

## Roadmap for Resolution of Valvular Heart Disease (Resolva)

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We are cardiologists in Brazil of rheumatic fever prevailing as the pathogenesis of valvular disease<sup>1,2</sup>, a reality that is different from countries leading international scientific journals. It is exciting!

We take care of valve diseases and combined routine: 1) accuracy of clinical examination and complementary examination; 2) effectiveness of the therapeutic method; 3) patient safety; 4) impact of costs; and 5) rigor with ethical principles. It is the classical quintet!

We follow the natural history of the disease for a long period of time after the diagnosis of valvular heart disease, because our conduct is often waiting while the patient continues to have few symptoms, even when the valve disease is important. It is the practice!

We strive for the hemodynamic correction of severe valve disease when there is the clinical expression of discomfort that limits the quality of life of patients with valvular diseases<sup>3-6</sup>. It is the state of the art!

We declare ourselves as non-compliant with certain recommendations for “early action towards symptoms” and “preventive action towards late complications<sup>7-9</sup>”, although we are not inflexible. It is characteristic of physicians!

We develop assistance/research/education about treatment, knowing that most of proposals for solving valve disease in the literature, including guidelines, is based on expert opinion - rather than on the findings of a randomized study. It's a fact!

We use therapeutic techniques that were endorsed by the time of use and we are interested in innovations, especially those highly progressive in nature, such as percutaneous implant that benefits the elderly with blurred clinical prognosis and “prohibitive” surgical risk score. Bioethics and technology!

And because we are committed to the harmony between the plurality of the clinical expression of heart valve disease - and comorbidity - in various target organs and the uniqueness of the patient being assisted, we introduce the dimension of bioethics into the quintet mentioned above<sup>10,11</sup>. It is the human attitude!

### Keywords

Rheumatic fever; heart valve diseases/therapy/diagnosis/prevention & control.

Anyway, after confirming the valvular, extravalvular and non-cardiac components of severe valvulopathy, we move to the therapy with three reasons: 1) the inseparability between technoscience (medical knowledge and tools) and attitude (interaction with circumstances); 2) strength of science evidence; and 3) force of the doctor-patient relationship.

They give support to the 04 movements below: 1) we start with the selection of the conceptual benefit given by the scientific knowledge; 2) we go through the analysis of patient safety; 3) we respect their freedom of consent, and then complete the first phase, with an individual therapeutic indication. Then, we complete the strategy of resolution in a second phase of critical appreciation: 4) we go through the proposition thus constituted by considering two ethical screening methods about what could be the external review of diligence (to avoid negligence) and prudence (avoiding imprudence) (Figure 1).

We call the strategy of Roadmap for Resolution of Valvular Heart Disease (RESOLVA) and the essential elements of composition are given in Box 1.

### Benefit

We know the dimension of the effect and the estimated precision of the benefit and of the non-benefit of antibiotic prophylaxis, cardioactive drugs, non-cardiac drugs, we indicate hemodynamic repair by conventional or innovative surgical access (apical, for example) and we are getting familiar with the implantation of bioprosthesis transcatheterly (aortic and mitral). It is the dimension of the Medicine!

We use the matrices available by molding convergences and disagreements with collectivized guidelines, as pre-established recommendations, as those listed in guidelines, serve to interact with most - not with all - expressions of patients with severe valvular heart disease<sup>5</sup>. It is the dimension of the doctor-patient relationship!

We organize class III/IV and left ventricular dysfunction into a hierarchy as determinants of intervention on the culprit valve(s). It is the beneficial routine!

We are continuously reading the literature that proposes early hemodynamic correction of important valve lesions, i.e., interrupting the natural history while there is good quality of life and normal left ventricular function<sup>8,9</sup>. It is the pro-beneficence tension!

Therefore, we reanalyze ancient and recent evidence that support our preference for the clinical conduct in class II, based on the idea that it is the transition phase to class III. The purpose is to maintain scientific evidence on our usual understanding that the presumed benefit of: 1) reversal of adaptive remodeling; 2) avoid atrial fibrillation

