Comparison of a Novel Thin-Walled 25-gauge Needle Push Button Blood Collection Set to a Standard 23-gauge Needle in a Cancer Patient Population

Article:
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Guest: Dr. Sam McCash is an Associate Attending in the Department of Pathology and Laboratory Medicine at Memorial Sloan Kettering Cancer Center.

Randye Kaye: Hello and welcome to this edition of *JALM* Talk from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. I'm your host Randye Kaye.

Phlebotomy can be an uncomfortable and even painful experience for some patients. The outer diameter of a phlebotomy needle has been shown to correlate with pain felt during the blood drawing process. Needle diameter is represented in units of gauges with an inverse relationship, meaning that larger needle gauges represent smaller outer diameters. While larger gauge, and therefore smaller diameter, needles may be associated with less pain, blood samples collected with larger gauge needles are more prone to hemolysis, the rupture of red blood cells in the specimen. Hemolyzed specimens frequently yield test cancellations, or potentially worse, inaccurate laboratory results.

The March 2023 issue of *JALM* features an article that evaluates a novel thin-walled 25-gauge needle push button blood collection set. The investigators compared the pain experienced by cancer patients and the sample integrity assessed via hemolysis index resulting from blood collection in the novel device relative to a standard 23-gauge needle.

Today, we're joined by the article's senior author, Dr. Sam McCash. Dr. McCash is an Associate Attending in the Department of Pathology and Laboratory Medicine at Memorial Sloan Kettering Cancer Center. Dr. McCash, welcome!

What motivated you to perform this study of evaluating different blood collection devices?

Sam McCash: Well, the big driver really is patient care. Now, what do we mean by that? Cancer therapy has been advancing considerably over the past 10 to 20 years, to the extent that cancer is becoming a chronic disease for cancer patients. As such, these patients have to come in for frequent follow-up visits, usually accompanied by a blood draw for evaluation.

Since cancer patients have such a higher frequency of blood draws than the normal population, it just made some sense to take a look at phlebotomy and see how we can make it more comfortable for them.

In the past, we've tried using smaller needles to see if that would cause less pain, which they did, but they had this problem of hemolysis that really messed up the specimen and we couldn't use it. So, when this new needle came out, that was engineered to be smaller but not have the problems of hemolysis, we kind of jumped on it, thinking, okay, we could use this to make the phlebotomy experience much more comfortable for our patients and still preserve the integrity of the blood specimen. So we set up a study to prove that.

Randye Kaye: Your paper explains that a 23-gauge needle is often used to perform phlebotomy. What are the advantages and disadvantages of using that standard 23-gauge needle?

Sam McCash: Well, the standard 23-gauge needle is of a decent size. It's a larger size that has the advantage of providing higher volume flows at lower speeds. This enables the tube to fill up fast, which prevents clotting to occur, which will mess up the specimen, and allows the time to be much shorter, in which the needle has to be in the arm. The higher volume flow is very good at preventing the shearing forces, which can cause hemolysis of the red blood cells.

The 23-gauge needle has shown over time to be the smallest needle that can be used without causing hemolysis. The disadvantage of course is that with a larger needle size, it could be more painful than those seen with the smaller needle such as those used with vaccines. Patients have often asked why we don't use the smaller needles that they typically get for things like flu shots, which are less painful.

But then we have to convey to them that the problem with the smaller bore needles is that they can often mess up the specimen, causing hemolysis and forcing us to do another needle draw on them, which nobody wants.

Randye Kaye: Right. So can you explain how this novel 25-gauge needle that you evaluated in your study, how is that designed to work better than the current standard needle?

Sam McCash: Of course. A very simplistic way to look at it is to think the needle as a pipe, pipe in which water can flow through. If you look into the end of the pipe, you'll see a hollow center and that's surrounded by the walls of the pipe. The outer diameter of the pipe is dictated by the inner diameter of the hollow center and the thickness of the pipe wall. So let's say if the inner diameter is 3 inches and the wall thickness is half an inch that would mean that the pipe is 4 inches in diameter.

