with Helicobacter pylori is widespread and is recognized as a common condition of major clinical and economic importance. About half of the world population is estimated to be infected by HP[5,6]: the worldwide prevalence is between 30% and 60%, with higher

pick of 84.1% reached in a general population sample from Japan[7]. Recently, it was reported a median cumulative incidence of 4.5%, ranging from 0% to 49.4%, over median follow-up times of 5 years (range 0.45-32 years)[8].

Breath tests are usually request from both general practitioner and specialist, but it is not easy to perform and requires hospital settings or specialized laboratories.

In Italy, hospitals generally deliver this test in an ambulatory settings (outpatient clinic): patient can be required to give a co-payment and the test is reimbursed by the national health service, according to regional pricelist. The national pricelist encode only four breath tests: C13 urea breath test, H2 breath test for bacterial overgrowth (glucose BT and lactulose BT), oro-caecal transit time (lactulose BT). The regional tariffs vary widely from Region to Region and in some case are considerate inadequate to cover the cost: the national (and minimum) tariff for C13 urea BT is 13.94€, with a maximum of 44.34 in Lombardia Region, while for Bacterial Overgrowth, oro-ciecal transit time (lactulose breath test) and lactitol breath test the national tariffs are, respectively, 41.83€, 74,89€, and 27.89€, with a minimum in Puglia Region of 38.90€, 69.64€ and 25.90€ respectively and a maximum in Piemonte Region of 59.85€, 107.10€ and 39.90€ respectively. Lazio Region tariff is according to the national pricelist.

Several papers analyzed the economic implication of the C13 breath test from the perspective of the national health service: Gee at al report that direct referral to a HP breath test service saves about 14 pound per person with dyspepsia (including treatment of positive patients and endoscopy cost of patients endoscoped) in respect of the breath test service had not existed[9], and several study analyze or review the cost-effectiveness of the BT in respect of the other possible strategy, with different results that go beyond the objective of this study[10]. However, little is known about the Hydrogen breath test and especially from the perspective of the service providers (e.g. hospitals).

The increasing cost in health settings in time of limited resources generates increased interest in cost analysis of high prevalence diseases both for health systems, to decide the best resource allocation, both for the delivery of services, to understand which productivity line are feasible.

Considering the high prevalence of the above mentioned diseases, the high request of the breath tests and the difference in the regional reimbursement, specific cost data could be useful for the management of hospital to decide the best way for the delivery of the service in ambulatory settings. This study aims to measure the cost of 13C, H2-lactulose and H2-lactose breath test in order to describe key aspects of costs and reimbursements.

Source data

A hospital based cost-analysis of the delivery of several breath test in ambulatory setting was performed. Mean salary for professional nurses and gastroenterologists was obtained from the internal administrative database and results in conformity to Italian National Collective Agreements. The hourly salary rate was multiplied by 1.13 (52/46) to account for vacation days and holidays[11].

Costs for the delivery of breath test are associated with the preparation used, disposable materials, purchase and depreciation of the instrument and the testing time. All these variables are considered in the sensitivity analysis.

In the base model we have utilized the average wholesale price of C13 Urea, H2-Lactulose and H2-Lactose at a single oral dose of, respectively, 75-100 mg, 20 g and 25 g, according to guideline recommendations (Gisbert JP, Pajares JM. Review article: 13C-urea breath test in the diagnosis of Helicobacter pylori infection – a critical review. Aliment Pharmacol Ther 2004; 20: 1001-1017) (Malfertheiner P, Megraud F, O'Morain CA, Atherton J, Axon AT, Bazzoli F, Gensini GF, Gisbert JP, Graham DY, Rokkas T. Management of Helicobacter pylori infection – the Maastricht IV/ Florence Consensus Report. Gut 2012; 61: 646-664).

However, the cost of the C13 UREA, as costs of lactose and lactulose, are influenced by the choice of agent and contract price, varying, respectively, between 9€ and 20€ and from 40 cent to 10 euro each dose.

Disposable materials costs were obtained from the internal administrative database. Finally major differences could be found also in equipment costs and utilization.

C13 urea breath test could be read by infrared or mass spectroscopy[12-14], and this could produce initial costs for devices ranging from 10,000€ until 75,000€ or more.

