Diagnostic pathway of syncope and analysis of the impact of guidelines in a district general hospital. The ECSIT study (Epidemiology and Costs of Syncope In Trento)

Maurizio Del Greco, Susanna Cozzio*, Marco Scillieri**, Francesca Caprari***, Alessandro Scivales***, Marcello Disertori

*Division of Cardiology, *Division of Internal Medicine, **Medical Management, S. Chiara Hospital, Trento, ***Health Economics Research Center, Fondazione Medtronic Italia, Milan, Italy*

Key words:
Costs; Guidelines; Syncope.

Background. **The ECSIT study was aimed at evaluating the hospital management of syncope patients, at comparing the appropriateness and costs of the hospital diagnostic pathway before (phase 1) and after (phase 2) the introduction of new guidelines and at analyzing the physicians' compliance to the guidelines.**

Methods. **All syncope patients admitted to the emergency room between August 1 and October 31, 1999 (phase 1) and between March 1 and May 31, 2000 (phase 2) were enrolled and their clinical records were analyzed in a blind fashion.**

Results. **During the study 538 consecutive patients came to the emergency room for syncope with a hospitalization rate of 53% in phase 1 (n = 151) and of 42% in phase 2 (n = 107). The in-hospital stay increased from 9 days in phase 1 to 11.3 days in phase 2 and diagnostic tests from 2.6 per patient (phase 1) to 2.9 per patient (phase 2) with total costs that rose from €3,474 to €3,647. Patients with no diagnosis decreased from 51 to 45.8% and the principal causes were identified as vascular brain disease (36.1 vs 33.7%) and neurally-mediated mechanisms (35.3 vs 42.2%).**

Conclusions. **Despite the high costs of syncope management, the appropriateness and efficacy of the hospital diagnostic pathway remains far from ideal and simply introducing new guidelines seems unable to modify clinical practice.**

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Address:

Dr. Maurizio Del Greco

*U.O. di Cardiologia
Ospedale S. Chiara
Largo Medaglie d'Oro, 1
38100 Trento
E-mail: DelGreco@tn.aziendasanitaria.trentino.it*

Introduction

Syncope is commonly defined as a transient loss of consciousness and of postural tone with spontaneous recovery, and is often considered a puzzling disease for clinicians. It is responsible for 3% of emergency-room (ER) visits and for 1% of hospital admissions[1-3] and between 12 and 48% of the population will experience at least one syncopal episode during their lifetime even if the majority of these episodes are not investigated[4,5].

In most cases, the initial clinical and laboratory investigations (detailed clinical history, 12-lead ECG and physical examination with a combined diagnostic yield of 50%)[5-7] produce precise diagnoses. However, in certain cases even with additional diagnostic and laboratory tests, the diagnosis for patients with recurrent syncope remains a common and challenging problem. This is because it may result from a wide range of possible causes (cerebrovascular, neurally-mediated or cardiac) and because of the intermittent and infrequent recurrence of symptoms.

Overall, the mortality and serious morbidity associated with syncope are generally rare but in high-risk patient groups with cardiac causes the 1-year mortality reaches 33%[2,5].

Patients with recurrent unexplained syncope frequently undergo extensive investigations which consume significant health care resources: every year, in the United States, syncope accounts for more than 1.5 million physician visits and 150 000 hospitalizations with resulting costs exceeding $1 billion[8]. The average cost of a diagnosis is $23,000 (data from 1982) and the average length of stay (LOS) is 9 days. In spite of these high costs many patients remain without a conclusive diagnosis.

Given the extent and gravity of this clinical problem, we decided to analyze syncope management (from ER admission to hospital discharge) by evaluating the clini-

cal and economic outcomes in the S. Chiara Hospital of Trento, a third level Italian hospital. The aims of the study were:
• to observe the current hospital diagnostic pathway (HDP) of syncope patients in order to evaluate the appropriateness of patient management (phase 1) and the relevant costs;
• to evaluate the clinical and economic impact of the implementation of national guidelines on the HDP (phase 2).

Introducing guidelines should: 1) reduce variability in the approaches; 2) increase the diagnostic yield; and 3) decrease the costs associated with patient management and its organizational impact on the hospital structure.