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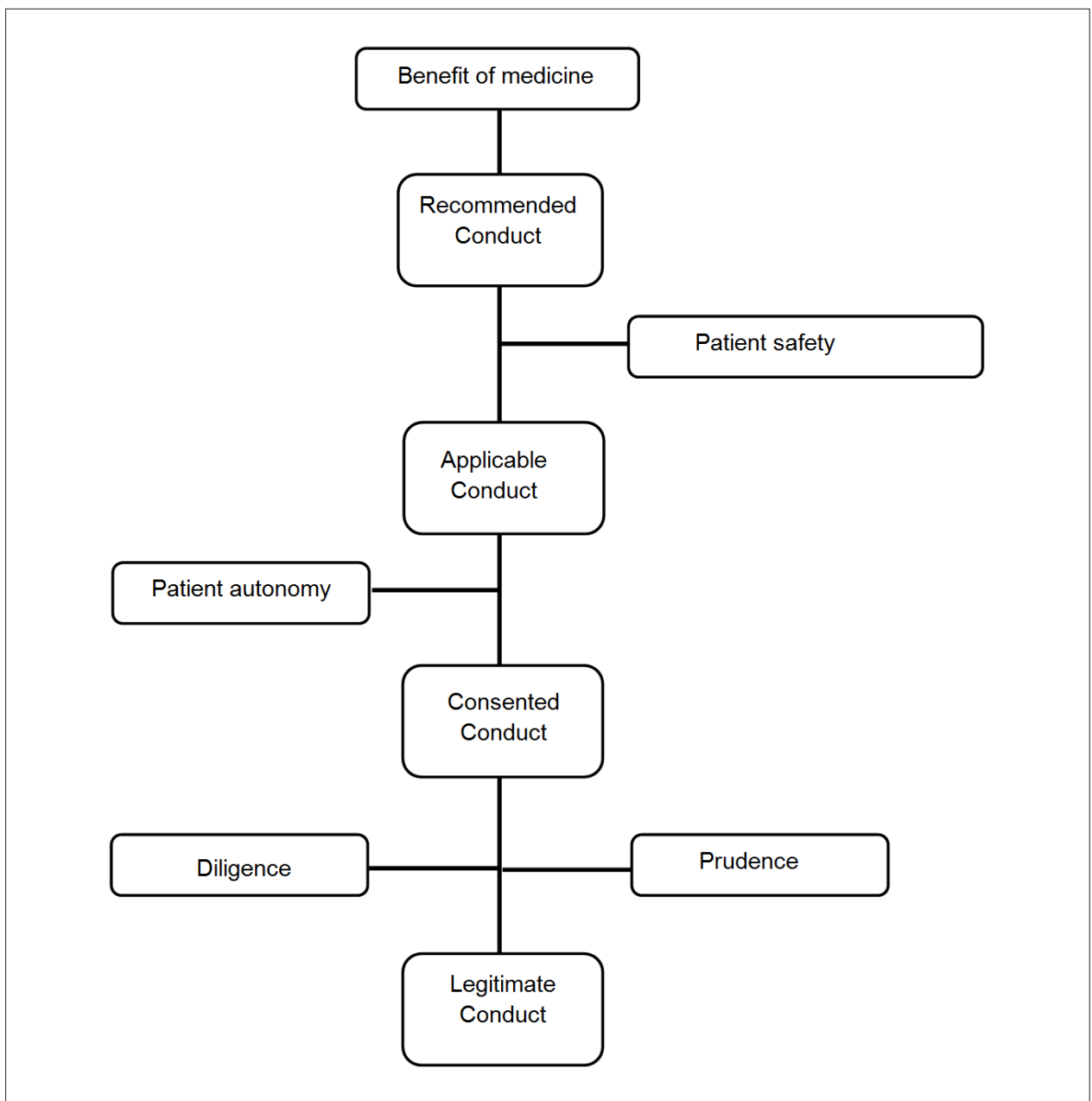


Figure 1 - Resolution of Valvular Heart Disease (RESOLVA).

(and anticoagulation), pulmonary arterial hypertension and tricuspidation during class II; should not speak louder than: 1) the realities of good quality of life; 2) the potential for morbidity and mortality of techniques for hemodynamic correction of severe valve disease.

It is the ethical significance of the bedside, we observe clinical truths, but not necessarily see them as certainties for the prognosis!

In short, we define the therapeutic usefulness for the moment of the natural history of the valvular heart disease (RECOMMENDED CONDUCT) and we employ it as a starting point of the clinical reasoning to devise the individualized strategy.

### Safety

Because there are real therapeutic benefits for the patient with valvular heart disease, we believe that Safety in implementing them is more appropriate than Nonmaleficence (the name of the principle of Bioethics), since there will always be admissible adversities to make use of them, which should be anticipated and avoided wherever possible<sup>12</sup>.

