The Decision-Making Process in Percutaneous Coronary Interventions

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1. Introduction

As the range and quality of endovascular instruments improve, the industry supplying these tools is increasingly trying to create the impression that percutaneous coronary intervention (PCI) is a simple and straightforward procedure. It is nothing of the sort. In PCI, in fact, an operator performs high-risk procedures under time pressure, with only indirect and incomplete angiographic information about the interventional site, and is constantly trading off one risk against another. Mastering this complex process requires years of experience and an attitude characterized by the constant willingness to learn and reflect when faced with each unexpected development or new situation. Unfortunately, to the best of our knowledge, the complexity of this repetitive and evolving process, consisting of the triad of angiographic imaging, image interpretation, and interventional action, has not yet been fully described. Furthermore, there is no data on the factors determining the decision trade-offs or their relative weights in various common situations. Consequently, physicians learning PCI today need a gifted teacher or have to gain experience the hard way, by trial and error, which exposes patients to avoidable risks and complications. Existing materials on learning PCI (e.g., (1-4)) only describe formal training requirements and the parameters of institutional and operator competence. They provide no help on how to make hard decisions during an intervention.

The purpose of this chapter is to start filling this void by providing an overview of some important basic factors and how they interact. One can obviously not fully describe the actual decision-making process because, although each component of the triad and the resulting trade-offs are quantitative in principle, most of these quantities cannot be measured in practice. Therefore, only general decision-making rules can be formulated to facilitate the training and clinical experience so necessary for becoming a master PCI operator. We hope that this description will help transform a rather vaguely formulated practical exercise into a conscious process of skill acquisition. The goal is to become capable of successfully handling even unexpected and adverse developments in the course of complex interventions.

The following section describes the basic elements of the PCI decision-making process, while the process itself is described in subsequent sections. We assume that the reader has a basic understanding of the PCI process and that the elements therefore need little or no description.

1.1. Input and Output Variables

The PCI decision-making process involves a number of input and output variables. The input variables include:

- Operation scenario
  - emergency or elective
- General patient status
  - general health
  - cardiac function
  - cardiovascular risk factors (e.g., type II diabetes)
  - history of cardiovascular diseases (e.g., coronary bypass surgery)
  - stability (clinical, hemodynamic, electrical)
- Current physician status
  - rested or exhausted
  - skilled in handling unexpected developments or overwhelmed by them
  - stress resistant or low in morale
- Accumulated time and costs
  - procedure time
  - radiation exposure
  - contrast agent dose
  - monetary costs (physician, staff, equipment, material)
  - schedule pressure (availability of physician, staff, and laboratory)
- Current interventional status
  - presence of single/multiple lesions
  - presence of single/multiple coronary artery diseases
  - presence of stents or coronary bypasses
  - target vessel size and status
  - location, severity, and complexity of the target lesion
  - status of the antegrade coronary blood flow
  - amount of dependent myocardium
  - availability of required instrumentation
  - status of deployed instrumentation
    - guiding catheter

        - guide-wire
        - balloon catheter
        - stent
        - pressure/volume sensor
        - ultrasonic sensor
    - performance of deployed instrumentation
        - as expected
        - suboptimum
        - malfunctioning
        - tracking, crossing, pushing abilities
    - uncertainty about the reliability of all of the above information

The output variables in PCI decision making, i.e., the potential actions of the operator, include:

- Initial actions
    - establishing arterial access
    - placement of the guiding catheter
- Imaging
    - image acquisition (cine, fluoroscopy) and visualization of the target vessel and lesion
    - imaging by ultrasonic sensor
    - review and interpretation of acquired images
- Initial and subsequent interventions
    - placement of the guide-wire
    - placement and inflation of the balloon catheter
    - stent deployment
    - employment of auxiliary techniques (whether diagnostic or revascularization)
    - removal of equipment and instrumentation
- Auxiliary acts
    - drug administration
    - addressing and responding to staff
    - addressing and responding to the patient
- Termination of the procedure

1.2. Risks and Benefits

The primary categories used to judge the consequences of each subsequent interventional step are those of *benefit* and *risk*. Benefits are what we would like and expect to achieve in both tactical and strategic terms, while risks we would rather avoid, but can never be sure of doing so. The benefits we strive for include remedy or palliation of the coronary artery syndrome and an improved prognosis, or at least preparing the ground for later definitive repair. Since most risks and risk considerations are inherent in the PCI procedure itself, they play a prominent part in the entire decision-making process. They are discussed in the following section.

2. Risk Considerations

The central consideration in the decision-making process during PCI is risk and how to prevent, evaluate, and control it. A thorough understanding of the character and magnitude of the risks and benefits involved in each interventional step is crucial for effective decision making during a PCI.

Risk can be defined qualitatively or quantitatively. Qualitatively, a risk is just any undesirable event that may or may not occur. If it occurs, the risk is said to *materialize*. Quantitatively, risk is the product of the probability of the event and the damage expected if it happens. Here, we are interested in the quantitative understanding of risk: *Risk* is the extent of damage expected in terms of its probability. It is important to note that we may use this notion of risk even if we understand the probability and the size of the damage only vaguely (high uncertainty). In the context of PCI, we clearly cannot express risk as a number, but the notion will still help to distinguish greater risks from lesser ones.

The task of a PCI operator is to identify the course of action with the lowest overall risk and highest benefit for the individual patient.