Methods

The investigation involved the S. Chiara Hospital of Trento, a third level hospital which is fairly representative of the situation at a national level in terms of structure complexity and of DRG case-mix. The hospital chosen for the study (about 1000 beds) is situated in the autonomous region of Trento and, being the principal public hospital in the area, attracts the vast majority of the patients from that region (500 000 inhabitants).

First of all, we conducted a feasibility study on the epidemiology of syncope using the hospital administration's DRG database from 1998 in order to establish the workload involved. Providing a gold standard HDP for syncope patients can be difficult because syncope is a symptom of various correlated pathologies. This renders patient selection rather problematic. Consequently, in the light of these problems and of the study objectives, we elaborated a very simple protocol in which we enrolled only those patients admitted to the ER because of a loss of consciousness as the only or prevailing symptom.

ECSIT study design. In order to select the patients to enroll in the study (according to the above-mentioned criteria) we performed an analysis of the ER admission records of all syncope patients for 3 months (from August 1 to October 31, 1999). The existing HDP was assessed by analyzing the selected clinical records (only in the hospitalized patients) and the relative diagnostic yield and hospital costs were subsequently defined (phase 1). At the end of this first phase several meetings were organized with the physicians involved in syncope evaluation (general medicine, cardiology, geriatrics, neurology, hospital management staff and ER staff) with the aim of reaching a consensus on best practice, admission indications, tilt testing and the neuro-imaging test specificity in accordance with the task force ANMCO guidelines published in 1995[9]. Thus, new internal guidelines were drawn up and publicized within the hospital by means of a general meeting and the distribution of 100 handbooks and 10 posters. Subsequently, we analyzed the clinical records of the patients enrolled in phase 2 (3 months, from March 1 to May 31, 2000) to evaluate the impact of the guidelines on the HDP and relevant costs.

Data collection. This was done through blind assessment (two physicians not involved in the study) of the HDP by analyzing clinical records. Patient data were collected by dividing patients into the following four categories:
• certain diagnosis (class 1): when a direct and certain correlation between the pathological event and syncope symptoms was demonstrated. This is possible in two cases: 1) if, during hospitalization, syncope spontaneously develops in conditions in which it is possible to accurately record the event (e.g. an atrioventricular block during ECG) or 2) if syncope is reproducible in the laboratory;
• probable diagnosis (class 2): during the diagnostic iter, a cause which can produce a syncope is identified but not reproduced;
• hypothetical diagnosis (class 3): the clinical characteristics of syncope allow a diagnosis to be made even if no pathologies are identified;
• no diagnosis (class 4): when the identified pathologies do not justify the development of syncope and the clinical characteristics do not allow the identification of a specific class (so-called unknown syncope).

To correctly assess the category for each patient, the two physicians only considered the type and number of diagnostic syncope tests carried out during hospitalization. Diagnostic and therapeutic procedures regarding co-morbidity were not used.

The diagnostic tests employed were: electrocardiography, electroencephalography, exercise testing, brain imaging, echocardiography, carotid sinus massage, head-up tilt testing, electrophysiological study, carotid echo-Doppler, and neuro/cardio consultancy.

The drawing up and distribution of guidelines. The diagnostic flow-chart implemented during the second observational 3-month period was developed through meetings with the physicians involved (general medicine, cardiology, geriatrics, neurology, hospital management staff and ER staff), in line with the most recent national guidelines for diagnosing syncope[9]. The flow chart (Fig. 1) was distributed to each department involved in the study in poster form and all physicians received a handbook containing information about the aims of the study, the first phase results, the guidelines to admission according to Olshansky[10], an introduction to the flow chart and the main indications for the various diagnostic tests (neurological tests and tilt test).

