Treatment for sunken chest reflects trend toward patient-centered care

HEALTH CARE

Patients now have more say in experimental treatments. When should doctors say no?

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Mat Besch removed his shirt during a recent appointment at the Overland Park Regional Medical Center to reveal a large red welt across his chest.

The welt is a good sign, said Besch's doctor, Corey Iqbal. It means the teen has been wearing the vacuum-suction device his parents ordered from Europe to try to correct the 3-inch dent in his chest.

Iqbal has performed dozens of surgeries to correct the condition, but Besch is his first patient to try the suction device, which is called a vacuum bell. Iqbal told Besch he couldn't give him any guarantees it will work, because there's not much data on it. But he's game to help them try it, after reviewing the pros and cons.

"I think one of the mistakes we can make as a health care provider in any capacity is when we decide to take a paternalistic approach and (say) 'This is what it's going to be,' as opposed to looking at the patient-doctor relationship as a partnership," Iqbal said. "My job is to impart expertise, make them experts on the condition, and then they can make an informed decision."

That philosophy reflects a movement toward patient-centered care that has become widespread in the United States over the last 30 to 40 years.

While doctors used to make decisions about what treatments are best for patients, the standard now for most major medical associations is for physicians to lay out a series of options, explain their risks and benefits, and let patients make the call.

That can become an ethical minefield for physicians when little research is available.

Besch's sunken chest is due to a genetic condition the medical community calls "pectus excavatum." It's common, but Besch's case is severe and it's more than just cosmetic. He's in the bottom 10 percent of his age group for exercise tolerance because his ribcage constricts his heart and lungs.

The vacuum device was approved by the U.S. Food and Drug Administration as a medical device in 2012, but it's considered an experimental treatment, thus not covered by insurance because of its limited track record.

Marshall Kapp, a Florida State University College of Medicine professor who has studied medical ethics, said the vacuum bell device exists in a gray area he called the "innovative phase" because it's beyond the research phase — hence the FDA approval — but not yet considered standard care.

"His goal presumably is to gather enough data so that some day what he's doing will be standard of care," Kapp said of Iqbal. "But it's not there yet."

The research phase has formal ethical guidelines for patient participation. But Kapp said the only guidelines for practicing medicine within the innovative phase is to make sure the patient is fully informed about all of the available research on risks and benefits.

Besch's father, David, said Iqbal has done that.

"We've been very impressed by him," David Besch said. "He will answer all the questions and I don't feel like I'm being rushed out of the room any time."

Most of the research on it comes from a study out of Switzerland with about 140 patients. Iqbal said those results are enough to make him comfortable trying it, as long as Besch understands the risks and benefits.

The risks seem minimal, Iqbal said, and the benefits potentially large. If the device works on Besch it might help him and future patients avoid surgery.

But experts like Kapp said changes in the law and in how hospitals are reimbursed are complicating doctors' decisions about when to help patients get the experimental treatments they want, and when to hold back.

Patient values versus available evidence

Christian Sinclair, a doctor and professor of palliative medicine at the University of Kansas Medical Center, said the patient-centered care movement started in the 1970s or 1980s. He said some research suggests it coincided with the adulthood of baby boomers, a generation used to asserting their civil rights and skeptical of authority.

The internet has strengthened the movement, he said, by giving patients easy access to information about treatments. But Sinclair said online searching also could make patients more likely to favor medical interventions that might not be necessary.

“Physicians saying ‘Hey, let’s watch and wait about this issue, maybe it’s not that serious,’ that sometimes brings up anxiety on the part of the patient or the family member,” Sinclair said.

Kapp said there’s financial incentives for doctors and hospitals to give patients what they want because some insurance plans, most notably Medicare, now base their reimbursements partially on patient satisfaction surveys.

“After many, many years of not paying attention to patient satisfaction, the pendulum has kind of swung pretty far in the other direction,” Kapp said. “So there is pressure on the part of physicians to keep patients happy and there is a potential for conflict between keeping a patient happy and practicing good clinical medicine.”

Kapp said doctors have told him they will sometimes go along with patient requests even if the doctors don’t think it will help, as long as they also don’t think it will hurt.

But Kapp said the best patient-centered care occurs when patients and doctors negotiate medical decisions based on three factors: hard evidence, the physician’s judgment and the patient’s values.