We distinguish between two very different kinds of risk, namely, latent and actional risk, and two different ways of dealing with each of them. Actional risk is further subdivided to reflect a possible adverse course of PCI (see Fig. 1).

2.1. Latent Risk

Latent risk is risk that is already inherent in the individual situation before any procedure is initiated and which remains there unless removed. The most typical example of latent risk in the context of PCI is myocardial infarction. Latent risk may materialize at any time or, at least in elective cases, it may remain dormant.

There are two ways of dealing with latent risk: one may either *accept* it and not address it, or *mitigate* it by working actively to reduce it.

The two main purposes of PCI are mitigation of the latent risk and reduction of a patient's symptoms.

2.2. Actional Risk

Actional risk is that risk created by the actions of the operator, whether diagnostic or interventional. PCI involves many different actional risks including vessel closure, dissection and perforation of the target vessel at the target lesion, and vessel wall damage elsewhere in the coronary circulation or along the vascular access path, with ensuing local and/or systemic complications and patient instability.

There are two ways of dealing with actional risk (see Fig. 2): one may either *avoid* it by not performing the respective action, or *accept* it and perform the action anyway.

The main issue for PCI is to identify those actions which, given the context of the current procedure, result in the maximum reduction of latent risk with a minimum and acceptable level of actional risk. Much of PCI decision making revolves around the question of what constitutes acceptable actional risk.

In terms of risk management, there is a great difference between emergency and elective PCI. During emergency PCI, the operator will be prepared to accept substantially higher levels of actional risk for two reasons. First, in patients with acute coronary syndromes and hence the high latent risk of permanent myocardial damage and/or cardiovascular death, there is a lot to be gained by taking higher actional risks. Second, the need for rapid action conflicts with the lengthy evaluation of risk factors and the consequent risk reduction that might be possible in elective situations.

Actional risk is always accompanied by two other effects. First, the intervention entails concrete financial *costs,* which rise with its duration, the number of steps involved, and the materials required. Second, if successful, the intervention will result in some kind of *benefit*. This benefit, whether a reduction of latent risk or merely the preparation of such a reduction, must be traded off against both actional risk and costs. Furthermore, when looking at the actual PCI decision-making process, it is useful to consider the three additive components of actional risk: optimum-choice actional risk, knowledge risk, and indirect risk.

2.2.1. Optimum-Choice Actional Risk

Optimum-choice actional risk refers to that part of actional risk that an ideal operator acting under ideal circumstances would accept, in particular, given perfect information about the current status of the vessels. Optimum-choice actional risk is the actional risk incurred by those interventional steps that are required for optimum success.

2.2.2. Knowledge Risk

Knowledge risk is the part of actional risk incurred only because the operator's information about the vessel and lesion status is incomplete and imprecise (see Chap. I.3.2.1 for the shortcomings of X-ray coronary angiography in visualizing the interventional site). Incomplete information or incorrect image interpretation may start a chain of inaccurate judgements, possibly leading to a suboptimal or overly dangerous intervention, and which in turn leads to increased actional risk. This *increase* in actional risk we call knowledge risk. There are three ways to reduce knowledge risk: first, by means of optimized image acquisition and evaluation; second, by performing additional diagnostic evaluations such as flow/pressure measurements or intracoronary ultrasonography; and third, by obtaining tactile information if the operator demonstrates advanced manual dexterity and operational skills. Note that extending diagnostic evaluations will always imply actional risk and must be traded off against the reduction in knowledge risk.

2.2.3. Indirect Risk

Indirect risk refers to the part of actional risk incurred by voluntarily giving up existing benefits. This is best explained by an example: Assume we have a guiding catheter in place in a vessel. If the PCI is not yet terminated, this is a benefit. Now, assume we want to exchange this catheter for another one (say, to switch from 5F to 7F). Obviously, this step involves actional risk since we may inflict damage on the patient during catheter exchange. However, even if no damage occurs, it may happen that for some reason the target vessel cannot be accessed because it proves impossible to appropriately position either this new catheter or any other one tried later. Thus, by removing a guiding catheter, we risk losing the benefit of having a well-positioned catheter (even if only 5F) in place. The possibility that this will happen is represented as indirect risk.

The only way to reduce indirect risk is by carefully planning the potential courses of intervention that may lie ahead, and how to proceed without giving up any intermediate benefits.

Indirect risk can often be reduced at the expense of financial cost by using the equipment best-suited for a job rather than the cheapest that is expected to be sufficient.

2.3. Risk Level Classification

To roughly classify the level of risks, we propose a five-level ordinal scale with the levels *very low, low, medium, high,* and *very high.* The component aspects *probability of the adverse event* and *expected resulting damage* can be described on the same scale. In principle, it is possible to describe the meaning of the probability levels numerically as a percentage. However, as people are known to estimate probabilities poorly, this is unwise. In any case, no inter-subjective scale is available to quantitatively represent the damage incurred. Overall, the classification of both probability and damage (and thus of the total risk) is subjective and difficult. Therefore, a significant aspect of the skill of a master PCI operator consists in the ability to accurately (if not precisely) assess and compare the levels of alternative risks.