But what if you needed a pipe to be thinner but not sacrifice the flow of the smaller inner diameter? One can use a stronger material to make the pipe walls thinner. Let's say in this case quarter of an inch and that could reduce the outer diameter to 3.5 inches without changing the inner diameter, where the flow is going to happen.

We've just decreased the size without affecting the flow and this is the same thing that we do in a needle, enabling a smaller size that would be less painful for the patient.

A second feature that the needle has is the pencil-point bevel, which is a special cut of the bevel, allowing for an easier insertion with less force on the surrounding skin tissues. Basically, we're changing some of the angles to be distributed over the entire bevel so it's much easier to insert into the skin.

Randye Kaye: All right, thank you. So now overall, you found no statistical difference in median pain scores between the two needle types. However, you did discover some unexpected and interesting findings by further stratifying the data. Could you elaborate on that?

Sam McCash: Of course. So, we originally looked at the median pain scores, which did not show a difference. What we didn't expect was the high degree in which the data was skewed towards little to no pain for both needles. We attributed this to the expertise of our phlebotomists and their ability to use the 23-gauge needle with minimal pain.

So, consulting with our statistician, we thought that further stratification of the data might give us some extra details. When we did this, we had one particular unexpected finding. This is when we compared patients with--that didn't experience any pain with patients that experience any pain. Pain was graded on 1 to 10. So we're comparing the scores of 0 to anything that was 1 to 10, and we did find a statistical difference where no pain actually had a higher association with the larger 23-gauge needle.

Now, this didn't make any sense to us. How could a larger needle size have a higher association with no pain? So after much review, we decided that it was actually the spring mechanism in the new needle that caused an audible click, a loud audible click that was perceived as pain. In our study, these were scores of 1 and 2.

So we went back and looked at the data and stratified it comparing scores of 0 to 2, against scores of 3 to 10, and here again we found a statistical difference but in this case

we found that the larger pain scores were associated with the standard 23-gauge needle when compared to the new needle.

And so in summary, we felt that this was evidence that showed that the smaller needle was indeed better at preventing high scores of pain. In this case, scores of 3 to 10.

Randye Kaye: All right. Thank you! Interesting! Now finally, now that your study has demonstrated that specimen integrity is maintained in that smaller needle size, what other aspects of this device do you think should be evaluated?

Sam McCash: So what we looked at was just the cancer patient population and the outpatient setting, and on purpose, we used our top skilled phlebotomists. We wanted to keep at least the phlebotomists as controlled as possible so we use them for all of the needle sticks. I believe that further studies looking at perhaps sicker cancer patients in the hospitals on the floors may be able to show us additional information and maybe an increased benefit in these patients because cancer patients on the floors tend to be much harder sticks. They're harder to access their veins and that's because they often have smaller or even scarred veins due to chemotherapy and cancer-induced inflammation.

So, it'll be great to see what they would think if they were able to experience the smaller needle and hopefully that we might be able to see that in the future. It will also be good to see what kind of pain scores and satisfaction use scores would be if we used a different user group.

So again, we used our best phlebotomists, most seasoned phlebotomists, who would show that they could apply phlebotomy without causing pain with either needle. But what if we were to look at health care providers that perform phlebotomy much less frequently than our seasoned phlebotomists. I think there, we might be able to find some more information and maybe show even more use for these smaller needles in that type of user population.

Randye Kaye: All right, thank you. Well, we look forward to further results. Thank you so much for joining us today, Dr. McCash.

Sam McCash: You're welcome and thank you for having me.

Randye Kaye: That was Dr. Sam McCash from Memorial Sloan Kettering Cancer Center, describing the *JALM* article "Comparison of a Novel Thin-Walled 25-gauge Needle Push Button Blood Collection Set to a Standard 23-gauge Needle in a Cancer Patient Population."

Thanks for tuning in to this episode of JALM Talk. See you next time and don't forget to submit something for us to talk about.