

## Overtreatment

Marco Bobbio,<sup>1</sup> Luigi Lusiani,<sup>2</sup> Roberto Frediani<sup>3</sup>

<sup>1</sup>Department of Cardiology, Santa Croce e Carle Hospital, Cuneo; <sup>2</sup>Department of Internal Medicine, Hospital of Castelfranco Veneto (TV); <sup>3</sup>Department of Internal Medicine, Hospital of Verbania-Domodossola, Italy

### ABSTRACT

Over the years, dissociation between the widespread use of procedures and the lack of evidence (evidence-practice dissociation) has been observed in many circumstances in cardiology. Thirty-three years ago Mc Kinley described in 7 stages the *career* of a new procedure: from the enthusiastic presentation of pilot research up to oblivion. The *Choosing Wisely*<sup>®</sup> project in the United States and the *Doing more does not mean doing better* project in Italy are intended to identify very commonly prescribed procedures at high risk of inappropriateness that do not bring significant benefits to many patients. Finally, the implementation of local experience of identifying inappropriate procedure in an Italian hospital is described.

### Introduction

Eleven years ago, the results of the TEMISTOCLE study<sup>1</sup> (a collaborative research ANMCO-FADOI on patients admitted for heart failure in the Departments of Cardiology and Internal Medicine) were published. In cardiology departments the study revealed a higher prescription rate of echocardiography (89.3 vs 54.8%; P<0.001), of Holter monitoring (29.0% vs 8.0%; P<0.001), of coronary angiography (7.5 vs 0.9% P<0.001). However 6 months after discharge the incidence of hospital admittance [43.7 vs 45.4; P=not significant (NS)] and of mortality were similar (13.9% vs 16.7%; P=NS). This was confirmed even after adjusting data for severity and complexity (relative risk 0.97; 95% confidence interval 0.67-1.42). Therefore, a greater use of diagnostic procedures and a more careful evaluation of patients do not seem to affect the subsequent clinical course.

Ten years before, investigators conducting the

SAVE study<sup>2</sup> (comparison of captopril and placebo in patients with recent myocardial infarction) used the data base to follow the outcome of 1573 patients recruited in the USA and of 658 in Canada;<sup>3</sup> they observed that coronary angiography was performed in 68% of the formers and in 31% of the latter, and revascularization respectively in 12% and in 3%. Investigators would expect to find a substantial reduction of events among patients treated with a more aggressive medicine; instead mortality (23% of US patients and 22% of Canadians) and incidence of re-infarction (respectively 13% and 14%) were identical. A year later those data were confirmed by a group of investigators<sup>4</sup> who analyzed the outcome of patients admitted in two similar university Centers in the USA (Stanford University) and in Canada (McGill University); 55% of American patients and 34% of Canadians underwent coronary angiography, 40% revascularization *versus* 17%. In the face of an almost double impact of procedures, after 20 months the death rate was comparable (27% vs 28%). Analogous results were observed scrutinizing all cardiac infarctions occurred in Belgium from 1999 to 2001: 5 years post myocardial infarction mortality of patients admitted in a Center with onsite angiography lab was similar to that observed in Centers where coronary angiography was not available.<sup>5</sup>

### Evidence-practice dissociation

Over the years, dissociation between the widespread use of procedures and the lack of evidence has been observed in many other circumstances in cardiology. In patients with stable coronary artery disease, a coronary lesion and objective evidence of myocardial ischemia percutaneous coronary intervention did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy;<sup>6</sup> the presence of onsite cardiac

Correspondence: Marco Bobbio, via Pietra del Gallo 45, 10025 Pino Torinese (TO), Italy.  
Tel.: +39.388.6188631.  
E-mail: mbobbio51@gmail.com

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catheterization facilities did not appear to be associated with lower short-term mortality;<sup>7</sup> management of atrial fibrillation with the rhythm-control strategy did not offer survival advantage over the rate-control strategy;<sup>8,9</sup> no significant between-group difference in clinical outcomes was observed between patients who underwent mitral-valve repair and those who underwent mitral-valve replacement;<sup>10</sup> renal-artery denervation did not reduce systolic blood pressure in patients with resistant hypertension in 6 month follow-up,<sup>11</sup> nor benefits with respect to the prevention of clinical events;<sup>12</sup> the use of intra-aortic balloon counterpulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction;<sup>13</sup> in patients with acute decompensated heart failure complicated by persistent congestion and worsened renal function ultrafiltration was not inferior to pharmacologic therapy for the preservation of renal function;<sup>14</sup> hospitals with higher imaging rates did not have substantially different rates of therapeutic interventions or lower readmission rates for acute myocardial infarction, but were more likely to admit patients and perform angiography;<sup>15</sup> closure of a patent foramen ovale in adults who had had a cryptogenic ischemic stroke did not offer clinical benefits to medical therapy;<sup>16</sup> in patients with intermediate-risk pulmonary embolism, fibrinolytic therapy increased the risk of major hemorrhage and stroke;<sup>17</sup> in patients with severe sepsis, albumin replacement in addition to crystalloids, as compared with crystalloids alone, did not improve the rate of survival at 28 and 90 days;<sup>18</sup> Several more examples from different clinical setting could be added. The negative results of these trials do not mean that those procedures are useless, since data are highly conditioned by type and heterogeneity of patients recruited, by the duration of follow-up, by the number of the sample size, by the type of the control group. These data inform us, however, that normally adopted procedures are not as effective as we would have expected from biased studies and from personal experience, tending to overestimate the effect of what we do.