It is important to understand that potentially all aspects of PCI entail actional risk, even such apparently innocent acts as considering a decision (because that takes time during which the patient may become instable) or terminating the procedure by suturing the access site (because that involves removal of the sheath and wound closure, and hence lack of an emergency access in case of acute complications). Nevertheless, some actions carry an obviously greater risk than others. The most risk-intensive actions during PCI are usually the following:

- Using force in advancing instrumentation
- Inflating a dilatation balloon at high pressures (with or without a stent)
- Inflating an oversized dilatation balloon at any level of pressure (with or without a stent)
- Recanalization of subacutely occluded vessels
- Crossing subtotal occlusions
- Re-crossing iatrogenically unstable lesions, iatrogenic coronary artery occlusions, and incomplete stent apposition

For all of these, the actional risk is high because of the large knowledge risk component involved. Knowledge risk is high for several reasons:

1. The information available about the status of the interventional site based on X-ray angiography is incomplete and imprecise.
2. The ensuing damage when an injury is inflicted is usually severe.
3. Access to the vessel may be compromised, making further deployment of instrumentation dangerous or impossible.

2.4. Value of Operator Experience

The difficulty with minimizing risk during a PCI is obviously the fact that the risk inherent in any situation or step is usually uncertain and can only be estimated. Much of the experience of a master PCI operator is reflected in the precision and accuracy of his or her risk estimates and also the ability to manage unexpected and adverse outcomes.

A PCI beginner will only have a vague understanding that "something may go wrong" at some point, but will have serious difficulties classifying the likelihood of problems or discerning their nature and the limits imposed on their resolution.

A PCI operator with some experience can assess risk with a certain amount of accuracy and can also explain the nature of the risk in terms of which specific set of adverse events is currently to be feared (as opposed to those that are implausible in the given situation); his or her repertoire of technical skills allows the management of standard complications.

A master PCI operator has still greater accuracy in assessing the risks, though his or her knowledge is still imperfect due to deficiencies in the input information and the intricacies of individual cases. More importantly, he or she cannot only enumerate the plausible adverse events, but can also estimate with competence the likelihood of each one of them separately. The intervention strategy can hence be adapted accordingly in order to minimize risk and to be prepared to manage any adversities that occur. It appears that for the majority of master operators the estimation of risks and adaptation of the process is not a conscious sequence of estimates and decisions. Rather, it is perceived as an intuition that tells them what and what not to do. Only a minority of master operators can easily explain *why* they decide upon a specific course of action and *how* they do *what* they do. The details of the decision-making process of a master PCI operator remain largely unexplored at this point.

3. The Basic Decision-Making Process

The decision-making process in PCI consists of three overlapping, but different stages:

1. Initialization: Considerations before or at the beginning of the intervention. They pre-structure the entire interventional process. Changing decisions made here is possible later on, but should be avoided as far as possible.
2. The main cycle of assessment and intervention: Many, if not all, interventions consist of multiple, consecutive interventional steps. The decision in each step is based on an assessment of the situation resulting from the previous step. The primary question is always: Which intervention promises the highest reduction in latent risk per investment of actional risk? Cost considerations may suggest deviations from this ideal path of the intervention. A helpful rule of thumb is to keep the number of interventional steps to a minimum, as these tend to increase both procedural costs and actional risk.
3. Termination: The decision when to terminate the intervention is based on the question of when, considering all available interventional approaches, the required investments in further procedural costs, time, and actional risk actually outweigh the expected resulting reduction in latent risk.

We will discuss each of these stages in a separate subsection.

3.1. Initialization

Initialization produces two consecutive results:

1. Decision whether to intervene
2. Decision how to intervene (decision as to the initial interventional approach, including selection of the access site)

We will discuss each of these in a separate subsection.

3.1.1. Decision for or Against Intervention

The decision whether a PCI should be attempted at all is based on three sets of information:

1. The coronary vascular status of the patient
2. Other data on the patient's health status
3. Technical feasibility and practicability of the intervention

We will not discuss issues of patient consent here.

The patient's **coronary vascular status** is assessed on the basis of existing diagnostic coronary angiography and supporting clinical information such as clinical symptoms and ECGs. The decision to intervene requires that (1) the target coronary lesions are sufficiently critical and sufficiently likely to cause the perceived symptoms to warrant PCI and (2) a suitable balance of latent risk, PCI actional risk, and expected PCI benefit appears to be present. Although the available initial data may be different, the issues to be considered are the same as during the main cycle of PCI and will hence be described there.

The estimate of PCI actional risk must now be modified by taking into account **other patient health status data**, such as the presence of multiple-vessel coronary disease, generalized vascular disease, co-morbidities, further major cardiovascular risk factors, and status of the left ventricular function. The presence of any of these additional risk factors increases individual PCI actional risk considerably and may tip the balance towards nonintervention. If intervention appears desirable, one should consider whether it appears technically feasible and operationally practicable.

To decide on the **technical feasibility and practicability** of PCI, the operator typically considers the following aspects:

- Localization and percutaneous accessibility of the target lesion
- Status of vessels constituting the interventional path to the target vessel
- Status of the neighboring segments of the target vessel
- Status of other vessels near the target vessel
- Status of the dependent circulation distal to the target vessel
- Expected ability of the patient to handle the stress imposed by the intervention
- Expected incurred procedural costs

Adverse characteristics may indicate an unacceptable level of actional risk for the given intervention or make the intervention completely impossible. Positive characteristics serve as indicators for a decision to intervene.