We have used the concept of Safety for patients with valvular heart disease as the second step in the development of clinical reasoning. The assumed benefit is filtered through the eyes of the related morbidity, both intrinsic to the method and the one resulting from the circumstances of application in order to establish the APPLICABLE CONDUCT.

### Box 1 - Key elements of the RESOLVA strategy

<b>Benefit</b>
Collectivized experience (literature)
Updated guidelines
Recent post-guideline studies
Actual experience
Individual
Team
<b>Safety</b>
Morbidity of the method
Clinical severity of valvular heart disease
Influence of comorbidities
<b>Patient autonomy</b>
Authenticity (personal values)
Free action (search for reviews)
Deliberation (see options)
<b>Diligence</b>
Pro-attention
Pro-decision
Pro-activity
<b>Prudence</b>
Pro-reflection
Pro-opportunity
Pro-tolerance

We are aware that the historical deficiencies in the safety of the surgical technique, however much progress has happened, benefit our approach to prioritize quality of life, which is closely linked to the efficiency of adaptive mechanisms to valvular heart disease, in defining the best opportunity to solve the valvular dysfunction. In a sense, the clinical effectiveness of the “natural treatment” (concentric or eccentric hypertrophy) raises concerns about the safety of therapeutic intervention.

Other lines of thought, however, propose to focus on the future quality of life to the detriment of the current quality of life, for believing in the success of hemodynamic correction in Class II, meaning that the consolidation of the recommendation of the therapeutic methods occurred simultaneously with the increase of the safety degree<sup>13,14</sup>.

We recognize that there is a gray area in class II next to the expression of class III, where the critical judgment about the realities of the case (evolution of variables such as degree of ventricular dilatation and calcification, as well as the patient’s wish to settle immediately, by example) would support the need for an “early treatment”. This situation, where the objectivity of physical and complementary workup would outweigh the subjectivity of history, demonstrates that we must deem mandatory, in any circumstance, the profound enlightenment of the conduct adopted with patients with valve disease and their opinion - right to participate in decision making, according to the principle of autonomy.

## Autonomy

In professional practice, we should respect what the modern codes and laws applicable to Health signals: contemporary society wishes citizen participation in decisions about their own health<sup>15</sup>. As a result, we apply the principle of autonomy to patients with valvular heart disease.

On the diagnostic platform of valvular disease, we inform the patient with an indication of therapeutic intervention on the benefits and filters for their own safety, we clarify the resulting risk-benefit and encourage dialogue on consent (or not) of patients with severe valve disease.

Except in the imminent risk of death (as explicit in the Code of Medical Ethics), we wish that the APPROPRIATE CONDUCT be dealt with authenticity (judgment according one’s own values), free action (chance to search for other opinions) and deliberation (choice after knowledge of usability options) by the patient with severe valve disease, thus resulting - or not - in a CONSENTED CONDUCT, with or without adjustments with respect to APPLICABLE CONDUCT. We observe that there is heterogeneity of effective inclusion of patients with valvular heart disease in the resolution, depending on emotional, social and cultural aspects.

In short, we rely on the principle of autonomy to modulate the best scientific evidence of treatment with personal particulars of the patient with severe valve disease and establish the CONSENTED CONDUCT.

Experience has taught us that it is worth conducting a final reviewing evaluation for Diligence and Prudence purposes, the two precepts of Ethics mostly judged in Medical Councils, so that the resolution be largely ensured as a LEGITIMATE CONDUCT. What happens is that only after certain complaints of dissatisfaction with the results, we realize the usefulness of the final ethics check.

## Diligence

We stress the sequential examination of conformity of cautious conduct as an indispensable guarantee to stave off any pronouncements of neglect, especially when there are clinical demands for adjustment to the recommendation class I/IIa in the case. In finalizing the RESOLVA strategy, the ethical reaffirmation of Diligence makes the therapy proposal to pass through a tripartite screening method.

At first, we reconfirm the potential of the consented Benefit and which can represent a possibly non-consented component. Secondly, we review the extent to which what was consented represents a permissible degree of Safety for the patient with valvular heart disease. In other words, we assert the doctor’s autonomy about whether we should apply the CONSENTED CONDUCT or refuse to apply it. The third stage of analysis of Diligence makes us reconsider whether there was in fact an active and conscious participation of the patient with valvular heart disease in the decision making process.

