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Released: 02/27/2024 Valid until: 02/27/2025

Time needed to complete: 1h 08m

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ABC-ICH: Does Care Bundling Improve Outcomes for Patients with Intracranial Hemorrhage?

Announcer:

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Dr. Gibler:

Our next speaker, we brought all the way over from Manchester, UK. So, Dr. Adrian Parry-Jones is globally known as an expert in care bundling. And it's very interesting if you work in an environment and understand the multidisciplinary environment, it makes sense that bundling care from multiple different providers, but also multiple different therapies, why that makes sense. So, Dr. Parry-Jones is a Stroke Association Reader and Consultant Neurologist from the Geoffrey Jefferson Brain Research Center, University of Manchester, Manchester, United Kingdom. Dr. Parry-Jones, thank you.

Dr. Parry-Jones:

Okay, so it's a pleasure to be here this evening with you all. So, as Brian's explained, I'm going to go through care bundles for intracerebral hemorrhage from my perspective of working on this in the UK and then some of the more recent evidence around it.

So, I just wanted to start by thinking about what we can currently do for intracerebral hemorrhage and what other therapeutic targets might be. So, basically, this is largely what we do from a medical perspective when we see ICH patients, we're targeting in-hospital hematoma expansion. So, we give anticoagulant reversal, we lower blood pressure, you've been hearing about that. I think the jury's still out on hemostatic drugs, there's trials ongoing of tranexamic acid in factor VII. And we have some randomized controlled trial evidence that giving platelets to patients taking antiplatelet drugs might be harmful from the PATCH trial. So, that's kind of what we know about inhospital hematoma expansion and how to target it.

And of course, we can also clear the hematoma out through surgery. So, hematoma evacuation can be lifesaving by reducing mass effect, and it can also potentially, theoretically, might reduce some of the secondary injury.

Now, we also have other potential therapeutic targets that we, you know, there's research going on to look at which may become something that we do in the future. It obviously stands to reason that everybody's hematoma expands in the pre-hospital setting, and we don't know very much about that. And that might be something that we can move towards targeting with better identification of intracerebral hemorrhage in the ambulance. But we're a long way off that yet.

There's, of course, a process of secondary injury which occurs around the hematoma, which you see radiologically as edema. That, again, is an important therapeutic target and something we can look at in the future. And also, it might be that the rate at which the hematoma clears is ultimately important. And you may be able to target that medically as well.

Despite of all this that we can do, however, I think one of the great problems in cerebral hemorrhage and why there perhaps hasn't been much of a shift in the mortality over the years is that there's quite a bit of pessimism around the management of ICH patients. And that's perhaps understandable, given their poor prognosis and the relative lack of treatments compared to ischemic stroke. I just include this





slide. There's similar studies around. This is one we did in the UK. And we looked at whether there were differences in care decisions between intracerebral hemorrhage and ischemic stroke patients using a year's worth of our National Audit Program data. So, we adjusted for everything that we could to try and adjust for any bias in this. And we found that there was no difference in the odds of being admitted to higher level care or critical care for ischemic stroke or ICH. But what we did find very strongly was that you're far more likely to have palliative care commenced if you've got an intracerebral hemorrhage than an ischemic stroke, which I think is fairly good evidence that pessimism exists. This was a while ago, it might have changed a bit since, but I suspect not too much.

So, we sought to try and address this by thinking, well, if we brought together everything that you can do for these patients into a care bundle and tried to implement it very effectively for every patient that came in, would that make a difference to the mortality that we see? And would it shift this pessimism that exists? So, we did a quality improvement project in 2015, and came up with this idea of the ABC care bundle. So, it's very quick anticoagulant reversal, implementation of blood pressure lowering to the INTERACT2 protocol, and we put together a care pathway which was about making sure very prompt neurosurgical referral happened when it needed to, but also that you didn't refer patients where it really wasn't necessary. Because that would often distract people away from delivering A and B in a timely fashion. So, we set about doing that and used the quality improvement approach. We very closely monitored our data, looked for problems in our care processes, and tested changes to address that. And over the course of a year, we were getting gradually better, all the process targets were improving.