3.1.2. Initial Strategy

The initial strategy to intervene is determined by selection of the access site and initial instrumentation. More specifically:

- Selection of **the vascular access site** is based primarily on the status of the intended vascular path between the access site and the target vessel, and on the experience and personal preference of the operator. Due to its high versatility, right transfemoral access typically is selected. Alternative access sites are the left femoral, left and right brachial, and left and right radial arteries.

- Selection of initial instrumentation consists primarily of decisions as to the **French size, form, and type of the guiding catheter** on the basis of considerations such as: required back-up, expected need for larger devices such as bifurcation stents or thrombectomy catheters, use of special techniques such as “kissing” balloon dilatations, and the topography and vulnerability of the ostium. Choices regarding the performance requirements of the guide-wire and balloon catheter with or without stent complete the selection of the interventional starting set.

The importance of these initial decisions cannot be overemphasized. Any suboptimal choice will make the operation unnecessarily difficult and may even prevent its successful completion. Any initial choice that must be revised during the intervention entails additional actional risk and increases overall procedural costs.

The intervention commences with the placement of the introductory sheath, followed by advancing and positioning the guiding catheter at the ostium over a guide-wire (typically 0.035 inch). Optimum positioning and back-up of the guiding catheter represents a primary success factor for the subsequent intervention.

It is important to be aware of possible problems at this stage of the procedure and to solve them, if at all possible, before the actual intervention has started; this increases the prospect of positive outcome and keeps indirect risk low. Typical considerations include:

- Selecting a **sheath** of appropriate French size and length that can overcome possible problems such as excessive length, tortuosity, or luminal obstructions in the conduit vessels. If the initial choice does not work well, the operator should consider switching at once to an alternative approach.
- Checking the adequacy of the **guiding catheter** to provide optimum back-up and positioning at the ostium. If the initial choice does not work well, the operator should consider switching at once to another catheter.
- Being aware of other unexpected **difficulties** of any kind during the initialization of the intervention, including changes in the patient's clinical status in response to vascular manipulations, and complications in advancing the instrumentation within the target vessel and across the target lesion. If difficulties occur, the operator should reconsider the strategy and the decision to intervene. Stopping the intervention at this point should also be considered if the risk/benefit ratio no longer appears good.

If changes in overall strategy are needed, the operator should not hesitate to make these changes. The intervention will be burdened with significant levels of avoidable indirect risk and may cause adverse outcomes if difficulties that are accepted at this stage make a change in strategy necessary later.

3.2. The Main Procedural Cycle

Once access to the target vessel has been gained, the intervention enters a repeated cycle of assessment and intervention. More specifically:

- Assessing the status of the target vessel and target lesion by acquiring and interpreting cine or fluoroscopic X-ray coronary artery images
- Deciding how to perform the next interventional step and carrying it out.

Coronary intervention may encompass any number of main cycles. In principle, the operator alternates between information gathering, data interpretation, and actual intervention. In practice, however, these phases are closely intertwined because information gathering and interpretation are essentially continuous processes during PCI. It should be noted that subsequent intervention steps can be directed at the same target lesion and vessel, or to different vessels or vessel segments, depending on the results of the evolving intervention.

The process ends when the termination criteria described in Sect. 3.3 are reached.

3.2.1. Assessment of Status

Assessment of the target vessel and target lesion is primarily based on X-ray angiography and less frequently on intravascular ultrasonography or pressure/flow sensor probes. Discussion of the characteristics, limitations, and interpretation of each of these sources of information can be found in Chap. I.3.2. We will therefore limit the description here to

1. The risk considerations involved in interpreting the available information and

2. The lesion characteristics to be considered.

In terms of **risk considerations** for a particular target lesion, two issues must be addressed:

1. Objective situation: Is an intervention objectively appropriate for the selected lesion, i.e., would an intervention provide a favorable ratio of risk (and cost) to the expected benefit to the patient?
2. Subjective evaluation: Is an intervention appropriate for this lesion in the operator's opinion?

If both answers are "no", we have a *true negative,* and the intervention should not be performed.

If both answers are "yes", we have a *true positive,* and the selected lesion is correctly considered for intervention as described below.

If the subjective evaluation is "no", although objectively it should be "yes", a *false negative* results. The intervention does not take place, and an opportunity to benefit the patient is lost.

If the subjective evaluation is "yes", although objectively it should be "no", a *false positive* results. The subsequent intervention exposes the patient to a substantial risk. Depending on the outcome, the intervention will either be merely fruitless or may cause damage that could have been avoided.

It should be noted that in reality the answers to these questions are usually not "yes" or "no", but somewhere in between. The lesion receiving the most positive answers in the subjective evaluation will become the candidate target for the next interventional step in the evolving scenario of the intervention.

In complex procedures with several candidate lesions, the process of selecting the target lesions and their sequence should consider the following **criteria**:

- Selection criteria from the patient's point of view:
    - Which lesion is likely to be the most critical for myocardial salvage and/or perfusion? Identification and successful removal of this lesion promises to yield the greatest potential benefit in terms of clinical improvement.
    - Which lesion is likely to be the most dangerous one? Repairing unstable lesions (or stabilizing them) promises to bring about the greatest reduction in latent risk.
- Selection criteria from the operator's point of view:
    - Which lesions provide the best substrate for successful repair? The likelihood of successful repair depends on reasonably well-determined criteria such as length, degree, and complexity of stenosis, but also on characteristics that are rather difficult to assess, such as the tissue composition of the atheroma and overall plaque burden of the adjacent vessel walls.
    - Which lesions carry the highest risk of complications such as vessel wall dissection or rupture upon mechanical intervention? The consequences of severe complications may be such that PCI of lesions with a high risk of severe dissections or ruptures (such as high-grade stenosis in diffusely degenerated venous grafts) should be performed only with reservations in exceptional cases, if at all.

