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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Does Care Bundling Improve Outcomes for Patients with Intracranial Hemorrhage?

Announcer:
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Dr. Parry-Jones:
Right. Thank you. So I'll try to bring some of this together into the idea of care bundles for intracerebral hemorrhage. But before I do, I'd just like to begin by touching on some of the key aspects about hematoma expansion after intracerebral hemorrhage. Because this is really what we're targeting with our acute treatments when the patients come through the door in our emergency department or stroke unit. So first of all, obviously, depending on the size of the hematoma, what size it's got to, where it is, a patient will begin to show symptoms and will call for help. An ambulance will be arriving to pick them up and take them to hospital. And during that time, the hematoma is probably expanding for everybody. It stands to reason that it does for everybody. We don't know a lot about that process, but very interestingly today, we've seen the INTERACT4 trial, suggesting that if you can manage some of these key things around hematoma expansion in the ambulance, we may be really getting to all of the patients as early as possible. So I think obviously we'll see more and more about this pre-hospital hematoma expansion. But when we talk about it in all of the data that we have is really from the point that the patient has had their scan, and then we usually rescan them again at 24 hours, and that's what we're talking about.

So we know that, as Natalie's already said, about 1/3 of them will expand and have significant expansion. And the key predictors are the time since symptom onset, so how far through the disease course they are, the size of the hematoma when they present, and whether or not they're taking antithrombotic treatments. Those are the big things. And many of you will have seen these curves on the right before, showing these relationships.

So on, to care bundles. So just to reiterate, the idea of a care bundle is to bring together, say, three to five components of care that are independent of each other, but together might be more than the sum of their parts. So you saw some data in Natalie's presentation from a nice German observational study, which suggested that if you get anticoagulant reversal and blood pressure management right, they have some additive benefits.

So at our center, we set out a fairly simple care bundle. So we focused on A, anticoagulant reversal, let's do that as quick as we can. Blood pressure lowering, deliver intensive lowering as quickly as possible to the INTERACT2/3 protocol. And then we also, because the other thing we think about in the emergency department is, should I refer my patient to the surgeons? And the default in our center, and probably in many centers, is that anyone who's got blood in the brain, you pick up the phone to the surgeon. And it's often the first thing people do. So we wanted to push it down the order of things and think a bit more in a nuanced way, and not make unnecessary referrals. So we set up a care pathway with some clear referral criteria.

So without going into the details of what exactly we did, we did a quality improvement project. So we continuously monitored our data and looked at the care processes and the times that we were taking to do all of these things, and drove them down over the course of the year. And what we found was that it led to quite a dramatic improvement in survival. So the survival curves on the left show you the 2

years before we ran the project, is the solid line. The dashed line is the year we were implementing the changes. And the dotted line is the year that we had them all in place. So quite striking improvements in survival. And we compared ourselves to the rest of the UK using our national audit data, and we had a 10.8% absolute reduction in mortality compared to the rest of the country. So it was having a big effect.

We wanted to understand why that was, so we did something called a mediation analysis. We looked at some of the key things to do with the aspects of the bundle. So first of all, we looked at the speed of anticoagulant reversal. Now, during the project, we'd done a lot of work before we started it to get the speed of reversal quicker. So we didn't really gain much more during the course of the project. So there's no way it could have mediated the benefit. But we found that to be true.

In the INTERACT2 trial, there was no benefit in terms of survival. So remember, we're looking at survival here, not functional outcome. So we didn't see any benefit from metrics around blood pressure management. But the two things that came out, which I guess are kind of unintended benefits of delivering the care bundle, is that the level of supportive care that these patients got went up. So more of them got to the high-dependency unit, that mediated 12.3% of the benefit. And perhaps one of the most striking things was there was a bit of a behavior change amongst the clinicians. They were putting less DNR orders in place in the first 24 hours for our patients, which was not part of the care bundle. We didn't try to influence that; that just happened, and that accounted for over 50% of the benefit in terms of mortality.

So we subsequently had the INTERACT3 trial, which many of you will be familiar with, and it used a similar goal-directed care bundle. Same blood pressure intervention, but with additional management protocols for hyperglycemia and pyrexia. Notably, there's not surgery in this bundle, and I'll come on to a subsequent slide, and I'm sure you'll realize why. Management of abnormal anticoagulation was also included, but was only reversal of warfarin down to an INR of below 1.5.

So there were over 7,000 patients in the trial, and the primary outcome was the mRS at 6 months. And as you'll all be aware, it was a positive trial. So there was a significant shift towards benefit, towards less disability across the trial, with fewer serious adverse events with the care bundle. So here's additional evidence in a cluster randomized trial that a care bundle approach also improves functional outcome.