And perhaps to our surprise, we found that there was quite a big change in the mortality of our patients. So, if you look at the survival curve on the left, there's 2 years' worth of patients is the solid line at the bottom. During the year that we were running the quality improvement project, there was quite a sharp improvement in mortality. And then once it was fully implemented, we saw a further improvement again. So, we compared ourselves to the rest of England and Wales using our National Audit Program data, and that's on the right there. So, you can see the rest of the country is the orange line staying completely steady. And we saw this step change in terms of our mortality. So, this was a 10.8 percentage points difference in mortality, it was a reduction of 1/3 of the deaths that we were seeing.

So, why was it happening? So, we've looked into this further, and two things particularly that happened that were not directly part of the care bundle, and we didn't try to change these, was that there was a drift down in how often DNR orders were being used for these patients. So, we looked at the proportion getting them put in place in the first 24 hours, it was about 35% before we ran the project, and it dropped to around 20-25% afterwards. Critical care admissions likewise increased. Again, we had no criteria around who should go there, it was just that they were more willing to accept them, more of them we're moving up to critical care.

And then when we tried to look at this statistically by running a mediation analysis, we found that, if you see on the bottom there, the things that were part of the bundle didn't actually mediate the improvement in survival. So, we were already doing quite well with anticoagulant reversal, and it didn't particularly improve, so there was no way it could have mediated the change. In terms of blood pressure lowering, ICU admission, and surgery didn't seem to make any difference. And there was these two things: access to high-dependency unit care, so level 2 care, and this reduction in DNR orders that seemed to mediate what we saw. So, it was probably a shift in this culture around how we were treating ICH patients.

We did some qualitative research alongside this. And this is kind of the things that we learned from that, was that the care bundle was seen as a systematic way to deliver care by clinicians. And staff described this culture shift. So, they felt that more could be done to improve outcome and they felt they had something to offer the patients. In terms of what worked with implementing the change, we had quarterly regional meetings, so we ran this at another two hospitals in our region, and we're currently running it across the north of England. And staff have described that having quarterly meetings where everyone gets together, you've got some accountability for how you're doing, and you share learning between sites was quite helpful. Having early and proactive involvement of other departments seemed to help a great deal so that all the hematologists, emergency department, surgeons, critical care all knew that we were doing this, were on board with it. And we tried to publicize it as much as we could around the hospital. And then finally, one of the key things was that you had to really closely monitor your data. So, you had to be close to it, you had to see what was going on, and you had to sort of make staff aware of how they were performing.

So, last year, we had the INTERACT3 trial, which has taken this a step further. So, this was a randomized controlled trial, a cluster trial, that looked at whether a goal-directed care bundle in hospital improved outcome after ICH. So, the INTERACT3 bundle was quite similar to ours, but included protocols for managing hyperglycemia and pyrexia.

So, as I say, the design was a stepped wedge. So, you can see from the diagram on the right, there were three steps there, everyone started off delivering usual care, and then they gradually transitioned over to delivering the care bundle. There was data collected at day 7, and the outcomes were at 6 months by central follow-up. It was initially conducted in China, and then it was expanded to other countries in 2020. There were 9 low- to middle-income countries, one high-income country, and 144 hospitals that participated. So, as





you're probably already aware, it was a positive trial. So, there were just over 7,000 patients included in the trial. The primary outcome was 88 to 90% complete. And you can see there was this significant shift in the Modified Rankin Score towards better outcomes in the care bundle group. And also importantly, there were fewer serious adverse events with delivery of the care bundle as well.

So, I think I'll just conclude by sort of stressing that bundled care for ICH has quite a lot of wider effects beyond what's in the bundle and can really improve outcomes for patients with ICH. I think having it called a bundle and running it like that provides a framework and supports buy-in and allows you to run a quality improvement project around it. As I've shown you with our projects, there were quite a lot of indirect effects on supportive care, which are likely to be at least as important as the specific interventions. And I think I'd also stress that implementation is very context specific. So, in spreading this project up to other hospitals in the north of England, we found that the barriers are completely different in different sites. And everyone's got to kind of look at their own systems, look at their data, and just test changes and see what speeds things up.

Dr. Gibler:

Excellent. Excellent, Dr. Parry-Jones. Yes?

Dr. Connolly:

I've got a couple of questions. So, I mean, the first question is a simple one, that RCT was not just warfarin patients, so your last answer was actually not technically correct.