Statistical analysis. In the present study, data concerning the patient's sex, age, hospitalization ward, admission and discharge diagnoses, syncope class

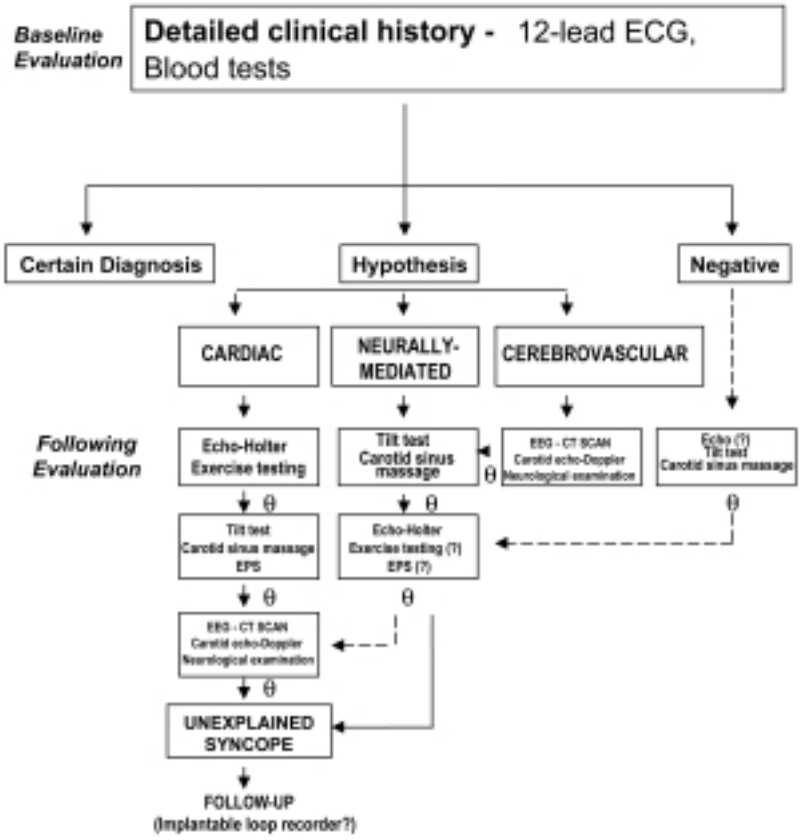


Figure 1. *In line with the most recent national guidelines for diagnosing syncope, the diagnostic flow-chart implemented during the second observational period was developed through meetings with the physicians involved. θ = no diagnostic test for syncope; ? = to evaluate according to circumstance. CT = computed tomography; EEG = electroencephalogram; EPS = electrophysiological study.*

(cerebrovascular, cardiac, neurally-mediated, metabolic, psychiatric and other class), LOS, syncope recurrence, traumas and the tests carried out in the ER and in the various wards were collected. All data were considered as percentages and to determine the level of significance we used the Mann-Whitney two-tailed non-parametric test and the Fisher's exact test for a 2×2 table.

Cost evaluation. To identify the current HDP for syncope, we tried using an activity based management methodology but the excessive variability of the diagnostic approaches (even inside the same departments) rendered such an approach impossible. For this reason we only collected data which concerned the diagnostic tests used.

Considering that it was impossible to estimate the useful economic working life of the diagnostic and structural equipment used during the examinations and during hospitalization and in view of the fact that there was no correspondence between the records of depreciable assets and gathered data on the assets of the different wards involved in the study, the costs of diagnostic tests were calculated according to the current outpatient rates while the costs for in-hospital stays were calculated using the hospital accounting reports (1999).

Results

A pilot retrospective study on the incidence and management of syncope had already been performed in 1998 in the main hospital (S. Chiara Hospital) of Trento (110 000 inhabitants). This study revealed that syncope accounted for 1.5% (n = 838) of ER visits, 44.4% of which resulted in hospitalization in 12 different departments. In total, 429 patients (1.01% of hospitalizations) were discharged with a diagnosis of syncope producing DRGs of €1,173,999.49. The mean duration of the in-hospital stay was 6.63 days. The results of this study highlighted the importance of this therapeutic area and indicated the direction which should be taken by the ECSIT study.

During the first observational period (phase 1), 285 consecutive syncope patients came to the ER (1.7% of the total ER patients) and 151 (53%) were subsequently hospitalized in 12 different clinical wards with a mean LOS of 9 ± 5.6 days (range 1-30 days). There were 77 males (51%) and 74 females (49%), the mean age was 69.6 ± 17.3 years (range 14-95 years) and 51 (33.8%) had recurrent episodes. The general medicine and geriatric wards admitted the majority of cases (51 and 20.5% respectively) followed by cardiology (11.3%), neurology (10.6%) and other wards (6.6%) (Fig. 2).