But I think our study and the INTERACT3 study have some quite significant differences, which I'd just like to highlight here in this table. So most of the patients were recruited in China. And in the INTERACT3 group, after the bundle was implemented, over 1/4 of them had neurosurgery, and it was very similar beforehand, so there was no change in that. At our center, it was only 7.1% of patients who had neurosurgery, even after the bundle was implemented. We saw an increase in patients going to intensive care, but we still only reached 18.3% compared to the 34.6% in INTERACT3. Nearly 5% of our patients got palliated within an hour of coming into hospital; that was below 1% in INTERACT3. And far fewer had IV antihypertensives after the implementation of the bundle, and that was simply because they were presented too late, or their systolic blood pressure wasn't high enough to require treatment. However, when we did treat people, we did it quicker, so under an hour, and we saw far more patients on anticoagulants. And if we looked at this now, this would be more like 20-25% so this was quite some time ago, so 12.7 in our group, versus 0.9% in INTERACT3. And we also reversed anticoagulation in a median time of 1.8 hours. Now in INTERACT3, they reported it as the time to achieve an INR below 1.5. So you can see this would be dependent on when you gave the treatment, but also when you chose to repeat the INR, so it's a little bit difficult to interpret, but you can see the times are quite long.

So to conclude, a care bundle is really a way of providing a framework for a quality improvement project, and it supports buy-in from clinicians, because they understand that there's this simple set of measures which they should be focusing on. The mechanisms by which a care bundle might mediate a benefit will differ, as I hope you appreciate from the previous table, in terms of different healthcare settings, and it might be that different bundles are required depending on that. We found that there were indirect effects on supportive care, which seemed to be at least as important as the specific interventions, at least in terms of mortality. And when you come to implement a bundle, it's very context specific, which we've found as we've scaled this project up. So sites need to work towards achieving process targets, but they need to do it in their own way, and they need to be able to adapt the bundle towards their own care.

Dr. Gibler:
Panel, any discussion questions? Hiren?

Dr. Patel:
So why do you think that their rate of neurosurgery is so high compared to ours? Do you think, you know, I've tried to think as to why that might be myself, I don't think we've discussed that before.

Dr. Parry-Jones:
To be honest with you, I don't have a clear answer for that. I think without having kind of experienced directly the culture of care for ICH

patients in China, it's very hard to comment. But I think most of it points towards being very aggressive about treatment, and perhaps being very reluctant to accept that treatment is futile in a patient. So that's what the data seems to suggest to me, and perhaps that's the underlying culture which drives it.

Dr. Patel:
Do you think the neurosciences are the primary caregivers in China?

Dr. Parry-Jones:
Yes. Yeah, I think they are. I think most of the patients in INTERACT3 were on a neurosurgical unit. Yeah.

Dr. Gibler:
Can you talk about the consensus panel paper that was published in December, you as the lead author and Josh Goldstein is the senior author?

Dr. Parry-Jones:
Yeah, absolutely. So this time at the conference last year, we got together a multidisciplinary panel of experts. And I think when you come up with a care bundle, it's really important that everybody's involved in the care of the patients has a say in what goes in the care bundle, because they'll be the ones delivering it. So we had a really nice multidisciplinary panel. We had emergency medicine, critical care, several neurosurgeons, and stroke neurologists. So we had a very long and interesting discussion to talk about, you know, what we felt ought to be in a care bundle, in light of INTERACT3 and in light of other studies that have happened. So we had this published in the *European Stroke Journal* around about Christmas time, and made some suggestions around what process targets people might want to be striving for, basically, with all of the key things that we talked about. So I certainly recommend looking at that, and hopefully it will be useful if you wish to implement something similar at your center.

Dr. Gibler:
Any other discussion from the panel?

Dr. Seiffge:
Adrian, can you comment on these time metrics and time measures that were in the guidelines – in the – recommend that, do you think they are ambitious? Are they too ambitious? Or should we be less ambitious?

Dr. Parry-Jones:
Yeah. I mean, I think with quality improvement, you want a target that people feel is challenging and inspiring, but if you push it too far, it's a bit disheartening, isn't it? It puts you off, and you think this is ridiculous, there's no way we're ever going to do it. So I think it's perfectly reasonable to look at where you're starting. And you know, if it's currently taking you 4 hours to reverse anticoagulation, doing it in 30 minutes is maybe not where you want to start, because you need to start to see achievements. But you know, it's very clear from a lot of the evidence around, the quicker you do this, the better. So, you know, I think those should be your ideal targets, but I think it's reasonable to think about where you are now and not to dishearten your team thinking they're never going to get anywhere near it, because sometimes there will be contextual things about your care processes that are insurmountable. There might be that you know you just can't do things that other centers could do to achieve times within 30 minutes, and sometimes you can't overcome that.

Dr. Gibler:
Thank you, Adrian.

Announcer:
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