Since the beginning of the patient-centered care movement, there have been ethical questions about how to balance those.

A case study

In 1984, University of Loyola School of Medicine doctor Kenneth Micetich co-authored a case study about other doctors considering the request of a 70-year-old patient with advanced cancer who had decided she wanted to try an experimental regimen that combined four different chemotherapy drugs.

Oncologists at two medical centers told her that it probably wouldn’t work; that her tumor was incurable and that the drugs she wanted to take were highly toxic. But nothing changed her mind.

The case study, published in the Cancer Journal for Clinicians, said the treating physicians carefully weighed their ethical imperative to “first, do no harm,” against the possibility that the treatment could help the patient in some way.

They didn’t think the chemotherapy could cure her, but they thought it might prolong her life. The toxic effects could be monitored and the treatment stopped if necessary.

Because of that, Micetich and his co-author, David Thomasma, said the doctors should defer to the patient’s values when deciding whether to go forward, as long as the patient truly understood what she was getting into.

“A competent adult may choose to suffer greater risk, even when there is no scientific evidence to justify the choice, because that person is willing to balance this harm against potential extension of life,” they wrote.

Micetich and Thomasma ended the paper by saying that even though the patient seemed to be basing her decision on a logical fallacy — some medicine is good, therefore more medicine is better — they considered her request for the drug regimen justified.

“I don’t know that she ever got it, but it led to an interesting discussion about the role of the physician,” Micetich said in a phone interview this week. Micetich said that discussion continues to this day and it’s starting to advance into areas he finds disturbing.

“Right to Try” laws proposed in Congress and throughout state legislatures in recent years seek to give terminally ill patients access to treatments that are still being studied in FDA clinical trials. Missouri became the third state to pass one in 2015. Kansas has had multiple hearings on it but has yet to pass a bill.

Micetich said those laws put physicians in the tough spot of being gatekeepers for treatments that have no track record.

“I think the physician is duty-bound to offer things that are likely to work or at least have evidence to support them,” Micetich said. “Otherwise, how can you have an informed consent discussion with the patient if you really don’t know how often it works or about the side effects for certain patients?”

Limited evidence

Iqbal said that in the Switzerland study, about 80 percent of those who used the vacuum bell saw some improvement in their chests, and about 15 percent got what they considered a full repair. Some of the patients had only used the device for about a month, so they could have had more improvement later. But some might also see their chests sink back in over time.

Side effects were generally mild: 13.6 percent reported skin irritation where the bell was suctioned to the chest, 12.1 percent reported pain at that site and 7.1 percent reported hematoma, a severe bruise, at the deepest point of their sunken chests.

Besch, 17, said Iqbal has been upfront about the device’s limited track record.

“It’s not exactly reassuring, but from what we know, it should work,” Besch said.

There’s only a couple of other hospitals in the U.S. that are using it. But Iqbal, a 38-year-old surgeon who graduated from the University of Missouri-Kansas City’s School of Medicine and did his residency at the Mayo Clinic, has a track record of trying new things.

He established the first fetal surgery program at Children’s Mercy Hospital in 2013. From there, he moved to Overland Park Regional, which is part of the HCA Midwest Health chain, and performed the Kansas City area’s first pediatric robotic surgeries in 2016 as the hospital’s medical director of pediatric and fetal surgery.

This year Iqbal became one of the first physicians in the region to offer adults the Nuss procedure, a surgery to correct sunken chest that entails inserting a metal bar through a small incision and then using it to expand the ribcage. The procedure has traditionally been done only on children and teens because their ribcages are more flexible, which makes the the procedure less painful and the chest less likely to sink back in after the bar is removed.

Besch said that if the vacuum bell doesn’t work, he’s prepared to have that surgery, which requires months of recovery and years before the bar is removed.

“It’s more the lung capacity, but I’m not going to say the looks are not a factor in it,” Besch said.

Iqbal said that even if the suction device doesn’t work, it might loosen the cartilage of Besch’s ribcage enough to make the surgery more tolerable and effective. He said it’s not for him to judge why Besch or other patients want treatment for cosmetic or functional reasons.

“I want to fix what’s going on with them,” Iqbal said. “I want to have answers for them and if I don’t have the answers, I want to find innovative ways we can solve those problems.”

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