Dr. Parry-Jones:

Well, so INTERACT3 had less than 1% of patients with warfarin.

Dr. Connolly:

Anyway, the real question I had was like, you seem to imply that it has nothing to do with the treatments that they're receiving; it was more not calling a patient to DNR too early. And, I mean, it was more the morale of the ICU staff. Is that what you really think's going on? Or what do you think's going on? Because you seem to make a case that it's not the treatments, they were pretty much neutral?

Dr. Parry-Jones:

Yeah. So, I think just to stress that the outcome we were looking at was mortality, first of all, not functional outcome.

Dr. Connolly

So, not calling a DNR usually is, you know, I mean, it means you're going to die pretty soon if you call someone DNR. So, I mean, that would have an effect that you can reduce that.

Dr. Parry-Jones:

Right. So, we looked at – we further went on and looked at the patients who had been given the DNR order. So, we found that if patients had DNR orders, as you might expect, it had further knock-on effects beyond the actual DNR order. So, we found that, as you might expect, when someone's got a DNR order, they don't get to critical care. So, that doesn't happen. And so, that that was probably a key factor as part of it. And also, there were some other key decisions which seemed to be less likely, like starting antibiotics for pneumonia, fluid decisions, things like that which were different, some patients had DNR orders in place. So, I think they have a creet beyond what they're intended to do.

Dr. Connolly:

So, why do you think there was this reduction in DNR? I mean, what was going on there?

Dr. Parry-Jones:

Well, I mean, I think, as I say, we made no effort to change it as part of the QI project. So, based on what we heard from the qualitative research, I think people were feeling they had more to offer these patients, they felt they had, you know, medical interventions to deliver in the acute phase, and therefore, were less likely to put DNR orders in place, is my best guess.

Dr. Connelly:

Pretty interesting.

Dr. Gibler:

You know, you just got through first authoring a paper that was from a care bundling consensus panel, primarily European, but also included Josh Goldstein from the U.S. And you were the first author of that. The fascinating piece of being involved with that was the interaction of the neurosurgeons. Do you want to talk a little bit about that, because we have three neurosurgeons that actually came together in a very positive way. This is in the *European Stroke Journal*. It's from December, if you're interested in reading it. Do you want to talk a little bit about what it took to get all these individuals on board, particularly neurosurgery.





Dr. Parry-Jones:

Yeah, so I mean, you know, I think we had we had three neurosurgeons. And I think the evidence for neurosurgery, I guess, is growing, but still at the very early stages. So, when you look at the most recent meta-analyses of all the surgical interventions, overall, there does seem to be benefit, but there's a lot of bias in the trials and there's a lot of heterogeneity in terms of the interventions. We've had the ENRICH trial presented on several occasions in the last year, which appears to be positive, it's yet to be published. And there's quite a few different RCTs going on, looking at different minimally invasive surgical approaches at different time windows. So, I think until we have that level of evidence, it's going to be very difficult to be very specific about what you do with neurosurgery. So, I think what we ended up agreeing amongst the neurosurgeons involved is that they were all optimistic that, in the future, we might be able to offer neurosurgery to quite specific group of patients. That they were certainly behind the idea of having a very streamlined referral approach. That there are certain groups of patients that they feel definitely do benefit. We've heard about cerebellar hemorrhages, etc. And that also that it's important to think about patients who really aren't going to benefit and not to waste time referring those kinds of patients. So, you know, we recommended in the end, something quite nonspecific, I guess, which was that, that each region must develop their own criteria around who's referred, pending better evidence, really.

Dr. Gibler:

Well, that was an important point as far as having a local, essentially a culture of who you call the neurosurgeon about. You know, you can go from calling about every bleed to let's get ones that are targeted that will likely have your involvement. That was an important point of it.

Dr. Parry-Jones:

Yeah, I mean, I don't know if it's the same in the U.S., but certainly every site we've worked with as part of the care bundle project, the baseline is that everybody gets - everyone refers everyone. And quite often, the report from the radiologist says urgent neurosurgical referral recommended, so it's the first thing people do sometimes.

Dr Gibler

Great. Dr. Parry-Jones, thank you very much.

Announcer

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