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Preventive cardiovascular surgery: ethics, shared decision-making and informed consent

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ABSTRACT

Preventive surgery aims either to prevent the occurrence of a disease or its progression to a point where it causes adverse outcomes for the patient. The ongoing Early valve replacement in severe ASymptomatic Aortic Stenosis (Easy-AS) trial is an example: asymptomatic patients with severe aortic stenosis (a condition in which the heart's main valve becomes narrowed and restricts blood flow out of the heart) are being randomised to early intervention, which may include surgical valve replacement (open-heart surgery) or transcatheter aortic valve replacement (a minimally invasive procedure to replace a narrowed heart valve without open-heart surgery), before the onset of symptoms, or standard care of waiting till symptoms before treatment. Data from our qualitative substudy of the trial around decision-making showed that patients' decision-making is complicated by an increased role of time trade-offs in such asymptomatic conditions and non-health values such as caring responsibilities and satisfaction with current quality of life. In this paper, we argue that these are ethical concerns and suggest how they may be tackled. In particular, we suggest a process of shared decision-making using patient decision aids (PtDAs) which include elements to help, such as values clarification. PtDAs have been shown to improve outcomes such as reduced decision regret and increased involvement of patients in the decision. Treatments such as preventive surgery in cardiovascular diseases would benefit from development and use of PtDAs to ensure adequate and ethical shared decision-making.

INTRODUCTION

Preventive (or prophylactic) surgery aims either to prevent the occurrence of a disease or its progression to a point where it causes symptoms or adverse outcomes for the patient. This paper arises from our recently published interview substudy of an ongoing randomised control trial,¹ the Early valve replacement in severe ASymptomatic Aortic Stenosis (Easy-AS) trial. Easy-AS is an example of preventive surgery, where asymptomatic patients with severe aortic stenosis (AS) (a condition in which the heart's main valve becomes narrowed and restricts blood flow out of the

heart) are being randomised to early intervention, which may include surgical or transcatheter aortic valve replacement, before the onset of symptoms, versus standard care of waiting till symptom onset before treatment.² The interview substudy highlighted some of the complexities of informed consent and shared decision-making (SDM) in preventive cardiovascular surgery.¹ In this paper, we argue that these are ethical concerns and suggest how they may be tackled.

TERMINOLOGY AND BACKGROUND Preventive cardiovascular surgery

We have chosen to use the term 'preventive' in this paper as a modifier to 'cardiovascular surgery'. Other terms that occur in the literature include: 'preventative', 'risk-reducing' and 'pre-emptive'. These are less commonly used; furthermore, the latter two do not feature as MeSH terms (that is, as terms under the Medical Subject Headings kept by the National Library of Medicine for indexing and searching). 'Preventive' is thus preferable in our view. By contrast, the term 'prophylactic' is more widely used and some sources mark a distinction between prophylactic and preventive surgery. Roughly, prophylactic surgery is the surgical removal or modification of tissue that shows no signs of disease, whereas preventive surgery is the surgical removal or modification of tissue that shows signs of disease but where there are no or few symptoms yet. At present, however, the distinction is not consistently applied. In addition, the term 'prophylactic' is more often used in relation to cancer rather than cardiovascular treatment. Preventive surgery is quite common in the realm of cancer surgery, with operations done to cure patients and prevent death when cancer is diagnosed through screening programmes. However, it is far less common in cardiovascular diseases.

A Medline search for preventive (and related terms) cardiovascular surgery found around 70 papers. The majority related to genetic conditions, such as Marfan syndrome, which predispose patients to cardiovascular events that may be avoided through preventive surgery.³ There were papers on other predispositions to aortic disease, such as bicuspid aortic valve (where people are born with two cusps or leaflets instead of three within their aortic valve)⁴ and to screening for aortic diseases.^{5,6} Valve disorders such as mitral valve regurgitation (a condition where there is a 'leaky' mitral valve, where some blood leaks backwards when the valve is closed)^{7,8} and AS were also covered.^{9,10}

The papers were primarily scientific and hence did not extensively cover ethical issues apart from in relation to institutional review board ethical approval. In this paper, however, we are concerned primarily with two issues arising from the aforementioned interview substudy of the Easy-AS trial that were, we suggest, ethical issues. This requires clarification of what we mean here by the term 'ethical'.

Ethics and value judgements

The grounding questions in science concern empirical facts about how the world is. In medical science, these concern health and illness; for example, whether a certain treatment performs better than another against certain parameters. By contrast, the grounding questions in ethics concern how people should live or, more prosaically, what should we do in the light of how the world is. These questions require the application of values, that is, judgements of what things matter and how much.