In short, we learn that checking according to Diligence, by the end of the resolution sequence, helps us to: 1) conduct ourselves under an acceptable justification - and documentation - for any shortcuts to the usual, with respect to characteristics (clinical and/or autonomic) of the patient

with severe valvular heart disease; or 2) we become aware that a certain will of the patient with severe valvular heart disease makes us feel negligent and decided to refuse to continue the assistance.

## Prudence

Just like Diligence, we use the screening method of Prudence to finish off the resolution to the patient with severe valvular heart disease, in order to reaffirm a safeguard against a breach of ethics of recklessness.

While the use of the foundation of Diligence helps us protect ourselves from a neglecting “unethical non-practice”, Prudence helps us to further reflect on the ethical nature of the commitment with “practicing in a timely manner”.

It is particularly in the context of the class IIb effect dimension, where there is a need to ensure the relevance of the recommendation, because the estimates of certainty levels B and C (there is no IIbA recommendation in valvular heart disease guidelines) imply conflicting scientific evidence and expert opinion. The very semantics suggested in the guidelines<sup>5</sup> for the implementation of recommendation class IIb can be considered reasonable, obscure and not well-established for a possible application when the CONSENTED CONDUCT fits into class IIb.

Implementing the RESOLVA helps to maximize critical accuracy on the risk-benefit ratio in the specification of the therapeutic conduct of interest for patients with severe valvular heart disease.

## Case report

A 54-year-old man has severe mitral regurgitation associated with echocardiographic images suggestive of myxomatous degeneration and posterior mitral leaflet prolapse. He does neither manifest any symptoms of heart disease nor heart rhythm disorders, or signs of left ventricular dysfunction and pulmonary arterial hypertension; he is a smoker, has a moderate degree of pulmonary emphysema and reports right nephrectomy caused by trauma.

The patient wants to undergo mitral valve disease repair immediately, “while the lungs are good”. He reveals that his father had “a late heart surgery” when he had several symptoms of some diseases and died two days after the surgery.

*Benefit* - The clinical-echocardiographic evaluation estimated a 92.0% probability of success of conservative surgical treatment of the mitral valve. According to the Guideline 2006 ACC/AHA, there would be Class IIa recommendation with level of evidence B for surgical treatment, considering the team’s expertise. On the other hand, the routine of the health service that assists the patient waits for the symptoms of valvular heart disease for surgery indication.

*Safety* - A discussion between the team members pointed counterpoints: 1) low operative risk; 2) risk of usual perioperative complications, emphasizing the potential of pulmonary and renal complications due to pulmonary

emphysema and nephrectomy; 3) failure to ensure the effective implementation of a corrective maintenance of the mitral valve despite the existing expertise.

*Patient autonomy* - The risk-benefit aspects were informed to the patient and a multidisciplinary team felt he was well informed about the immediate aspect (risk > benefit to the quality of life) and the late aspect (impossibility of determining whether there is a higher surgical risk and/or changes in the probability of keeping the valve upon manifestation of symptoms). Nevertheless, the patient was proven able to undergo surgery immediately.

*Autonomy of the team* - There is no unanimity regarding complying with the patient’s “hastening” request.

*Autonomy of the institution* - The director of the health care service expressed his concern with respecting the institutional routine of waiting for symptoms, justifying a strong connotation of social justice considering the continuing and enormous demand for advanced clinical situations demanding surgical treatment in the short term.

*Neglect* - Failure to apply the recommendation class I requires a well-grounded clinical and/or ethical justification not to characterize evidence of negligence (omission of necessary and indispensable treatment) by the team. As for the recommendation class IIa - conceptually applicable to the case - passes at a different level of ethical appreciation, as it is less assertive (“it may be useful” replaces “it is useful”).

*Recklessness* - A possible compliance with the patient’s request would not characterize recklessness. There is scientific basis for the benefit in the circumstance of the case and there is no prohibitive risk, which rules out insensibleness and timelessness.

*Resolution* - According to the reflections guided by RESOLVA’S sequential items, the patient was informed and had recorded in his medical files that the team decided to keep the clinical conduct and periodic follow-up for observation of outcomes, whereupon it was emphasized that any modification of the clinical picture was to be immediately reported to the team and that this team would determine the resolution. Also, the team informed the patient that he had the right to seek a second opinion and find another health care service that accepted his willingness to “hasten” the surgery because there was no unanimity on the item “Autonomy of the team”.

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## Study Association

This study is not associated with any post-graduation program.

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