- Interventional priorities. Generally, the most critical stenosis should be approached first, not only because it promises the greatest benefit, but also to reduce the risks involved in subsequent interventional steps on associated lesions. In lesions of similar criticality the most distal one is commonly tackled first to avoid re-crossing.
- Sequences and staging of intervention. In patients with multiple lesions it is important not only to decide the sequence in which the competing lesions should be revascularized, but also whether single- or multiple-stage revascularization would optimize the risk/benefit trade-off while keeping the indirect risk low. The possibility of surgical or hybrid, i.e., combined percutaneous/surgical revascularization should also be considered.

3.2.2. Performing Interventional Steps

The actual intervention typically consists of five steps, some of which may have to be repeated several times in the course of the procedure:

1. Selecting the guidewire
2. Positioning the guidewire distal to the target lesion and verifying the position
3. Selecting the dilatation balloon or stent catheter
4. Performing dilatation
5. Checking the results

The **guidewire** is selected primarily for its expected ability to track the target vessel up to the lesion, cross the lesion without producing trauma, and reside distal to the lesion with enough support to enable tracking of the endovascular instrumentation. The rigidity of the shaft for optimum support has to be traded off against the greater risk of vessel injury.

While **positioning the guide-wire**, which in coronary interventions is typically 0.014 inch in diameter, the operator may experience difficulties in tracking the target vessel, and in reaching, crossing, or advancing beyond the lesion. Several situations are common:

- The guide-wire tip is inappropriately shaped for navigating towards and along the target vessel. The usual procedure is then to withdraw the wire, reshape the tip, and try again; the indirect risk from withdrawing the wire is clearly lower than the actional risk from working with a wrongly shaped tip.
- The stiffness of the tip is inappropriate for avoiding or crossing obstacles while avoiding traumatization of vessel walls along its path. The usual procedure is then to withdraw the wire and try a softer or stiffer one. Note that the new wire may need to have a differently shaped tip. The risk consideration is like the one above.
- The guide-wire shaft is too stiff to navigate the course of the target vessel or too soft to support tracking of the endovascular instruments. The usual procedure is to withdraw the wire and to try again with the next softer or stiffer option. Again, the risk consideration is as described above. In difficult cases, switching from rapid-exchange to over-the-wire techniques, employing a second guide-wire, or even changing the guiding catheter for extra support may become necessary. In all of these cases, the operator is usually willing to accept the indirect risk involved in withdrawing the current wire, because the actional risk of working with an inappropriate wire (or catheter) is high and the time lost during multiple ineffective positioning attempts increases it further.

In any of the above cases, the decision for or against correction trades the expected tactical benefit against the increased indirect risk associated with making the correction. In a few cases, the indirect risk may be high enough to warrant abstaining from the intended correction, which in turn requires reconsideration of the overall strategy and feasibility of the intervention.

When the lesion has been passed successfully, the operator decides what will be the **final position of the guide-wire tip distal to the target lesion**. The common choices are:

- Aggressive approach. The distal segment of the target vessel is selected for optimum control of the target vessel and maximum support. In more forceful interventions, this action runs the risk of damaging the distal vessel wall. It may be inappropriate for guide-wires with stiffer shafts or tips.
- Conservative approach. An intermediate distance from the lesion is chosen to avoid distal target vessel wall damage, particularly in diffusely diseased vessels and in interventions requiring the use of greater force. This provides greater clearance for the to-and-fro motion of the guidewire tip, while trading the better support associated with a greater risk of damage in favor of risk reduction.
- Alternative approach. “Parking” the guide-wire in functionally less important side branches avoids the guide-wire tip making contact with the distal segment of the target vessel. The aggressive lean-on approach may become more acceptable in this case.

Once the guide-wire tip has been securely positioned, it is critical for at least two projections with the guide-wire in place to be acquired to **verify** and document unequivocally its correct placement in the target vessel and the lack of trauma along the guide-wire passage. Accidental placement in a different vessel that runs parallel to the target vessel must be avoided.

The selection of the **type of dilatation balloon catheter** or stent catheter is based on the overall assessment of the severity of the stenosis, its length, its location with respect to the left main coronary artery or ostium, side branches, and expected plaque burden. In selecting the balloon catheter, it is important to bear in mind that information about the mechanical properties of the target vessel and target lesions is incomplete. The choice of using balloon dilatation or attempting direct stenting depends on a number of criteria discussed in Chap. II.3.5. Regardless of which is chosen, the following parameters should be considered:

- Balloon diameter. Does the balloon diameter match the nominal size of the target vessel at the lesion?
- Balloon length. Does the balloon length match that of the target lesion?
- Mechanical properties of the balloon/stent. Do the mechanical properties of the balloon catheter (pushing and crossing abilities, and noncompliance at high pressures) meet the requirements posed by the status of the target vessel and the stenosis?
- Balloon refolding ability. Will the balloon catheter refold safely to avoid damage during its retraction after successful dilatation?

As with positioning of the guide-wire tip, worst-case scenarios should be borne in mind during the selection and use of balloon catheters, considering the actional risk from choices that are too aggressive but also not ignoring the disadvantages of choices that are too conservative: actional risk from time lost due to multiple inflation attempts and indirect risk from perhaps having to withdraw more than one balloon.