H2 breath tests analyser could also vary between 10,000€ until 18,000€ or more. Two major types of instruments could be described: machines using a solid state sensor and machines using electrochemical sensor[3]. Machines using a

Figure I.
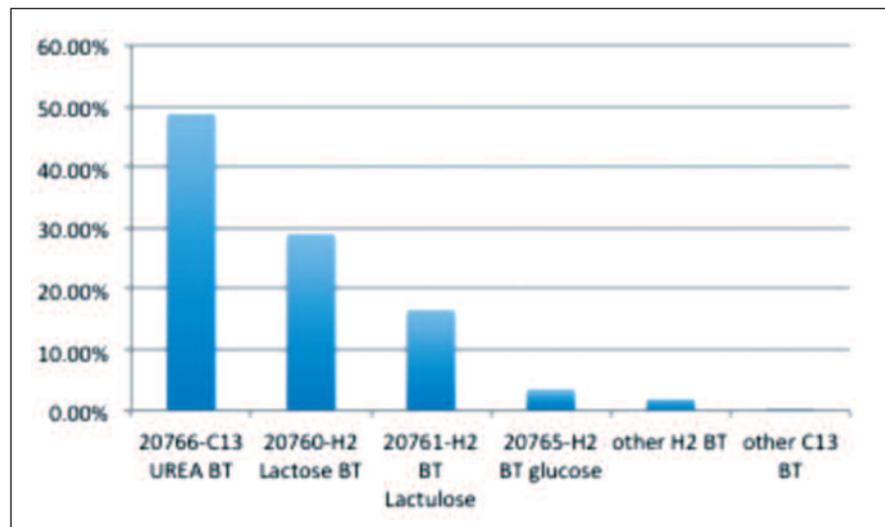
solid state sensor were the first to be proposed for H2 breath testing and usually they are more stable, accurate expensive then the other machines. Electrochemical sensor machines are usually also portable, being handler[3].

The basic model utilized for this paper accounts for the mass spectroscopy when dealing with C13 breath testing and with machines with solid state sensor for H2 breath tests, as both facilities are available in our Institution.

For each instrument was considered a depreciation virtual time of 8 years and an annual maintenance cost between 10 and 20% of the overall cost of the instrumentation.

The cost of labor for in-house breath testing was determined by summing the times to explain the test to patients (physician), set up, read, and enter results of testing into the computer system (professional nurse) and reporting (physicians). Mean total testing time was estimated trough pilot direct observations in our clinic. The cost of the purchase and depreciation of the instrument is influenced by the number of breath tests delivered and it was considered in the sensitivity analyses. Medication acquisition cost was added to labor cost and the price of testing to determine the overall cost of the breath test. Reimbursement rates for the breath test were based on the 2013 Italian National Health System ambulatory pricelist.

Results

Figure 1 represents the percentage of breath test performed by the gastroenterological division of our Teaching Hospital. C13 BT is the most commonly utilized (50% of all tests performed yearly), followed by H2 - Lactose BT (about 30%) and H2 - Lactulose BT (about 15%). Other C13 breath tests different from Urea display a relatively low relevance. The base model of the cost-analysis for C13 - Urea, Lactulose and Lactose BT are reported in Table I. The mean cost for these BT are, respectively, Euros 30,59; 45,20 and 30,29. Sensitivity analysis considering best and worse scenario are reported in Table II.

Mean time of C13 Urea breath test varies from 10 to 15 minutes, price of the drug also varies being the range of 10-20 Euros per test/unit. Finally, a big difference in costs of the instruments utilized for test assessment is also present, ranging from few thousands, in the case of infra-red machinery, up to 1 hundred thousand considering mass spectroscopy. National health system pays Urea breath test 13.94, even if with some Regional exceptions: this cost is clearly underestimating the real cost of the test within a

Table I. Cost analysis – base model.

Base Model	C13 BT	H-2 Lactulose	H2- Lactose
Number of exam/year	2000		
Timing (min)	11	43	27
Cost of labour (€)	9,40	34,95	22,20
Medication and instrumentation costs (€)	21,19	10,25	8,09
Total Cost (€)	**30,59**	**45,20**	**30,29**

Table II. Cost analysis – summary of the sensitivity analysis: Best and Worst case.

Scenario	Substrate	Number of BT/Year	Labour Timing (min)	Cost of labour (€)	Medication and instrumentation costs (€)	Total Cost (€)
Best case: higher number of exam (5000 BT/year); better instrumentation (more expensive, but requiring less labour time); lower medication prices.	C13BT	5000	10	8,00	12,48	**20,48**
	H2 lactulose	5000	26	21,35	9,11	**30,46**
	H2 lactose	5000	18	15,00	7,75	**22,75**
Worse case: lower number of exam (200 BT/year); economic instrumentation (cheaper, but requiring more labour time); higher medication prices	C13 BT	200	15	12,60	32,38	**44,98**
	H2 lactulose	200	62	50,20	17,88	**68,08**
	H2 lactose	200	36	29,40	15,875	**45,275**

public hospital. Similar consideration could be done for the other tests: a comparison between costs and National/Regional Reimbursement according to the base model and sensitivity analysis are reported in Table III.

Discussion

Much work has been done to evaluate the best strategy to assess dyspepsia in terms of efficacy and cost-effectiveness, being as other gastro-intestinal diseases, a high prevalent disorder in the eyes of the National Health Service perspective. However this is the first attempt to evaluate costs and remunerations for breath test in a large Italian third level hospital, using the perspective of the healthcare providers. This study, in particular, analyzes costs for C13 and H2-Lactulose/Lactose breath tests, the most utilized breath tests in our hospital and perhaps in Italy, in order to investigate its economic sustainability for the hospital.