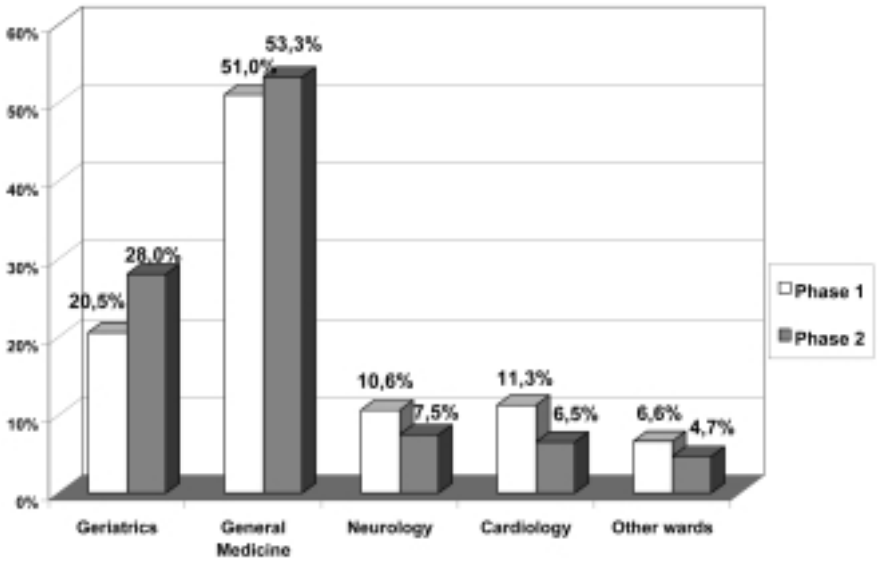


Figure 2. *Percentage distribution of hospitalization in the two phases: no significant changes were identified.*

On discharge, the principal results were: for 12 patients (7.9%) a specific diagnostic conclusion was reached, for 62 patients (41.1%) a probable cause of syncope was identified, whereas 77 patients (51%) were discharged with no conclusive diagnosis (for 45 of these a hypothesis was formulated). Cerebrovascular syncope was diagnosed in 36.1% of cases, neurally-mediated syncope in 35.3% and cardiac syncope in 20.2%. Other causes were identified in 8.3% of patients (Fig. 3). Cardiac causes constituted 83.3% of the certain diagnoses, neurally-mediated causes constituted 73.3% of the hypothetical diagnoses, and cerebrovascular causes accounted for 56.5% of the probable diagnoses.

During hospitalization an average of 2.6 diagnostic investigations were necessary in order to diagnose syncope. Figure 4A shows that in 56.3% of patients at least three tests were carried out. This percentage rose to 66.1% for class 2 (probable diagnoses). The percentage distribution of patients who underwent different tests was: brain imaging tests 36%, electroencephalography 30%, echocardiogram 24%, carotid echo-Doppler 22%, Holter monitoring 19%, carotid sinus massage 2%, head-up tilt testing 1%, and electrophysiological study 1% (Fig. 5).

To manage these patients, the S. Chiara Hospital spent €257,085.70 with a mean diagnosed syncope cost per patient of €3,474.13 (with a low value in cardiology at €2,159.58) (Table I).

After processing and distributing the new guidelines, a second survey (phase 2) was carried out during which 253 consecutive patients came to the ER (1.5% of the overall admissions). The hospitalization rate decreased from 53% (151 patients) to 42% (107 patients) ($p < 0.01$). There were 49 males (45.8%) and 58 fe-