From the above, it is clear that PCI entails active risk management throughout its entire course, but the phase of balloon inflation is typically associated with the highest actional risk.

In contrast to open heart surgery, it may become more difficult to control the consequences of severe vessel damage inflicted by mechanical overexposure during PCI. Careful decision making, including careful and rather conservative sizing of the balloon or stent, is therefore essential. It is at this critical point – removing a stenosis without inflicting uncontrolled damage to a vessel – that the superior power of judgment of an expert PCI operator makes the biggest difference.

Following deflation and removal of the device, a brief contrast flush injection is typically used to check the lesion after the intervention. Subsequently, at least two projections of the interventional site at high resolution must be acquired and thoroughly studied to assess the results. If there are doubts about the results, the operator must look closely at the projections that seem most unfavorable in order to obtain reassurance that the results are acceptable or to evaluate the problems. Evaluating the results of the preceding interventional steps also serves as an indicator for the next iteration with which the procedure will continue, unless it indicates that terminating the procedure is preferable.

3.3. Termination

Deciding when to terminate the procedure is relatively simple in patients with single-vessel, single-lesion coronary artery disease, but often difficult in more complex cases. In principle, the criterion is always the same: the procedure should stop as soon as the risk involved in further intervention appears to exceed the expected benefits. It is useful to distinguish between the following major reasons for terminating the procedure:

1. Full procedural success. All target lesions have been successfully repaired, and the patient's condition is stable and asymptomatic.
2. Satisfactory procedural success. Some target lesions have been successfully repaired, the patient's condition is stable and asymptomatic, with any remaining lesions considered not significant or amenable to later repair.
3. Palliative procedural success. Target lesions have been improved, but not completely removed, and the patient's condition is stable and largely asymptomatic.
4. Intractability. Despite one or more attempts, the goal of the intervention has not been met; the target lesion is unchanged; the patient's condition is stable.
5. Unacceptable risk of complications. Revascularization has to be aborted because of the excessive risk of local or systemic complications. Depending on the general clinical condition and coronary status of the patient, conservative and surgical treatment options will be considered.
6. Failed procedure. The intervention resulted in deterioration of the lesion or of the patient's clinical condition, requiring immediate consideration of alternative emergency therapy options.

In individual cases, procedural success might be interpreted differently by different operators, whereby the degree of freedom in defining procedural success is lowest for case 1 situations and highest for case 5. Additional variability is introduced by other factors, in particular the difference between elective and emergency cases: The level of risk the operator is willing to accept is considerably higher in emergency cases, thus greatly reducing the operator's willingness to terminate the procedure for reasons 4 or 5.

4. Decision-making Examples

In order to illustrate the use of this decision-making approach in practice, this section presents two real intervention scenarios (including patient status, intervention history, and coronary images) with examples of the reasoning behind them (including some discussion of alternatives) and their outcomes. The decisions are discussed in terms of latent risk (or patient benefit, respectively), actional risk, and the uncertainty about both.

4.1. A Straightforward Elective Case

This is a 61 year-old male patient with diffuse single vessel disease who underwent an elective complex stent coronary intervention of the left circumflex coronary artery 14 months prior to present admission. Following the intervention, his exercise tolerance improved, but then had declined for the past nine months. At the time of admission, the patient reported exertional angina and shortness of breath at a moderate level of exercise while on an increasing antianginal medication. Elective angiography confirmed a single-vessel disease with a subtotal occlusion of the left circumflex coronary artery elective revascularisation was indicated.

Given the symptoms and angiographic status (Fig. 3), coronary bypass surgery was not considered a primary revascularisation option due to its much higher actional risk and cost. Therefore, PCI was recommended. PCI for a subtotal chronic occlusion older than 3 months corresponding to a type C American College of Cardiology/American Heart Association lesion classification carries a likelihood of procedural success of about 60%. Overall, the expected risk was moderate, while expected benefits were high

Based on diagnostic angiograms, a standard guiding catheter (6French Judkins 4.5 left, no side-holes) was selected. The subtotal left circumflex (LCx-) occlusion was explored using the Boston Scientific Choice PT guide-wire. Reaching the site of the subtotal occlusion, the guide-wire tip could not be advanced on multiple attempts. To improve the support an over-the-wire (OTW) system along with Boston Scientific Choice PT^2 guide-wire was introduced and slowly advanced under probing pressure past the subtotal occlusion into the periphery; the maximum exerted pressure was small enough that the actional risk incurred by this procedure was clearly warranted by the expected success. At this point "no-flow" was noted and the OTW balloon catheter appeared wedged. Lack of the docking-wire prevented exchange for a low-profile monorail balloon; therefore side-branches were explored with the guide-wire tip to confirm the intraluminal position of the system in order to minimize wire-position knowledge risk. It was felt that the actional risk of perforation or vessel rupture or true lumen compression due to balloon inflation (2/20mm at 4 bars) within the false lumen was low and proceeding with the intervention justified. After multiple dilatations, the antegrade blood flow was restored. This demasked a high-grade restenosis at the occlusion site with longitudinal dissection lines corresponding to type D National Heart Lung and Blood Institute classification and intermittent thrombus formation as well as a hemodynamically significant lesion of the ostial left circumflex coronary artery – obtaining this information represents another important reduction of knowledge risk. Following intracoronary bolus and intravenous infusion of eptifibatide, the OTW system was exchanged for monorail and overlapping distal to proximal dilatations with increasing balloon diameters (up to 3.5mm) and pressures (up to 14 bars) were performed allowing a complete angiographic revascularisation of the proximal-to-middle left circumflex coronary artery. Such lengthy interventions inherently carry a certain amount of actional risk simply due to the time-on-table that they require, but the individual dilatations were not dangerous in the given case and there was clearly no better alternative route. Then, several angiographic projections of the ostium plaque were acquired and analyzed. Based on the angiographic plaque distribution within proximal left circumflex coronary artery, it was felt that plaque repair should be possible without left main intervention. Estimating the actional risk level of the left main intervention as low to intermediate, it was decided to stent the left circumflex coronary artery ostial lesion such that the last ring of the stent exactly matched the plane of the left circumflex coronary artery take-off with the rest of the stent fully covering the lesion. A 3.5/8mm Biotronik Lekton motion stent was selected and deployed at 12 bars. The final angiogram confirmed a complete revascularisation and intact left main artery. The patient remained asymptomatic and was discharged on day three. This case behaved as expected: no significant risk materialized, yet high patient benefit was attained.

