



# Not the Last Word

## Not the Last Word: Safety Alert: One in 200 Knee Replacement Patients Die Within 90 Days of Surgery

Joseph Bernstein MD

“Come to our hospital for your knee replacement—we did not have a single operative death last year!”

Can you imagine an advertising campaign with that tagline? Well, neither can I. But maybe such an

emphasis on danger is preferable. It would make patients safer.

Knee replacement is extremely popular. Last year, about 700,000 were performed in the United States. For a patient with end-stage arthritis, knee replacement can relieve pain and increase function. Still, the recent explosive growth in demand—in 1996, there were only 250,000 knee replacements performed [4]—suggests to me that people considering this operation are inadequately attuned to the possibility that it may kill them.

Here’s my back-of-the-envelope meta-analysis. I found three large studies looking at postoperative mortality. Katz and colleagues [11] reported 508 deaths among 80,904 patients; Mahomed and colleagues [13] found 875 deaths in their cohort of 124,986; and among the 222,684 in the study of SooHoo and colleagues [15], 1176 had died. That’s 2559 total deaths among 428,574 patients, 0.6%,

or more than one in 200. (For what it’s worth, these findings are comparable to more-rigorously collected data regarding hip replacement mortality [7]).

Now, one in 200 is a fairly small proportion, especially considering elderly patients’ baseline risk of mortality, even without surgery. Nonetheless, the event in question, death, is so important that a one in 200 risk is not low enough to be ignored. Indeed, one might argue this is the single most-salient fact to share in any discussion of informed consent.

Obviously, the details of every pre-operative discussion cannot be known. It very well may be that surgeons mention the risk of dying and frame it fairly [5]. There are, however, reasons to be skeptical. My own internet search on the topic—admittedly, a level of evidence weaker even than my back-of-the-envelope meta-analysis—did not find much on this. The American Academy of Orthopaedic Surgeons (AAOS) “Informed Patient Program” website on knee replacement, for one, doesn’t mention the risk of death at all [2]. This reticence might lull patients into a false sense of security, and expose them to risks they would rather avoid.

*A note from the Editor-in-Chief:*

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To appreciate why a sense of security can be dangerous, we need to think for a second about automobile crashes. Let's say you wanted to invent a device that would decrease the harm caused by motor vehicle collisions. What would that be? Anti-lock brakes? Air bags? Maybe not. According to the risk homeostasis hypothesis [6], people modulate their behavior to keep constant their exposure to harm. "Safety devices" such as anti-lock brakes and air bags, according to this theory, encourage dangerous habits (such as driving at higher speeds, tailgating, and making more frequent lane changes) that negate any benefits the devices may provide.

With that in mind, an improvement on air bags and seatbelts was proposed by economist Gordon Tullock: A metal spike attached to the steering wheel of the vehicle, aimed at the sternum of the driver. This takes the logic of Samuel Johnson's quip, "... when a man knows he is to be hanged in a fortnight, it concentrates his mind wonderfully," to its logical extreme. When a driver knows that any collision will lead to instantaneous death, his concentration on avoiding a crash will be maximal.

As Tullock's proposal teaches, thoughts of danger can keep us safe. Of course, one can raise the question of whether the theory has any role in protecting patients considering knee replacement. After all, it is not the

patient who must attend to all the medical, surgical, anesthetic, and nursing details that could, if fumbled, do him or her in. Still, patients have a fundamental role in the culture of safety, in that the decision to undertake the operation (and assume its risks) is theirs alone. If thoughts of danger dissuade a patient who is on the fence about having the surgery, such thinking indeed can be protective.

More than that, alerting patients to the risks of surgery may actually increase overall patient satisfaction. It is long known that seemingly successful knee replacement surgery—that is, "successful" from the surgeons' technical perspective—can still be rated as unsatisfactory by the patient. In fact, that may happen in as many as one in five cases [8]. Recent work [16] has shown that this high risk of dissatisfaction may be based on patients' high expectations about what knee replacement can do for them. Unmet expectations (especially in the setting of growing demand for the procedure without evidence of increasing prevalence of arthritis) might mean that patients are asking for knee replacement with symptoms that may be too mild to warrant the operation.