Take the Easy-AS trial. This is a large, multinational ongoing trial led by researchers in Leicester, UK, that started in 2020 and has recruited around 1300 patients so far. When complete, it will show whether people with asymptomatic severe AS who receive early intervention have better clinical outcomes than those who receive intervention only after the onset of symptoms. With adjustment for cost-effectiveness, the researchers can then make recommendations about the timing of treatment of future patients.

At this point, value judgements will have already come into play, particularly in the choice of outcomes. It will be assumed that endpoints such as living longer or living without breathlessness are worthwhile. Such values are so widely shared and uncontroversial that they usually pass unnoticed as value judgements at all. These hidden values are also found in the terms risk and benefit. Essentially, a 10% chance of something happening is a risk if we judge it to be bad, a benefit, if good.

Ethical issues tend to become apparent where the value judgements are contested or conflicted. For example, when patients withhold consent to surgery, it may be because of lack of understanding, but it may also be because their value judgements do not align with those of the clinicians. Our interviews for the Easy-AS sub-study suggest a particular issue concerning alignment of values

between patients and clinicians in preventive surgery. We turn to this next.

The Easy-AS trial

The Easy-AS trial concerns preventive treatment for those with severe but asymptomatic AS. The standard treatment in the UK for this condition has been expectant management, also described as watchful waiting (WW) for the development of symptoms, such as breathlessness, chest pain or collapse. At that point, where symptoms appear, aortic valve replacement is recommended. This can be either via open heart surgery (surgical aortic valve replacement—SAVR), or the less invasive procedure, transcatheter aortic valve implantation (TAVI). The latter is generally offered to those over 75 years old or at higher surgical risk. The Easy-AS trial tests the hypothesis that early intervention, before symptoms develop, will result in better clinical outcomes and a cost reduction when compared with WW. Patients are randomised between the early intervention or WW.

The interview substudy received independent funding and was led by one of the investigators of the EASY-AS trial, after addition of the substudy as an amendment to the main trial in collaboration with its chief investigator. The aim was to examine the factors influencing patients' decisions to accept or decline a major intervention (SAVR/TAVI) while asymptomatic and with an uncertain disease trajectory. It included 73 interviews with 41 participants. Most (n=25) were participants of the Easy-AS trial, some (n=9) were close relatives, and some (n=7) were people who had declined to participate in the randomised trial. The report of this sub-study is available elsewhere, including details of the ethics approval and recruitment process.¹ Our concern here is with two findings that relate to ethics and consent. These are: (1) The role of non-health values in patient decision-making and (2) Time trade-offs in decision-making. These are set out in more detail and discussed in the next section.

THE TWO FINDINGS

The role of non-health values

Interviewees who declined taking part in the Easy-AS trial generally shared the values of those who took part in terms of the importance of health and life and the risk/benefit profile in terms of health outcomes. However, they had other important values which were overriding. These tended to be more idiosyncratic and personal. For example, some had caring responsibilities which they did not want to risk through potentially having major surgery at that point. One older patient felt well, good enough to continue as he was. By contrast, at least one patient felt too unwell with other conditions to undertake arduous treatment for the AS. Those who declined to participate, in other words, did so not because they had different health values to those underpinning clinical care, but because they had non-health values that were overriding at the time or had other health values at odds with those

relating to their AS. These non-health values also featured in the reasoning of some who decided to take part in the trial; they were not overriding, however.

Trade-offs in decision-making

Decision-making is generally linked to trade-offs. Decisions involve losing the benefits of one course of action (the opportunity costs) in return for the benefits of another. To reach a decision, these must be weighed up against the decision-maker's values. In the Easy-AS interview substudy, the trade-offs included: (a) care for self against care for others; (b) current asymptomatic status against surgical risks and, in turn, against the risk of developing symptoms in the future and (c) the future burden of lifelong medication.

Of particular importance in preventive surgery are so-called time trade-offs (also called intertemporal choices). There is, of course, generally a time lag between costs and benefits in a healthcare decision. For example, if I have surgery now to treat symptomatic cardiovascular disease, the risks and potential harms of surgery are fairly immediate but the benefits follow close on their heels; the time lag is inconsequential. This, then, is simply a time lag, not a time trade-off. With preventive surgery, however, there is a noticeable time-asymmetric risk/benefit profile.