Figure 3: Subtotal chronic occlusion, a straightforward elective case. The angiogram revealed subtotal left circumflex coronary artery occlusion in a diffusely diseased vessel (No. 1). Initially, the guide-wire could not be advanced beyond the proximal third of the target vessel (American Heart Association classification segment 11) (No. 2) and was exchanged for OTW-system. On further exploration, "no-reflow" occurred (No. 3). Following the successful passage of the proximal dissection, the guide-wire has been advanced into the distal position and successive distal (No. 4) to proximal (No. 5) dilatations were performed. Following these dilatations, the antegrade flow was restored and dissecting plaques within the target lesion were documented (No. 6), prompting proximal redilatations (No. 7) which resulted in plaque shifts and intermittent thrombus formation (No. 8). Intracoronary glycoprotein IIb/IIIa receptor inhibitor bolus and repeated proximal dilatations restored vessel patency with a residual 70% ostial stenosis (No. 9). After stent placement (No. 10), a satisfactory revascularisation result was documented (No. 11, 12).

4.2. An Escalating Elective Case Forwarded to Surgery

This was a 52 year-old female patient with known two-vessel coronary artery disease and recent history of an inferior myocardial infarction and emergency PCI RCA. She was re-admitted for increasing anxiety and crescendo angina. Ergometry revealed 0.2mV ST-segment depression in electrocardiographic leads V3-V6 at 75 Watts. Diagnostic angiograms in steep left anterior oblique (LAO) and right anterior oblique (RAO) projections with cranial tilt revealed a Type B1 American College of Cardiology/American Heart Association classification, Type A Lefevre classification bifurcation lesion just proximal to the take-off of the first diagonal branch (Fig. 4). The lesion appeared no different from that documented by angiography two weeks earlier. The proximal segment was straight, the lesion appeared smooth, there were no signs of thrombus and no angiographic calcifications. right coronary artery (RCA) showed an excellent short-term result. Based on history and diagnostic evaluations, left anterior descending artery (LAD) revascularisation was indicated. Because of the angiographically benign appearance of the LAD lesion, PCI actional risk appeared modest and so PCI was selected.

A standard guiding catheter (6F Judkins 4.0 left without side holes) was selected and seated. A, Guidant Whisper M guide-wire was placed and direct stenting was performed, using a 3.5/15mm Medtronic Driver stent at 12 bars such that the distal ring of the stent was positioned just proximally to the bifurcation. The control angiogram revealed a distal edge dissection, requiring placement of a second stent (one ring overlap, 3.0/9mm Medtronic Driver at 10 bars). Subsequently, multiple dilatations using 3.5/20mm balloons at up to 20 bars were performed without a full stent expansion. The residual stenosis was 40% diameter.

The operator judged that no sufficient further benefits were to be expected for warranting still more forceful intervention, as that would imply rather significant actional risk. Therefore, the current result was considered adequate, the intervention was stopped, and the patient scheduled for a next day re-angiography.

While transferring the patient into a monitored bed close to the catheterization laboratory, the patient experienced a sudden crushing chest pain and drop in systolic blood pressure from 120mmHg to 60mmHg. Immediate repeat angiography revealed slow LAD flow with no other changes of the interventional situs compared to the previous film. The next angiographic sequence indicated normal coronary flow (Thrombolysis In Myocardial Infarction, TIMI III°). To reduce knowledge risk, an intravascular ultrasound (IVUS) catheter was employed but failed to pass the situs. Because of the symptoms' intermittent character, a thrombus associated with an incomplete stent deployment, strut damage, tissue intersusception, intimal flap or dissection were considered as the most likely cause. Based on these hypotheses, it was unclear whether PCI would be able to help (high benefit uncertainty), but there was also no reason not to try (acceptable actional risk).

To avoid proximal dissection in the course of high pressure dilatation, the stented segment was first reinforced by an additional proximal stent (3.5/9mm Medtronic Driver at 14 bars). Then a number of dilatations using 3.5/20mm and 4.0/10mm balloons inflated up to 24 bars were performed. However, the funnel-shaped LAD stenosis persisted. On the contrary, slight recoil corresponding to a partial radial stent collapse was noted during control angiography. This event is crucial for the course taken. It limits endovascular treatment options and hence the expectable benefit. Worse, it signals a sharp increase in actional risk. Therefore, the patient was referred to coronary artery bypass surgery the next day. The surgery and the postoperative course were uneventful.