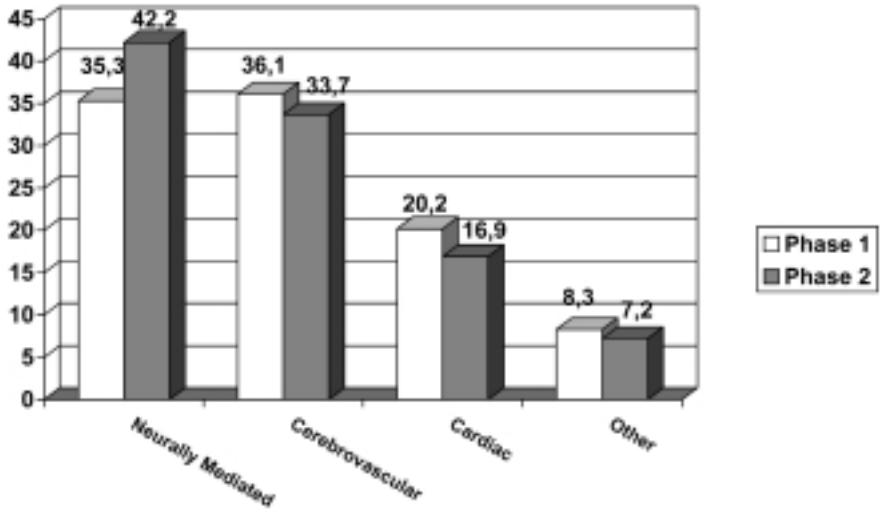
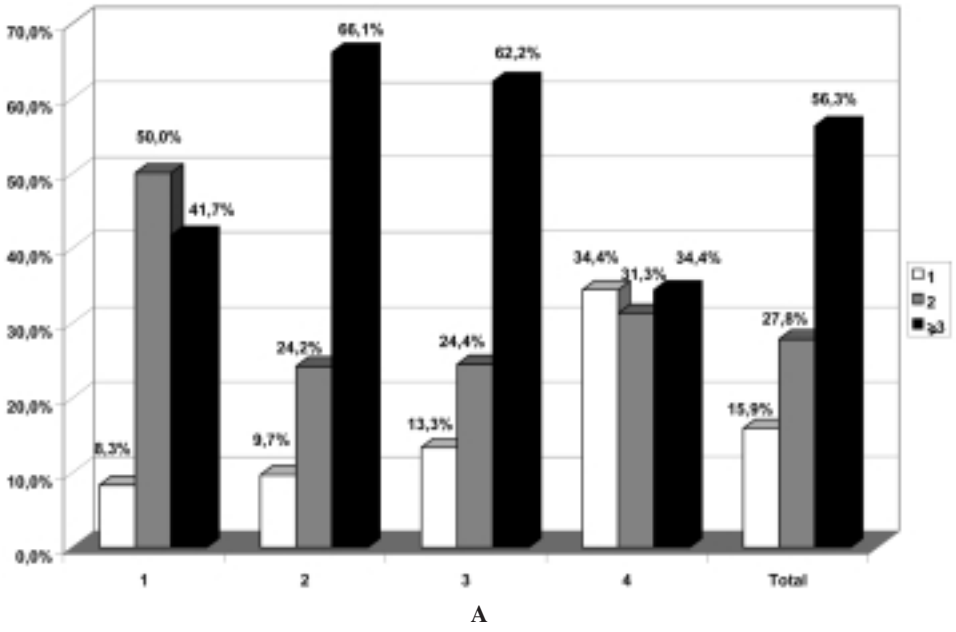
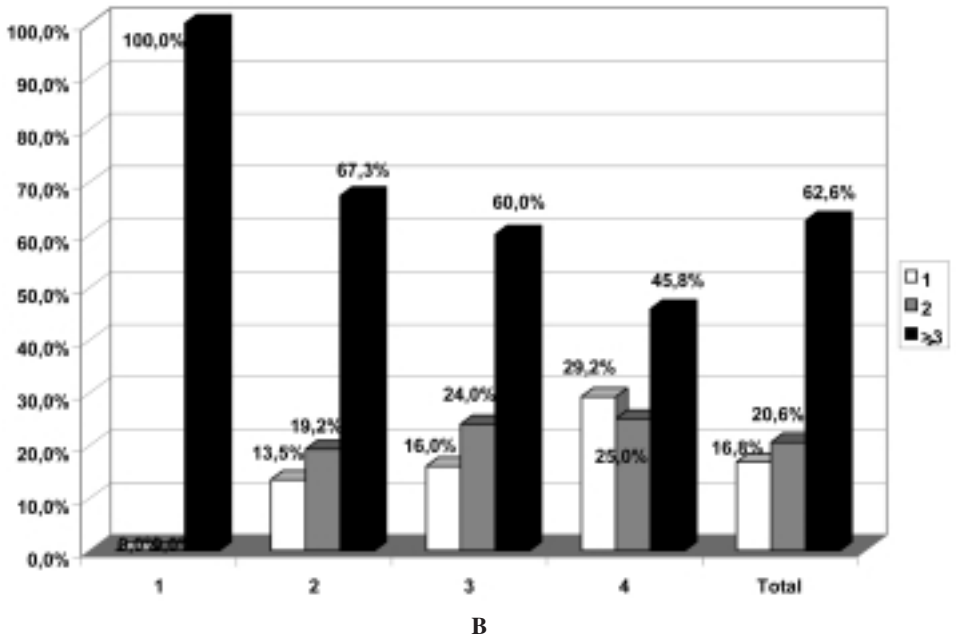


