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Numbers needed to treat (lives!) and numbers needed to save (money)

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The evolution of cardiovascular medicine over the last 30 years has allowed both a significant reduction in mortality and a continuous improvement in the quality of life for many patients with different forms of heart disease. Progress in medical treatment allied to technical improvements in both percutaneous and surgical interventions have all played a role. Optimal medical therapy, primary angioplasty in ST-elevation myocardial infarction (STEMI), implantation of cardioverter-defibrillators (ICD) and arterial grafts in coronary artery bypass surgery, among others, are obvious examples of this modern change. Such interventions support the fundamental missions declared by the major international cardiovascular scientific societies, i.e., "to reduce the burden of cardiovascular disease" (European Society of Cardiology) and "to reduce death caused by heart disease and stroke" (American Heart Association).

With an ageing population, allied to the ever-increasing complexity of care, the advantages of certain treatments in relation to their economic burden on society must be estimated. An easy indicator of this "weighed" intervention is the number needed to treat (NNT), a simple index commonly defined as a "therapeutic effort to clinical yield". In simple terms, it is the number of patients that must receive a given treatment to avoid a certain, measurable, clinical event, the most important being death. This should be counterbalanced by the number needed to harm (NNH) to provide an overall fair indicator of net clinical benefit.

It is well established that primary angioplasty instead of fibrinolysis in patients with STEMI will save one additional life per 35 treated patients within one year of the event (NNT=35). Furthermore, the advantage of angioplasty increases with time, with one life out of 30 saved at two years, and one out of 10 at five years follow-up (NNT=10). If the STEMI is complicated by acute heart failure, then one life will be saved with primary angioplasty within one year if only seven patients are treated (NNT=7)[1]. Similarly, following available recommendations for ICD, a NNT between 15-20 patients has been observed after implantation for primary prevention, and 10-15 patients for secondary prevention[2-4]. Such results are so impressive that appropriately used primary angioplasty or ICD have Class-I recommendations in the respective Guidelines[5,6].

In the last five years, cardiologists and cardiac surgeons have promoted a revolutionary new treatment: transcatheter aortic valve implantation (TAVI)[7,8]. What first was regarded as a new chapter in the "science-fiction saga of transcatheter medicine" has rapidly become daily practice. Indeed, by the end of 2011, more than 40,000 TAVI interventions had been performed, with an ongoing rapid expansion in numbers.

Treating surgically inoperable patients with aortic stenosis, as defined in the PARTNER trial, the NNT to save one life at one year is 5. This is remarkable when considering both the dismal natural history of the disease and also the procedure-related possibilities to harm (4 to 11% of patients may have a stroke or severe vascular complications). These complications, however, reflect the very initial experiences, with dramatic reduction of adverse events following growing proficiency, and a persistent benefit at two years. Such a formidable indicator of a "therapeutic-effort-to-clinical-yield" has never been previously observed in interventional cardiology, and has led to a Class-I recommendation for TAVI in inoperable patients in the recent European Guidelines for the treatment of valvular heart disease, a document co-authored by cardiologists and

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cardiac surgeons[9]. Nevertheless, some have argued that available evidence may still be premature, and/or in part influenced by economic interests[10], and that TAVI may not be cost-effective[11].

As for any new treatment, TAVI is expensive, and is currently only recommended for the "old and sick". Spending further economic resources in a population that already represents a significant burden to our social health system may be perceived as a "futile effort, or waste of resources". This is compounded by the current economic crisis in many European countries that has restricted the access to TAVI in some centres to contain costs and comply with assigned budget constrictions.

We certainly advocate rigorous patient selection so that TAVI is not inappropriately used in patients who are at the end of life for other reasons, and are incidentally discovered to have aortic stenosis. However, for doctors regularly performing TAVI in high-volume centres for years, policies to limit its appropriate use are difficult to accept because of the overwhelming potential of TAVI, to literally "resuscitate" patients faced with imminent death. Indeed, appropriately selected patients with end-stage aortic stenosis can experience a return to "normal" life soon after a 60-minute intervention, performed in a totally percutaneous or minimally-invasive manner. This emphasises the "curative" nature of TAVI that, relieving the obstruction to the left ventricle outflow tract, rapidly returns patients to a "normal functioning" state, and this is known to prolong life with a strong positive impact on its quality, and on the family context.

Other treatments with demonstrated cost-effectiveness, despite high economic costs, have become routine practice. This is the case, for example, with implantable cardioverter-defibrillators (ICD). Although the price of these devices has not declined significantly since their introduction more than 15 years ago, this treatment would not now be denied to a patient who merits it. Unlike aortic valve replacement, however, the ICD does not "cure" the underlying disease, but prolongs life with no, or minimal, impact on its quality[4]. On the other hand, despite the present high cost of TAVI, a first cost-effectiveness study has shown the economic advantages of TAVI over surgery among high-risk patients who can be treated by the transfemoral approach[12]. Most of this advantage is related to the rapid treatment and recovery of TAVI patients compared to open-heart surgery, and to the rapid improvement in patients who, if not treated, would remain hospitalised for weeks, often requiring prolonged intensive care, with several further readmissions and suffering, until death.

Obviously, it is not our intention to question overall budget strategies, but to advocate that cardiologists and cardiac surgeons should, together, affirm their support for this life-saving therapy that not only already "reduces the burden of cardiovascular disease", but which is likely to continue to improve rapidly. Politicians and hospital administrators should be appropriately advised about the ethical responsibility of denying patients a life-saving therapy, and the choice between the number needed to save lives balanced against the need to save money. A larger use of TAVI will not only save more lives, but by preventing repeated and prolonged hospitalisations also eventually save money.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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