The results of our model indicate an interesting situation: while for both H2-Lactulose/Lac-tose breath test the National tariff could cover the cost of the diagnostic, for C13 breath test the National reimbursement is quite lower and only 2 Regional pricelists (Lombardia and Friuli) fully cover its cost. The major determinant of C13 urea breath test cost is determined by the cost of the C13 UREA, a parameter that could be influenced by the choice of the local agent and contract price. However, according to our sensitivity analysis, even in the best case, with the lowest price of the substrate, Urea breath test tariff does not contra-balance the cost of the test. Face to this, urea breath test itself, for the diagnosis of helicobacter pylori infection, could save numbers of inpatients and outpatients gastroscopies, resulting in a cost-effectiveness test. (Sreedharan A, Clough M, Hemingbrough E, Gatta L, Chalmers DM, Axon AT, Moayyedi P. Cost-effectiveness and long-term impact of Helicobacter pylori 'test and treat' service in reducing open access endoscopy referrals. Eur J Gastroenterol Hepatol 2004;16: 981-986).

Table III. Cost analysis – summary of the sensitivity analysis.

Substrate	Name of the test in the National Registry	Basal cost	Range (best-worst case)	National Italian price 2013	Regional Range
C13 - Urea	Helicobacter Pylori BT	30,59	20,48 - 44,98	13,94	13,94 - 44.34
Lactulose	Bacterial overgrowth BT	45,20	30,46 - 68,08	41,83	38.90 – 59.85€
Glucose (similar to lactose)	Bacterial overgrowth BT	30,29	22,75 - 45,28	41,83	38.90 – 59.85€
Lactulose	Oro-caecal transit time BT	45,20	30,46 - 68,08	74,89	69,64 -107,10
Lactose	Lactose BT	30,29	22,75 - 45,28	27,89	25,90 - 39,90

Same problems arise also with other C13 breath test, as cost of substrate is high together with a longer time per test (from 2 to 6 hours). C13 breath tests (other than Urea) are now considered "research tests", as substrates are not clearly categorized as "aliment" or "drug". The lack of clear rules, together with non-standardized methods, make C13 breath test (other than urea) difficult to set up in a clinical setting.

For the H2-Lactulose/Lactose breath test one of the main source of cost is represented by the time of the professional nurse employed in the test detection, while the medication doesn't influence the overall cost. Of note is the importance of machines selection and utilization. Based on our analysis, the instrument represents a great expenditure, both for its purchasing that for the maintenance, and it is influenced by the number of performed tests.

In our analysis, considering respectively 1800 yearly C13 urea breath test, 600 H2 Lactulose breath test and 1000 H2 Lactose tests/year, using a mass spectroscopy machine and a solid state sensor chromatography, the estimated cost for each exam derived from the instruments utilization are, respectively, of 5.63€, 2.17€ and 1.20€.

It seems to be very important, for the correct allocation of resources, decide the type of machines based on number of exams and expertise. Our paper, however, is not meant to give any qualitative judgment on types of machines.

Going back to reimbursement, it is important to highlight that, even if Italian National pricelist has been recently updated[15], tariffs for breath test remain the same since 1996, when they were first introduced in Italy. Since then the cost of personnel, instrument and substrates raised up. In this sense, a possible solution to reestablish loss and gain for C13 breath test is, for example, to reimburse the cost of the drug separately, like in Tuscany Region.

However, in a big division with a complex economical system, urea breath test will probably poorly affect overall budget, particularly when associated to other tests like H2 breath tests, with a potentially positive balance between direct costs and tariff. In order to cut costs, particularly for C13 breath test, external service has been proposed. However, being the cost of the substrate a major contributor for C13 breath testing total costs, we think that service is just an option for big clinical centers.

This study has several limitations: first of all our cost analysis reflects a specific setting for the delivery of breath tests, represented by our institution, a teaching hospital. In this setting costs should not be major limiting factors for technologies, as university is the right place for research and teaching. Secondly, cost estimates of diagnostic kit used may differ among institution according to private negotiations.

Furthermore in our analysis we did not consider training costs, considered, in this case, negligible. Finally, we have performed a simple cost analysis from an hospital perspective, however it is more correct to promote cost-effectiveness evaluation of a diagnostic work up specific for each specific gastrointestinal disease.

Conclusions

Given the high request of non-invasive diagnostic tests in gastroenterology, cost analysis is crucially important from the perspective of the provider and also in view of rationalizing health system. Our analysis shows that while national reimbursement rates largely cover the costs of H2 breath testing, they do not cover sufficiently C13 BT, particularly urea breath test.

The real economic strength of these non-invasive tests, however, is not sufficiently measured as it should be considered in the overall organization of inpatient and outpatient clinic, accounting for complete diagnostic pathway for each gastrointestinal disease.

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Conflict of interest

The Authors declare that they have no conflict of interests.

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