Figure 3. *Percentage distribution of the syncope class in the two phases: no significant changes were identified.*



A



B

Figure 4. A: *number of diagnostic tests for syncope per patient carried out by diagnostic result types in phase 1.* B: *number of diagnostic tests for syncope per patient carried out by diagnostic result types in phase 2. 1 = certain diagnosis; 2 = probable diagnosis; 3 = hypothetical diagnosis; 4 = no diagnosis.*

males (54.2%), the mean age was 66.3 ± 20.2 years (range 14-96 years) and 22 (20.6%) had recurrent episodes.

During hospitalization, the LOS increased from 9 ± 5.6 (range 1-30) to 11.3 ± 8.5 (range 1-50) days but this difference was not significant (p = 0.07). The number of diagnostic tests increased from 2.6 to 2.9 per patient with a significant increase of the tilt test (from 1 to 9.0%, p = 0.009) and carotid echo-Doppler (from 22 to 32.7%, p = 0.05) (Fig. 5). Figure 4B shows that in 62.6% of patients at least three tests were carried out. On discharge, the percentage of patients with no diagnosis decreased from 51 to 45.8% (although a hypothesis was formulated for 23.4%) and the principal causes were identified as: cerebrovascular disease (36.1% phase 1 vs 33.7% phase 2), neurally-mediated mechanisms (35.3 vs 42.2%) and cardiac problems (20.2 vs 16.9%) (Fig. 3).

Cardiac causes accounted for 33.3% of the certain diagnoses, neurally-mediated causes constituted 92% of the hypothetical diagnoses, and cerebrovascular causes constituted 53.8% of the probable diagnoses.