Complete review of all angiograms has not revealed any cause for the non-dilatable character of the LAD-stenosis. In absence of angiographic calcifications the most likely explanation for the unusual rigidity of the lesion appeared the presence of a fibrotic or fibro-calcific stricture, or the presence of massive plaque burden with full circle circumferential distribution associated with negative remodelling. In such a case, the knowledge risk uncertainty is so high, that attempts at dilatation beyond those described above appear unjustifiable (at least in an elective situation), so surgery is required instead.

Figure 4: Failed PCI LAD, nondilatable lesion, an elective case forwarded to surgery. The previously documented proximal LAD stenosis appeared unchanged compared to the previous angiogram ("angiographically stable", No. 1 and 2). Direct stenting of the lesion with the distal ring placed just above the diagonal ramus take-off was performed (No. 3). Control angiography revealed distal edge dissection (not shown) prompting a second stent implantation (No. 3, 4). Subsequent multiple dilatation did not produce a full stent expansion, resulting in a residual 40% funnel-shaped stenosis (No. 5). This intermediate result was accepted and the intervention terminated. Severe chest pain and drop in blood pressure called for immediate re- angiography minutes later, which showed a subtotal LAD occlusion at the stent level (No. 6), resolving spontaneously on a second contrast agent injection (No. 7). To clarify the situs morphology, an IVUS transducer was introduced but failed to cross the lesion. To reinforce the proximal LAD, an additional stent was deployed and multiple dilatations were performed (No. 8-10). The stenosis persisted (Nr.11, 12), so the LAD lesion was considered non-dilatable and the patient was referred to semi-elective CABG. The images No. 13-15 show the situs in native and contrast angiograms.

5. Conclusion

This chapter presents an approach to understanding PCI on the basis of the notion of risk. The aim of PCI is to provide benefits that reduce latent risk by means of procedures that entail actional risk. From this point of view, PCI is an iterative process of highly complex decisions that aims to provide low-risk, low-cost, high-benefit endovascular repair of coronary artery lesions. We have provided a description of the PCI intervention process in terms of the risk considerations involved when the available alternatives are selected at each point of the intervention.

To develop a realistic model of PCI and a useful tool for teaching, further practical differentiations and improvements in the strategic and tactical decision-making processes are necessary.

6. References

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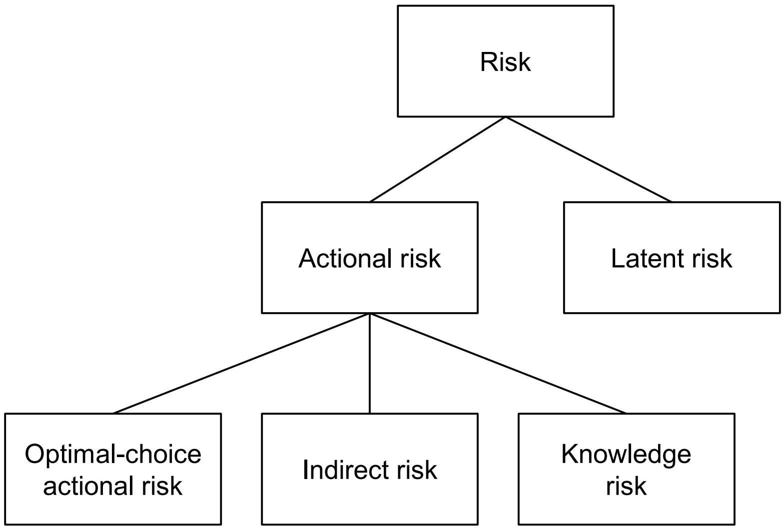

Figure 1: Types of risk. Upward lines signify a part-of relationship

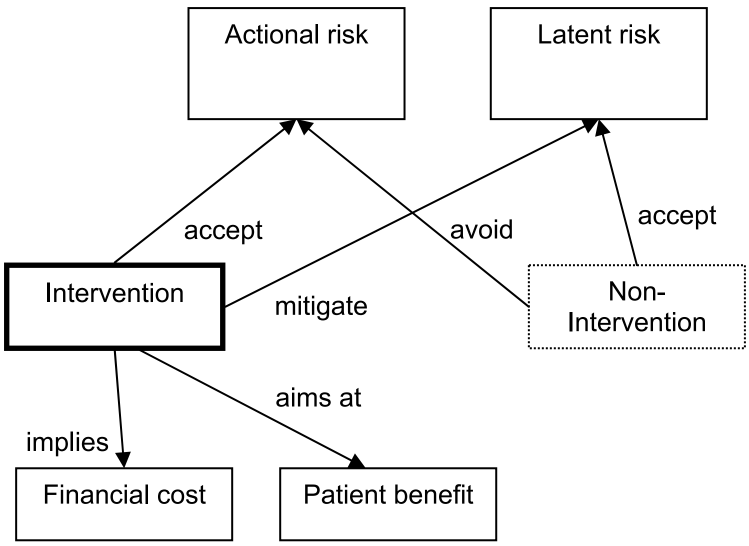

Figure 2: Relationship of intervention (versus nonintervention) to the risk types actional risk and latent risk