For many reasons, it can be difficult for a surgeon to discern when the patient's symptoms are just not severe enough, or to act upon that knowledge

once it is in hand. After all, only a patient knows what she herself is feeling, and there are professional, cognitive, and (yes) financial biases that make it easy for the surgeon to accede to a patient's demand for a surgical solution. Making sure that the patient knows about the mortality risk is one simple means of raising the bar. When a patient is told that the risk of dying from knee replacement surgery is far greater than the risk of dying parachuting out of an airplane, say, the prospect of using a cane might become more appealing.

In the end, patient safety takes many forms: Technical expertise, attention to detail, and a broad, team-based approach to rooting out error, among others. Yet because hospitals are inherently dangerous places, perhaps the most basic safety step is to ensure that only those people who must be in a hospital find themselves there. Keeping patients fully cognizant of the risks they face is a necessary first step towards that goal.

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There is no doubt that a person considering knee replacement wants a

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chance to weigh the possibility of death against the possibility of diminished symptoms and fewer limitations. That's just common sense. But as Dr. Bernstein notes, what a person would really want to know is the absolute increase in risk of dying after total knee replacement compared to the risk of dying without knee replacement. For instance—using invented numbers to make a point—the risk after knee replacement might be two in 500 compared to one in 500 without it. The 100% increase in relative risk of dying is misleading, but the absolute risk numbers are helpful.

Implicit in Dr. Bernstein's argument is that while death is the most attention-grabbing adverse event, there are other important ones to consider. I've witnessed two of my neighbors decline in physical activity and mental sharpness after major discretionary orthopaedic surgery. These declines might be incidental to the surgery, but what is clear is that the surgery—even though technically successful—did nothing to achieve their personal goals and likely hindered their quality of life. I think most of us would like to know the risk of this type of thing occurring, but it is seldom reported.

We also need to get the numbers right. I suspect these numbers come from database studies where the appropriateness of surgery can be questioned. For instance, we just

reviewed the National Surgical Quality Improvement Program database to study adverse events after total shoulder arthroplasty and found that 22% of patients had life-threatening severe systemic disease (ASA IV) or otherwise were inappropriate for discretionary surgery. Patients judged appropriate for discretionary surgery were at much lower risk of adverse outcomes [3].

The issue is not whether to convey this information, but rather, how to convey it. The conversation needs to be more than a list of risks recited by the surgeon prior to obtaining a signature on the consent form. As Dr. Bernstein points out, it's more intuitive to frame risk according to common daily events (such as parachuting, though perhaps that is not so common; more realistically, something like driving home from an office visit). There are also more-intuitive visual ways to convey risk. Decision aids often incorporate these methods and also use quizzes and preference sliders so that patients take an active role in decision-making. Dell Medical School and other sites are developing modifications to the informed-consent process that incorporate these features. Imagine a computer-based informed consent for a TKA that has a screen that patients must click through to provide full-informed consent: "I understand that I have a one in 200

chance of dying after total knee replacement." No click, no surgery. I think that would give most of us at least a little pause and would change forever the way we thought about the discretionary surgery.

TKA is a highly effective procedure, but there are alternatives. Many of us were surprised by a recent randomized trial comparing TKA to nonoperative management [14]. Of course, TKA resulted in greater improvements in symptoms and limitations than nonoperative management at the cost of the risks, discomforts, and inconveniences of surgery—the usual trade off. What is somewhat surprising is how well patients with an incurable, irreversible pathology (osteoarthritis of the knee) improved on average without surgery. That is resiliency at work. Resiliency is one of the most powerful promoters of human health—far more powerful than many of our medications and surgeries. We often are witness to it: The placebo effect is one familiar example [10].

We often describe the 20% or so of people who are unsatisfied with a technically adequate knee arthroplasty as having had "unrealistic expectations." It may be more accurate to consider this as a form of misdiagnosis. When a person is not satisfied with a technically successful surgery, it's likely that the care team did not diagnose and adequately treat factors that

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were limiting that person's resiliency such as limited social supports; financial, family, or personal issues (stress); symptoms of depression or anxiety (psychological distress); and less-effective coping strategies (catastrophic thinking).