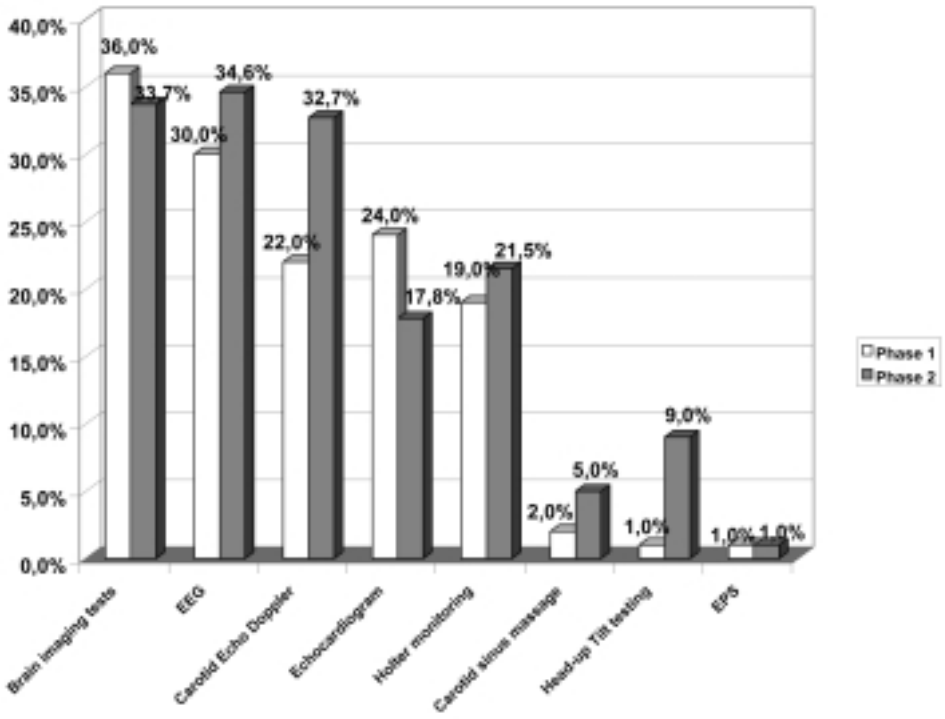


Figure 5. *Percentage distribution of patients who underwent different tests during hospitalization in the two phases: significant increase in the number of tilt tests (p = 0.009), and of carotid echo-Doppler (p = 0.05). The ECG was not included because it was carried out for all patients. EEG = electroencephalogram; EPS = electrophysiological study.*

Table I. Diagnosed syncope costs (€).

	Phase 1	Phase 2
Geriatrics	3,852.96	3,667.89
General medicine	3,511.67	4,102.84
Neurology	4,353.82	2,331.45
Cardiology	2,159.58	2,556.40
Other wards	5,788.47	4,094.06
Mean value	3,474.13	3,646.67

The syncope cost per patient increased from €3,474.13 to €3,646.67 (Table I), but this variation was not significant. In the cost evaluation of both phase 1 and 2, the LOS represented the main cost driver (> 90%).

Discussion

Syncope is a widespread and important medical problem with many causes involving different clinical specialists. This often renders the diagnosis of syncope a puzzling problem for clinicians and produces very high diagnostic costs. Despite a growing interest in the management of syncope the best way towards optimization of the syncope HDP is not yet well established and, in addition, the impact of guidelines on clinical practice is difficult to assess. With the aim of providing a response to these issues the ECSIT study was set up and was split into two phases: phase 1 as a "snapshot" of the basal situation of the management of syncope in the main hospital of Trento, and phase 2 carried out after the introduction and implementation of specific guidelines.

The first phase of the study confirmed the results of a previous Italian experience, the OESIL study[11], regarding the high rate of ER admissions (0.9%) and the subsequent hospitalization of syncope patients (57.6%).

The ECSIT study shows that more than two thirds of the patients admitted to hospital were hospitalized in the general medicine wards (Fig. 2) while most of the diagnostic tests were carried out in other structures of the hospital (radiology, cardiology and neurology). Such a situation can prolong the LOS and can render the HDP more complicated.

Despite about 10 days of hospitalization, an average of almost three diagnostic tests for each patients and an overall cost of about €3,500, the etiology of syncope was identified as certain or probable in no more than 50% of the observed group, with only 7.9% being certain. Similarly, Ammirati et al.[11] identified the etiology of syncope in less than 50% of the OESIL population. Furthermore, the high rate of cerebrovascular diagnoses (36.1% in phase 1 and 33.7% in phase 2) (Fig. 3) is very different from what would be expected at the end of an adequate HDP[12,13] and it strongly suggests that many of the diagnoses were inappropriate. However, the result is less surprising if we consider that cerebrovascular syncope was a probable diagnosis in 56.5%

of cases, mainly due to the widespread use of brain imaging tests and electroencephalography (Fig. 5). The result can be explained by the low diagnostic yield for syncope of these tests[10] and the high rate of detection of abnormalities is unlikely to justify the number of episodes of syncope occurring in an elderly population such as the one studied in the ECSIT study (average age 69 years). On the other hand, while a cardiac cause was a certain diagnosis in 83.3% of cases, neurally-mediated syncope (35.3% of diagnoses) was very frequently a hypothetical diagnosis (73.3%), mainly due to the low use of specific tests such as the tilt test and carotid sinus massage. Furthermore, the scant use of tests with a high diagnostic yield for syncope, such as the tilt test, is probably the most important cause of the low diagnostic rate observed in the study. All these results confirm that the choice of diagnostic tests influences both the HDP and the diagnosis, often leading to inappropriate therapies.