This was the case for the participants interviewed in the Easy-AS substudy. The risks and harms from the surgery were immediate; the potential benefits, given that the patients were asymptomatic, were deferred. Furthermore, the risks were clear and could be quantified, including, for example, a certain percent risk of death perioperatively depending on their other comorbidities. The benefits were less clear as the course from asymptomatic to symptomatic is less well charted and highly variable. This is often a feature of intertemporal choice—the immediate costs or benefits are more certain than the deferred ones.

People have different attitudes to risks and benefits,¹¹ particularly where there is a time trade-off.¹² And the extended period over which the decision plays out makes it likely that non-health values will play an increasing role. For example, age may affect how an individual values or prioritises immediate risks and deferred benefits.

How, then, can clinicians help patients negotiate these complex trade-offs? And to what extent should clinicians engage with non-health values to enable patients to make the health-optimal choice?

TACKLING THE QUESTIONS: INFORMED CONSENT AND SDM

The questions might be tackled first from a perspective of informed consent. Informed consent occurs when someone with adequate information and understanding, and capacity to do so, consents voluntarily to a healthcare procedure. This gives the three core elements: capacity, information/understanding and voluntariness.^{13 14} Hence, it might be argued, tackling the questions involves

accurately conveying the risks and benefits of preventive treatment in ways patients understand. Then, patients can weigh the risks and benefits and make the trade-offs.

More recently, however, the term SDM has been used in surgical and other clinical contexts. This is not simply a distinction without a difference. SDM conveys the idea of patients having an active role, whereas informed consent (at least, as it is commonly sought and obtained) is often viewed as passive.¹⁵ One example of this is the passive sentence construction in phrases such as “has the patient been consented?”. Increasingly, this passive view of informed consent is, of course, frowned on. SDM is one method used to ensure an active role for patients, including consideration of their non-health goals and values.

In most discussions of SDM, the use of patient decision aids (PtDAs) is recommended. A large number of these have now been developed. See, for example, the website of the UK Centre for Perioperative Care¹⁶ and the Canadian Ottawa Hospital Archive of Decision Aids.¹⁷ Many are in use and have been evaluated in trials and meta-analyses.¹⁸ The evaluations have involved a range of criteria. In the next section, we examine the evaluation of PtDAs in cardiovascular surgery.

THE USE AND EVALUATION OF PTDAS IN CARDIOVASCULAR SURGERY

Research on PtDAs

A Cochrane review with the objective of assessing the effects of PtDAs ‘in adults considering treatment or screening decisions’ was first performed in 2003 and updated in 2015 and 2024.¹⁸ By 2024, 209 studies were included; 22 concerned cardiovascular treatment. These were examined in a separate review by Lewis *et al.*¹⁹ of all the cardiovascular papers from the Cochrane review (finding 27 rather than 22) plus 5 found in an update to the search, a total of 32 papers. There have been at least two further reviews which we also draw on here for summarising existing PtDAs or those under development or trial for AS.^{20 21} The outcomes used for evaluation in the Cochrane and Lewis reviews were as follows:

Informed values-choice congruence; knowledge; accurate risk perception; feeling uninformed and having unclear values; participation in decision-making; proportion undecided; satisfaction with decision-making process; and adverse effects or decision regret.

Of these, knowledge and accurate risk perception would sit easily within an informed consent mode. The remainder gives a sense of where SDM differs, with its emphasis on the role of patients' values in particular.

As to the usefulness of PtDAs in cardiovascular surgery, Lewis *et al.*¹⁹ summarise their findings:

PtDAs were superior to usual care for improving the quality of decision-making process as evidenced by clinically significant better knowledge [...] more accurate risk perceptions, feeling better informed, feeling clearer about personal values, having significantly reduced proportions of

Table 1 Patient decision aids for aortic stenosis

Name of tool	Region	Decision choice	Is tool available?	Where	LINK
AVITA ^{31 32}	USA	TAVI/SAVR/Symptom management/Valve type	In part: it may be added to CardioSmart in the future	Coylewright ³¹ online supplementary file 3 page 132ff.	https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0302378#sec030
PCORI ³³	USA	Valve type (tissue vs mechanical)	Yes	Anaya online supplemental appendices 1 and 2	https://www.annalsthoracicsurgery.org/article/S0003-4975(19)30553-3/fulltext#supplementary-material
CardioSmart ³⁴⁻³⁶	USA	TAVI/SAVR/Symptom management	Yes	CardioSmart website	https://www.cardiosmart.org/topics/aortic-stenosis
CardioSmart (outside US context) ³⁷	Switzerland	TAVI/SAVR	Yes	A/A	
SEEK-AS ³⁸⁻⁴⁰	USA	TAVI/SAVR	No		https://academic.oup.com/eurjcn/article/22/Supplement_1/zvad064.089/7232986
Magic Evidence Ecosystem Foundation (2017) ²¹	UK	TAVI/SAVR	Yes	BMJ Evidence Ecosystem Foundation	https://app.magicapp.org/#/guideline/1308

