

Documenting the dramatic effects of operative treatment of mitral stenosis

Tom Treasure

Clinical Operational Research Unit, University College London, London WC1H 0BT, UK

Corresponding author: Tom Treasure. Email: tom.treasure@gmail.com

Introduction

Despite recent growth in randomised trials of surgery, some with blinded treatment and outcome assessments,¹ follow-up studies of patients treated surgically continue to dominate the surgical literature, an approach to evaluating the effects of surgery which has been used for at least three centuries.²

Surgical follow-up studies are prone to many biases. The proponents of an operation select which patients to use it on, and then have many opportunities to decide which patients to exclude from their analyses, how to judge benefit, and how and when to report their results. This enduring pattern led the editor of *The Lancet* notoriously to deride surgical research as ‘Comic Opera’,³ despite the fact that ground rules for reducing biased selection and outcome assessment in surgical follow-up studies were proposed by Codman 100 years ago.⁴

Until recently, comparisons of different surgical approaches, or of surgery with non-surgical treatments, only rarely used alternation or random allocation to generate similar comparison groups to ensure that ‘like would be compared with like’. When true treatment differences are modest and of the same order as the effects of uncontrolled biases, such controlled trials are essential to distinguish these two causes of any differences observed. When the differences are large, however, comparing outcomes in a case series with what is known about the natural history of the condition being treated has provided and will continue to provide strong evidence of surgical treatment effects, wanted and unwanted.⁵

Surgical treatment of Fallot’s tetralogy and mitral stenosis

Case reports and small retrospective case series still dominate cardiothoracic surgical reporting,⁶ but these rarely provide a basis for confident inferences about the differential effects of treatments. However, there are important exceptions to this general rule.

Glasziou et al.⁷ have suggested that randomised trials are unnecessary when patterns of responses to treatments are compared with information on the natural course (prognosis) of the condition being treated.

For example, the effects of the Blalock-Thomas-Taussig shunt for Fallot’s tetralogy (https://en.wikipedia.org/wiki/Blalock%E2%80%93Taussig_shunt) was dramatic. ‘Blue babies’ were a very familiar sight and, if they survived infancy, were commonly seen always deeply cyanosed, and becoming worse on the slightest exertion. Blalock visited Guy’s Hospital in London in 1947, and his operations, there were among 50 reported within two years.⁸ As soon as the vascular clamp was released to open the subclavian artery, which had been diverted and anastomosed to the pulmonary artery, the anaesthetist sees a child who has been blue since birth, turn pink. And at their first glimpse of their child, the parents see it too.⁹

The received wisdom in the 1940s was that mitral stenosis was not likely to benefit from surgery, and reservations were well founded. During the 1920s, there had been a number of operations. In London, Henry Souttar approached the mitral valve by inserting his index finger through the left atrial appendage.¹⁰ The patient and her family noted improvement and she was able to climb a flight of stairs, previously impossible for her. She lived for seven years afterwards.¹¹ In Boston, Elliott Cutler performed seven operations between 1923 and 1928 choosing to cut the leaflets at right angles to the commissure with a knife introduced through the apex of the left ventricle. Six of the seven patients died within hours or days of the operation; one, the first, lived for four years. By 1929, they had drawn a line under the surgical venture, publishing what they called a ‘final report of all surgical cases’.¹²

In successive editions of Price and Conybeare’s textbooks in the 1930s and 1940s, the opposition to surgery became more robust. Physicians were justifiably concerned by the danger posed to their patients

by what they saw as the recklessness of surgeons, but they also began to rationalise their reservations: many believed that the operation was not only hazardous but futile, because they declared that the heart muscle, not the valve, was the source of the problem.^{13,14} Sir Thomas Lewis¹⁵ views on mitral stenosis and the alleged illogicality of operation are set out in his 1943 edition of 'Disease of the Heart'; he sums up the prevailing view:

Although many symptoms may be complained of by patients suffering from mitral stenosis, there are none that can be ascribed properly and usefully to this deformity of the valve. (p. 130)