The effects of guidelines on clinical practice are still a matter of debate. With the aim of evaluating the "real" effect of guidelines on the HDP of syncope, the steering group chose to exclude the presence of a study investigator for each ward who could modify the clinical management only during the observational period of the study. In the ECSIT study the distribution of guidelines was achieved only through meetings and informative literature. This approach could explain the weak impact of guidelines in this study when compared with the findings reported in the OESIL 2 study[14] where the use of a specific algorithm significantly improved the clinical performance (a decrease of undiagnosed cases from 54.4 to 17.5%). In the OESIL 2 study indeed the whole HDP of the syncope patients enrolled was followed by the investigator of the hospital who also had the responsibility for the final diagnosis.

In the ECSIT study the main response to the new guidelines was the decrease in the hospitalization rate from 53 to 42% ($p < 0.01$). On the other hand, the modification of the syncope HDP was very moderate but showed a trend towards an increase in the LOS, the number of diagnostic tests and the relevant costs (Fig. 4, Table I). Furthermore, the number of diagnoses tended to increase and neurally-mediated syncope became the primary cause of syncope (Fig. 3). This was probably related to the significant increase in the number of tilt tests carried out (from 1 to 9.0%, $p = 0.009$) (Fig. 5). The opening of a new echo-Doppler laboratory in the general medicine ward during the second phase of the study is the only possible reason which could justify the abnormal increase of this test (from 22 to 32.7% of cases, $p = 0.05$). This rather confusing picture which emerged after the distribution of the new syncope guidelines needs some explanation:

• although all the physicians involved in the ECSIT study were aware of the protocol, the distribution of the guidelines alone seems not to have been sufficient to significantly modify clinical practice. The ECSIT experience showed the crucial role played by the hospital organizational processes in the feasibility of implementing guidelines. The impact should be assessed in more detail. The other aspect that clearly emerged was the difficulty in involving multidisciplinary physicians in a "sharing" experience. According to other authors[15], physicians clearly rank clinical practice guidelines on the basis of who has been involved in the process even when the guidelines are identical and funded by the same source;

• the trend in clinical practice was to add rather than use as substitutes the new diagnostic tests indicated in the guidelines (e.g. the tilt test). This can produce improved diagnostic yields but also increases the LOS and costs. As to the cost analysis, a true comparison between the two phases is not significant since the diagnostic flowchart was not sufficiently applied.

In conclusion, there are important lessons to learn from the firsthand experience of those who develop, evaluate and use guidelines[16]. The main results of this study were:

1. syncope remains a common cause of ER admission (1.5-2%) with a high rate of hospitalization (about 50%) and a consistent LOS (about 10 days);
2. despite the fact that every patient underwent an average of almost three specific examinations, the etiology of syncope was identified in no more than 50% of the observed group. In addition, there was a high rate of cerebrovascular diagnoses mainly due to the frequent use of low diagnostic yield tests as well as to the less common use of high diagnostic yield tests;
3. in our hospital the distribution of guidelines for syncope alone was not enough to significantly modify the clinical practice implemented by the physicians;
4. the higher cost of the HDP for syncope was due to the LOS rather than to the number or type of diagnostic tests employed.

The acceptance, by the various specialists involved, of new guidelines in a multidisciplinary area could be particularly difficult. Even within the same clinical area, the diffusion of guidelines and their implementation are hindered by the different opinions of the physicians and by geographic factors. Moreover, this study showed that the organizational setting is a major driver of the pathway and that it does not allow the standard sequence of actions to be followed. Consequently, a hospital faces a real challenge when adopting guidelines: to reengineer the process in such a way that it is consistent with the recommended pathway and agreed upon by all the professionals involved, from ER admission to discharge and across all disciplines. As already demonstrated in other countries, it is likely that only a syncope ambulatory context can optimize the HDP by improving the diagnostic yield and reducing the LOS. In particular, a single environment equipped with a single multidisciplinary team, where all syncope patients could be referred and evaluated, could optimize patient management, would improve

consistency in clinical patterns and would also increase the clinical and organizational appropriateness. A comparative cost analysis could then be carried out and may reveal real differences in resource consumption between the previous and the new patient management systems.

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