AVITA, Aortic Valve Improved Treatment Approaches; PCORI, Patient-Centred Outcomes Research Institute; SAVR, surgical aortic valve replacement; SEEK-AS, Shared decision-making for the treatment of aortic stenosis; TAVI, transcatheter aortic valve implantation.

clinician-controlled decisions, without any adverse effects. [p.7]

Limitations of the research

Faced with the two issues arising from the Easy-AS trial, how might clinicians use PtDAs to assist? One limitation is that only two of the studies reviewed by Lewis *et al.*¹⁹ are UK based; most are from the USA. PtDAs are likely to be locationally specific. USA-based PtDAs may have sections on the individual's level of insurance, for example, that would be irrelevant in public-funded health systems. No studies examined PtDAs with regard to preventive cardiovascular surgery. And no study was concerned with PtDAs with regard to the choice of timing of intervention for asymptomatic AS; this is, of course, unsurprising given that the Easy-AS randomised trial is ongoing. It means, however, that the issue of decision-making for asymptomatic patients facing potential major surgery is not yet addressed by PtDAs in Cardiology. In all, we found five PtDAs that have been used, or are in development and trial, for AS. These are shown in [table 1](#).

PtDAs and negotiating SDM in preventive cardiovascular surgery

Using [table 1](#), let us restate our two questions. How can clinicians help patients negotiate the complex trade-off, particularly time trade-offs, in preventive cardiovascular surgery? And to what extent should clinicians engage with non-health values to encourage patients to make the health-optimal choice?

Patients using the PtDAs are facing trade-offs. Where the choices are between TAVI, SAVR and symptom management, the choice of SAVR means more risk now but a better future prospect if the patient is likely to require re-dos. A similar argument might be made in favour of choosing a mechanical over a tissue valve. A patient with chronic illnesses may choose the likely

worsening and even death from AS over the problems that surgery would cause them.

These sorts of choices are covered in the five PtDAs in [table 1](#). The Patient-Centred Outcomes Research Institute (PCORI) and Magic tools are sectioned by age and sex. As such, time-specific information can be given, such as the difference in need for surgery re-dos in those following mechanical vs biological valve replacement (because biological valves have a relatively shorter life-span compared with mechanical valves). The most extensively reported PtDA is the CardioSmart from the American College of Cardiology. This also has time-related risk/benefit information, based more on the procedures themselves than the patients' ages. It also has illustrative patient scenarios. For example, in one, the patient chooses symptom management and, in the other, TAVI.

Initial research cited in Table-1 suggests these have been helpful for patients but is ongoing. The AVITA tool is not readily available but appears to be designed with an element of values clarification for patients in addition to providing statistical information in digestible form. The MAGIC tool appears to be the only one with links to the UK but seems underdeveloped and unresearched as yet.

The details of the five PtDAs might lead us to think that they will help clinicians negotiate SDM in preventive cardiovascular surgery. There is, however, a problem. The five PtDAs shown in [table 1](#) are aimed at those with symptoms. As such, they are not concerned with preventive surgery of the type seen in the Easy-AS trial, where patients are asymptomatic. And we have argued that time trade-offs and non-health values are likely to play a more significant role with this type of surgery.

As the Easy-AS trial is not yet complete, there is insufficient evidence to develop PtDAs for asymptomatic AS (except where used in a clinical trial), although other recent trials in specific cohorts have demonstrated some

benefit, and a meta-analysis of four trials confirmed a reduction in unplanned hospitalisation with early intervention, but no difference in mortality reduction.²² We can, therefore, speculate on what might be needed in addition to that developed for other cardiovascular surgery. This might involve, for example, looking at decision aids with a large time trade-off component within and outside healthcare. Within healthcare, examples might be found in cancer and end-of-life care. Many of the PtDAs cited in the Cochrane review were from cancer care. Outside of healthcare, financial planning often involves making sacrifices now for future benefit. The decision aids aim, in part, to counter various cognitive biases, such as preferring present utility over future utility and being overoptimistic about future developments.^{23 24}

Hence, the answer to the question of helping negotiate the complexities of SDM in preventive cardiovascular surgery is, in part, to adapt and develop PtDAs, in collaboration with patient user groups. This leads us to the question of engaging with patients with a view to enabling a particular choice viewed as health-optimal. In other words, when clinicians engage in SDM over preventive surgery, to what extent should they try to persuade patients to favour the health-optimum option. Might it be that patients should be enabled to choose the option that maximises their overall rather than simply their health-optimal well-being?