The undue emphasis placed upon disease of the cardiac valves in diagnosis was the chief reason why the prognosis of heart disease remained so unsatisfactory. This over-emphasis resulted largely from an exaggerated notion of the extent to which valve defects burden the heart mechanically (p. 143)

At Guy's Hospital, a multidisciplinary team of cardiologists, cardiac surgeons and anaesthetists were fully aware of the dangers, not only of operating on the stenosed mitral valve but also of the criticism of their medical colleagues. But they had a different idea – that the stenosis of the valve was indeed the central problem and that it could be relieved by an operation. On 21 April 1948, Russell Brock, the surgeon in the Guy's team, called a meeting of those involved in surgery for structural heart disease. They formed a club – the Peacock Club¹⁶ – and met from then until 1956 at intervals of about two months. There were 46 meetings in all, spanning some important years in the establishment of cardiac surgery.

The cardiologist Dr Maurice Campbell took the chair and the meeting included Dr Charles Baker (cardiologist), Dr Ernest H Rink (anaesthetist) and the staff of the Medical Research Council Unit then at Guy's. The meeting on Monday, 13 September was devoted to the assessment of patients with mitral stenosis and plans for their operations. The first was operated on three days later, using the commissural releasing approach of Souttar and not the valve cutting approach of Cutler.

Unlike others who went to the journals with their first success, the Guy's team stayed their pens until they felt they were able to present a series of successful outcomes with a consistent and durable effect. They published their first report in the *British Medical Journal* in 1950.¹⁷ At the time of publication on 3 June, seven of nine operated patients had survived. The survivors were 'able to walk farther and

do more without provoking cardiac asthma or pulmonary oedema'.

Rheumatic mitral stenosis was a very common condition and the unremitting nature of the pathology and the very familiar progression of symptoms and disability gave them sufficient confidence to attribute the benefit to the operative relief of mitral stenosis. In less than two years, on 17 May 1952, they reported a total of 100 operations.¹⁸ The authors, Charles Baker, Russell Brock, Maurice Campbell and Paul Wood wrote:

As soon as our first report appeared, the great need for operative relief of mitral stenosis was borne vividly upon us by the large number of patients presenting themselves for consideration, the requests coming from cardiologists, from general practitioners, and from the patients themselves. A future that previously seemed bleak for many patients, generally under 40 and often under 30 years of age, has been completely changed. It is only in dealing with a large number of these patients that one realizes the true extent of the tragedies that mitral stenosis can produce.¹⁸

Reflections

Surgical relief of mitral stenosis might be seen as meeting Glasziou et al.'s criteria for an intervention which can be accepted as effective on observational data alone.⁷ For operations, this requires a clear mechanistic explanation and a close temporal relationship between the intervention and the desired outcome.⁷ Much of what is done in cardiac surgery is accepted on that basis, provided it is backed up by evidence that the effect can be consistently replicated, achieved at acceptably low risk, and has sufficient durability to make it worthwhile. The 'mechanistic explanation' favoured by the Guy's team was correct, and the concerns about myocardium expressed by influential senior physicians proved to be no obstacle to successful operative treatment. Baker et al. were later to write of those relieved of mitral stenosis 'Improvement is immediate and they lose their orthopnoea and "tight breathing" from the second day'.¹⁸ That was not expected by physicians in the 1940s.

These two papers by the Guy's team are examples of how a single achievement, even though it might appear to meet the criteria proposed by Glasziou et al.,⁷ may not be enough. The obstruction of flow from left atrium to left ventricle may be relieved, but the consequences of the obstruction creating back pressure on the lungs and the right heart, the repeated

infection of congested lungs, the rheumatic damage to other valves and the myocardial disease feared by the physicians of the time, might have created too much ‘noise’ for the single intervention on the stenosed mitral valve to be demonstrated confidently. It required evidence that the effect was reproducible and durable and large enough to be appreciated by patients. Brock had also gathered a team around him to ensure he had advice, support and did not find himself isolated. Baker, Brock and Campbell, in alphabetical order, had the patience to wait before going public.¹⁹ Mitral valvotomy was taken up rapidly in all thoracic units around the world to become the standard of care. For suitable patients, and with surgeons who have retained the skill in less affluent societies, it remains so.

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