People considering discretionary procedures such as TKA should consider what risk of death and other adverse outcomes are acceptable. But this should be balanced by the hope associated with what resiliency can do for them and how resiliency can be grown and practiced. The physical decline of aging is taxing, but resiliency will keep us as happy and healthy, and will also enhance our recovery from discretionary surgery when we decide that undergoing it is worth the risks.

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Dr. Bernstein is asking a difficult question: Must a surgeon tell her patient that the risk of mortality is elevated after a knee replacement? But—as always in Dr. Bernstein's columns—the question is much deeper: What, in this era of patient autonomy, is the surgeon's appropriate role in medical-decision making?

For most of medical history, patients were not only excluded from the process of medical decision making, they were typically not even informed of the nature of the treatments offered or the rationale for them. Events in the 20<sup>th</sup> century (known especially by three city names: Tuskegee, Nuremberg, and Helsinki) now have elevated patient autonomy to an almost religious principle of medicine.

I can recall my teachers scolding me for expressing paternalistic thoughts. We were taught, and now we teach our students, that patients have full autonomy over their bodies and their treatment choices.

In the utopian world, the surgeon explains all the information, the patient fully understands the options, and the patient will make the best choice for herself or himself. Yet, in the real world, where surgeons have only partial understanding of the information (and perhaps trouble sharing even that), where patients come to the hospital with their own biases and limitations, there is no possibility for a truly free and well-informed choice. "Shared-decision making" was developed to bridge this gap, but the number of meanings of this term has equaled, if not exceeded, the number of authors writing about it.

But even in an ideal world, there is still a problem with the classic paradigm of patient autonomy: Namely,

the lack of physician responsibility. I am talking about the moral responsibility, not the legal one. In the model in which we grant full autonomy to the patient, we implicitly relieve surgeons from the responsibility of being empathic and responsible caregivers. This shift results in two main dangers. The first is that many patients are afraid of the responsibility and thus cannot make the choice. Some will express their reluctance directly—"Can you please decide for me?"—while most will phrase it in more socially acceptable form ("What would you choose for your mother?"). Because of the 11<sup>th</sup> commandment of patient autonomy, the surgeon will not step in to fill the gap. In such circumstances, a more-random decision is made. The other danger is worse: "Moral licensing" [9, 12]. The concept of moral licensing is that if the patient is told everything, surgeons are then free to act in their own interests, as the patient has been warned.

Although things can be somewhat easier when strict indications for surgery are used, for most conditions we treat, "soft" indications are the norm, such as pain severity and perceived functional limitations. Of course, soft indications are imperfect. Some patients might be more articulate or use better metaphors, resulting in a surgeon perceiving a patient's pain to be more severe. And seemingly

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objective measurement tools (for example Visual Analogue Scales) do not objectively quantify a particular patient's suffering, yet may convince us that they do. In response, many surgeons have developed their own criteria—pain at night to indicate knee replacement, for example—though this is artificial and rarely based on high-quality evidence.

It is well known that weight reduction and physical activity programs can help many patients with knee osteoarthritis [1, 17]. Further, perhaps 20% of knee replacement operations do not satisfy the patient. Considering these facts—to say nothing of the serious risk of death Dr. Bernstein mentions—the threshold for a knee replacement should be high. Despite this, the number of knee replacements continues to rise and the average age of patients' undergoing the surgery continues to decrease—evidence of expanding indications, if you were to ask me.

Back to the question at hand. Should we tell our patient that she has a 0.6% chance of dying after the surgery? On the surface, it is hard to say no. This mortality risk is a material fact, and those worshipping at the altar of shared-decision making consider it a sin to omit a material fact. But I am not so sure. To me, the real question is whether this knowledge will help the patient. Will it add to the anxiety of the

already-anxious patient, perhaps to the point of denying that patient a helpful operation? Or will this knowledge motivate a less-handicapped patient to stick to a diet and physical activity regime? Ultimately, then, the question boils down to the surgeon's judgment.

In the ideal world, surgeons would bravely guide their patients through the decision process—even at the risk of violating the holy principle of patient autonomy. To me, that is a risk worth taking.

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