A clear health-optimum option will itself often be the product of research using time trade-off methods. These methods are used extensively in health economics, such as in the creation of the quality-adjusted life-years system.²⁵ Typically, people will be asked to hypothetically trade off years of good health against bad. For example, how many years in perfect health would you trade for years in less than perfect health (such as with a disabling illness)? They might reply, for example, that 1 year of good health is worth 10 years in a reduced state. Huge amounts of data have been produced, leading to the creation of tables and scores that are widely used in allocation decisions, for example, by the National Institute for Health and Care Excellence (NICE) in the UK.²⁶ They are also used in quantitative research methods measuring health state outcomes—the EuroQol EQ5D is a commonly used example.²⁷ Hence, to the question of whether there is a course of action preferred in terms of health values, the answer is, yes. It is that which is recommended by NICE or similar allocation bodies.

As stated earlier, clinician decisions are made largely on the basis of what we've termed 'health values'. In most cases, patients share those values and often make the same decisions. But patients will decide on an all-things-considered rather than health alone basis. And, we have suggested, the all-things-considered element is likely to intrude significantly where there are time trade-offs of the type seen in preventive cardiovascular surgery. To what extent can PtDAs help here?

Many of the PtDAs reviewed by Lewis *et al.*¹⁹ included an element of values clarification which aimed either

to clarify the patients' values to themselves or to clinicians. However, there are many different values clarification methods, and their theoretical basis is sometimes weak. Witterman *et al.*^{28 29} have developed a taxonomy and suggested further research is needed. Fagerlin *et al.* suggest six attributes of value clarification that PtDAs should facilitate.³⁰ For our purposes, two are particularly relevant.

- (1) Identifying options, which can include either the narrowing down of options, or the generation of options that were not offered at the outset,
- (2) Identifying attributes of the situation and/or the options which ultimately affect the patient's preference in a specific decision context [page 3 of 7].

The term 'generation of options' is worth noting. As an example, preventive cardiovascular surgery may be right health-wise but wrong for the person caring for an aged parent. PtDAs should help patients explain their concerns and, as it says above, perhaps generate new options with the clinician. This might mean offering a TAVI rather than the surgical route, even when the patient doesn't fully meet the criteria. Or it could involve negotiation around putting a care package in place for someone the patient usually cares for. Our interviews showed that this generation of options matters for patients, perhaps particularly in preventive surgery.

CONCLUSIONS

Preventive cardiovascular surgery involves a time lag of varying length between risks and benefits. There may also be increased uncertainty over the long-term benefits. As a result, patients' consent decisions are complex. Patients need to trade off present risks and harms against future potential benefits. PtDAs are available to help but there are none specific to decisions around timing of intervention for asymptomatic AS. The development of such aids to help patients negotiate time trade-offs and the weighing of health values as well as non-health values is likely to be needed if treatments such as surgery for asymptomatic AS are recommended in the future.

Contributors PA was the main research assistant on the study and was responsible for the acquisition, analysis and interpretation of data for the work; drafted the initial reports and the manuscript (with AS) and gave final approval of the version to be published. BT made substantial contributions to the interpretation of data for the work; reviewed and edited the manuscript critically for important intellectual content and gave final approval of the version to be published. AT made substantial contributions to the conception and design of the work and interpretation of data for the work; reviewed and edited the manuscript critically for important intellectual content and gave final approval of the version to be published. TR made substantial contributions to the conception and design of the work and interpretation of data for the work; reviewed and edited the manuscript critically for important intellectual content and gave final approval of the version to be published. GPM made substantial contributions to the conception of the work; reviewed the manuscript critically for important intellectual content and gave final approval of the version to be published. AS made substantial contributions to the conception and design of the study and acquired funding for it; contributed to recruitment of participants, interpretation of data; drafted the manuscript (with PA); gave final approval of the version to be published and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or

integrity of any part of the work are appropriately investigated and resolved. AS is the guarantor for the study.

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Data availability statement Data from this study are available on request from the lead author.

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