### The career of a procedure

How do unproven effective procedures become consolidated into daily practice? Thirty-three years ago Mc Kinley described 7 stages of a new medical innovation.<sup>19</sup> The first step is referred to procedures launched with the appearance of an enthusiastic report of some promising performances; a *scientific* breakthroughs obtained in pilot studies usually conducted in highly specialized centers and in a small group of patients without control group. During the second stage more widespread and influential support is mobilized for its adoption by powerful interest groups, involving professional associations and institutional organiza-

tions. As a consequence of the previous two steps a general acceptance of the innovation emerges among the public as a generalized belief that the innovation is a *good thing* and ought to be available, supported by interested institutions. During the fourth step innovation (having received professional, public support, and legitimation through widespread endorsement) achieves the privileged status of a *standard procedure*. At this point (fifth step) the procedure appears to be satisfactorily settled by the sheer volume of observational reports that never really place the issue of the importance of the innovation beyond dispute. It comes that there are problems of designing and then conducting a randomized controlled trial (RCT) in situations where the innovation is already considered a standard procedure, and powerful interests and reputations are invested in its continuing success. In general, the more advanced the career of an innovation is, the more difficult it is to undertake a RCT. When findings of RCT appear to question what has become standard procedure, professional denunciation in the form of letters to the editors or critical editorials emerges in the literature. Often (seventh step) the innovation follows the fate of an *artist that is a major topic of conversation, receives rave reviews, much public recognition, but at a certain point quietly disappears into obscurity, leaving the public wondering whatever happened to so-and-so*.

### Choosing Wisely®

The outreach efforts of medical journals, including JAMA Internal Medicine's *Less is More* section and the BMJ's *Too Much Medicine* campaign,<sup>20,21</sup> as well as the recently started overdiagnosis conferences (<http://www.preventingoverdiagnosis.net>) are important contributions to critical evaluate new procedures before adoption into practice. Howard Brody<sup>22</sup> suggested that every scientific society should choose a list of five diagnostic tests or treatments (the *top five* list) that are very commonly ordered by members of that specialty, that are among the most expensive services provided, and that have been shown by the currently available evidence not to provide any meaningful benefit to at least some major categories of patients for whom they are commonly ordered. In short, the *top five* list would result in money saving without depriving any patient of meaningful medical benefit. The American Board of Internal Medicine (ABIM) Foundation and Consumer Reports launched the initiative *Choosing Wisely*® to favor a dialogue between patients and physicians in order to help them to choose evidence based procedures not redundant to previous low risk tests already performed.<sup>23</sup> Consumer Reports is developing educational materials to widespread in the population, recognizing that patients need better information about their care. In Italy *Choosing Wisely*® was launched by *Slow Medicine* (<http://slowmedicine.it>), a movement of

physicians, health professional, patients and citizens aimed to promote a measured, respectful and equitable medicine with the campaign *Doing more does not mean doing better* (*Fare di più non significa fare meglio*).<sup>24</sup> Differently from the American project, in Italy the costs of procedures were not taken into account to avoid the campaign to be interpreted as a way to ration healthcare for cost cutting purposes.

### ***Doing more does not mean doing better: a hospital experience***

In September 2013 the project *Doing more does not mean doing better* was launched at the Santa Croce e Carle Hospital, a tertiary 450-bed hospital in the city of Cuneo (Italy), with the aim to increase the quality and safety of hospital services throughout the reduction of procedures at risk of inappropriateness. Thirty-three departments identified 96 procedures and worked to reduce the prescriptions. Actually, some of those procedures are monitored to evaluate the reduction of prescriptions.

### **Conclusions**

The bottom-up experience at Santa Croce e Carle Hospital in Cuneo shows that the Choosing Wisely® project can be locally implemented and not only at national level with the involvement of scientific societies. The aim is the same: to invest in appropriateness to reduce the waste of performing not evidence based procedures. It would be extremely desirable the extension of the project to all Italian hospitals, mainly to Internal Medicine Departments that should become leader of a movement directed to health rather than to illness, reflecting that a measured, respectful and equitable medicine is still the most achievable.

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