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Italian Stroke Guidelines (SPREAD): evidence and clinical practice

Abstract Evidence-based medicine's aims are to retrieve, screen and compound the best external evidence with the experience of the physician, and to best respond to the specific medical need of each individual patient. Clinical questions are better answered when good systematic reviews of randomised trials or good randomised clinical trials are available. On the other hand, in a clinical scenario, difficulties in applying the evidence may be amplified due to variability of disease conditions, feasibility of intervention and patient's preferences. Guidelines are recommendations, based as much as possible on evidence, aimed at supporting clinical judgement/diagnostic skills/treatment decisions in everyday practice. Guidelines may improve the quality of care received by the patient and may contribute towards better consistency of care in a definite geographical area. However, guidelines risk reducing physician skills to critically appraising the evidence. In a clinical scenario, guidelines do not always provide substantial help, especially when no conclusive evidence supports them. The Italian Stroke Guidelines (SPREAD) have contributed towards more evidence-based and better harmonised stroke care in Italy. However, the number of high grade recommendations in SPREAD is still limited. Professionals should not forget that clinical decisions often reflect several issues, not only scientific ones, including personal experience, applicability of intervention and patient's preferences.

Key words Evidence-based medicine • Guidelines • Stroke

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Evidence-based medicine (EBM) is a technique to retrieve, screen and compound the best external evidence with the experience of the physician, to best respond to the specific medical need of each individual patient [1]. Practising EBM includes five steps:

- convert need for information into an answerable question;
- track down the best evidence with which to answer the question;
- critically appraise the evidence for its validity, impact and applicability;
- integrate the critical appraisal with individual clinical expertise and patient's unique circumstances;
- evaluate effectiveness and efficiency of the process and seek ways to improve it.

Applying EBM needs to start with an answerable question. The question may be divided into two components: background and foreground questions. In the background setting a general question regarding the disorder or aspects of the disorder presented by the patient is the main focus; foreground questions relate to selective diagnostic or therapeutic problems presented by an individual patient. The need to answer background questions decreases with increasing clinical experience, while the amount of foreground questions tends to increase. Evidence-based information, highly referenced recommendations and expert opinion usually form the sources of information. Critical appraisal of evidence includes the evaluation of levels of evidence. Questions are better answered when good systematic reviews of randomised trials or good randomised clinical trials are available (level 1 evidence). Answers may be more uncertain when the information is less valid. On the other hand, in a clinical scenario, difficulties in applying the evidence may be amplified due to variability of disease conditions, feasibility of intervention and patient's preferences.

Practice guidelines are a set of practical recommendations, based as much as possible on evidence, aimed at supporting clinical judgement/diagnostic skills/treatment decisions in everyday practice, helping the physician to avoid the time-consuming task of finding and examining the evidence

properly. Given a definite disease, a group of experts in that disease is called on to identify the different clinical scenarios, and as many clinical questions as possible that may arise in those scenarios, to extract and weigh the evidence supporting each recommendation, and to formulate them in such a way that they can reflect as closely as possible the evidence on which they are based, and are comprehensible enough and easy to be translated into practice. Panel discussions, adequately large consensus among external experts and different professionals involved in patient care, and confrontation with patient representatives are the necessary steps to validate the content and applicability of each single recommendation. The principal benefit of guidelines is to improve the quality of care received by patients; the final goal is to ameliorate disease outcomes, contributing towards implementing in clinical practice interventions that have been proved to reduce morbidity and mortality, always taking into account also quality of life. Guidelines can also improve consistency of care among different geographical areas, hospitals with different degrees of expertise and different professionals. Guidelines in the consumer format may help patients to understand and collaborate in clinical decision making. Finally clinical guidelines may help patients by influencing public policy. Limitation and harms of guidelines include the fact that recommendations may be wrong, or do not properly express clinical evidence, which can be lacking, misleading or misinterpreted [2]. Especially in a situation where high-grade evidence is lacking, recommendations risk substantially reflecting the opinions, clinical experience and composition of the development group [2]. Moreover, patients' needs may be not the priority in making recommendations [2]. Finally, taking into account the whole procedure, guidelines risk reducing physicians' skills to critically appraising the evidence or even to implementing it properly in the specific disease/patient circumstances [2]. In any case, development of guidelines must follow a rigorous methodology and must be managed by multidisciplinary

panels of experts. Moreover, guidelines have to be adequately supported by explicit and detailed reports of evidence.

The SPREAD collaboration, active since 1998 (first release in 1999), was started with the objective of making available in Italy guidelines for management of stroke patients [3], including prevention, management in the acute phase and rehabilitation. Evaluation of the evidence was made according to the Scottish Intercollegiate Guideline Network (SIGN) [4] methodology, and integrated by statistical considerations on alpha and beta error size from the Guidelines of the Centre for Evidence-based Medicine (CEBM) [5]. Guidelines were formulated following a multidisciplinary approach, involving experts from 34 different professional organisations and exponents of two patients' associations. Their engagement was to develop guidelines that had to be:

- applicable to the Italian setting;
- based on the best available research evidence;
- updated to the most recent scientific developments; and propositional and flexible.

For each recommendation a formal consent from the panels was sought on validity, reliability, clinical relevance, applicability, comprehensibility, flexibility and respect of persons. Besides flexibility, the formulation had to be minimally intrusive in clinical practice. After four editions, we do not yet have systematic and objective information about their implementation in clinical practice in Italy. Several clues indicate that SPREAD Guidelines have been disseminated largely throughout Italian health-care structures and professionals. This provides a clue towards the better harmonisation of stroke care in Italy. Experience from national stroke conferences, seminars and courses suggests that practising stroke care in Italy is much more adherent than before to the best clinical evidence. SPREAD has likely contributed towards a better delivery of stroke services in Italy. However, the proportion of high-level evidence in the field of stroke is still limited. "Grade A" recommendations were 12.4% (see Table 1)

Table 1 SPREAD, 4th edn. Italian Guidelines for Stroke (2005). Distribution of recommendations by grades

Section	Grade A (n)	Grade B (n)	Grade C (n)	Grade D (n)	GPP (n)
Diagnostic work-up	/	1	1	18	/
Primary prevention	9	6	4	9	2
Acute stroke: pre-hospital management and emergency phase	1	/	1	11	5
Acute stroke: hospital admission (diagnostic procedures)	/	/	/	9	1
Acute stroke: hospital admission (treatment)	8	3	4	49	2
Acute stroke: monitoring and complications in the steady-state	2	4	/	45	/
Secondary prevention: long-term pharmacological therapy	5	7	3	3	1
Surgical treatment	9	1	6	9	1
Rehabilitation and continued care	6	12	16	33	24
Post-stroke cognitive impairment and mood disorders	4	/	8	3	9
Total, n (%)	44 (12.4)	34 (9.6)	43 (12.1)	189 (53.2)	45 (12.7)

of the overall recommendations. Therefore a number of recommendations likely reflect the opinions and clinical experience of the Guidelines' development group. The large multidisciplinary composition has probably reduced this risk.

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