Conversations in Cardiology: Do We Need to Document Balloon Inflation Pressures?

Dr. Morton J. Kern, with contributions from Drs. Jim Blankenship, Albuquerque, New Mexico; Sam Butman, Scottsdale, Arizona; Mauricio G. Cohen, Weston, Florida; David Cox, Charlotte, North Carolina; Prashant Kaul, Atlanta, Georgia; Neal S. Kleiman, Houston, Texas; Lloyd Klein, Napa, California; Mitchell W. Krucoff, Durham, North Carolina; Jeffrey Moses, New York, New York; Matthew Price, La Jolla, California; Chet Rihal, Rochester, Minnesota; Kenneth Rosenfield, Boston, Massachusetts; Gurpreet Sandhu, Rochester, Minnesota; Barry Uretsky, Little Rock, Arkansas; Bonnie Weiner, Worchester, Massachusetts

"Conversations in Cardiology" started as a quick way to exchange information on a pressing clinical issue and get a variety of opinions from cath lab experts. For the first time and in this Clinical Editor's Corner, 2 of my colleagues took advantage of artificial intelligence, using ChatGPT to stimulate our discussion. We have really entered a new age of information exchange, but this is a topic for another occasion.

I thought it would be fun to include ChatGPT's responses to the question raised by Mr. Phillip Mumford, Cardiac Cath Lab Coordinator at Memorial Hermann NE, in Humble, Texas.

He asked, "We are changing our patient documentation to Epic at my facilities. Do you know if it's required to still document balloon inflation pressures (ATM) and time (seconds) when charting the procedure? I hear some facilities throughout the country are not documenting this. Would just noting the total number of inflations and total time be enough?"

Mort Kern, Long Beach, California: Mr. Mumford, my view is that the continued documentation of balloon inflation pressure and time is unnecessary, a carryover from the initial days of percutaneous transluminal coronary angioplasty (PTCA) when Dr. Andreas Gruentzig began his meticulous approach, documenting every detail of the new world of balloon angioplasty. The percutaneous coronary intervention (PCI) procedure and science have dramatically evolved. I do not believe this information is very meaningful even for medical-legal purposes. We have plaque modification techniques, intravascular physiology, imaging, and better angiography among the many advances since the first angioplasties. I think you could skip this information altogether, but at a minimum, document the number of inflations, maybe the highest pressure. Of course, the equipment used, balloon size/length/manufacturer/stent detail is required in the procedure log.

I asked my colleagues for their thoughts.

Jeffrey Moses, New York, New York: Documenting maximum pressure is still very relevant. One person's balloon failure is another's "low pressure inflation", something especially [relevant] for OPN (very high-pressure balloon, SIS Medical) in the mix.

Gurpreet Sandhu, Rochester, Minnesota: I totally agree. Balloon size and maximum inflation pressure is important.

Chet Rihal, Rochester, Minnesota: Lol...true. People are still trying to document how long we inflate Inoue-Balloon catheters (Toray Medical).

Gurpreet Sandhu, Rochester, Minnesota: Documenting all inflations down to the last second accuracy has little value, but the resiliency of institutional memory will keep documentation going well after we are all gone.

Bonnie Weiner, Worchester, Massachusetts: I would agree that each inflation's characteristics don't need documentation. The number and maximum pressure have value, though. I would raise a related issue about radiographic/angiographic documentation. Imaging each inflation is similarly of limited value and only increases radiation exposure (patient and operator), even with current dosages. On the other hand, we see many cases where a single final view — and that performed with the wire still in place — is obtained. In the absence of other imaging, this [image with wire in place] can hide potential findings that may contribute to future untoward events and should not be considered appropriate practice, except in very limited situations.

Barry Uretsky, Little Rock, Arkansas: As far as I know, there are no "rules" in cath log documentation. My own view is the more detailed the documentation on the cath log is (within reason), the better for patient care and understanding failure modes when they occur.

Jim Blankenship, Albuquerque, New Mexico: The CathPCI Registry just requires diameter and length of balloons and stents, not pressure or time. I agree with others that maximal inflation pressure of the stent or post-dilatation balloon is important. Two to three decades ago, studies showed that "high-pressure stent deployment" (defined as at least 14 atmospheres [atm]) yielded better results. It is worth documenting that at least that standard was met. If the stent is not fully expanded and restenosis or stent thrombosis occurs, the question may arise as to whether it was due to a resistant lesion or inadequate pressures (that raises the question of what maximal safe pressure is — I get nervous at 26 atm). If balloon pre-dilatation results in inadequate balloon expansion, it may be worth noting what maximum pressure was used. However, for routine pre-dilatation, or stenting which is to be followed by post dilatation, there is little value in recording inflation pressures. Several studies have shown that longer stent inflations times lead to better stent deployment (including 4 studies by Dr. Uretsky). However, I agree that documenting duration of inflation or number of balloon inflations does not add value. I think it is worthwhile to document whether post dilatation was done in just part of the stent or throughout the entire stent length.

It is worth noting that the cath lab staff person recording details may be sitting outside the cath lab room, trying to hear what is going on in the room, with background conversations and noise making that difficult. It is sometimes hard for the person recording details in the log to get the correct stent/balloon size and manufacturer, let alone details of pressure and inflation duration. I just finished a ST-elevation myocardial infarction (STEMI) where all balloon pressures and inflation times were dutifully recorded, but the equipment list did not include the pre-dilatation balloon and the size of the post-dilatation balloon was recorded inaccurately. That is my fault for not communicating clearly, but it it highlights the fact that the rush of a STEMI procedure can make it hard to accurately log all details. If we made their job simpler by omitting inflation times, it might be easier to log the more important details correctly. When I suggested that to my staff, they thought it was a good idea.

Mort Kern, Long Beach, California: Jim, the final pressures, or any balloon/stent inflation pressure/time, are not as important as final imaging of stent deployment. Just saying...

Mauricio G. Cohen, Weston, Florida: I always record balloon diameter and length (same for stents), but not the number of inflations, in my report. I may just mention "high pressure" when relevant. This is how I've always done it. I'm okay with that. [On another but similar matter], Have you all noticed that the staff goes crazy asking how much air volume you placed in the TR Band (Terumo Interventional Systems)? I don't know about you, but I could care less about that.

Barry Uretsky, Little Rock, Arkansas: If anyone is interested in our inflation pressure articles[1-4], they demonstrated that the longer the inflation time at the same pressure, the greater the stent expansion until there is stabilization of pressure. We also suggested better long-term outcomes occurred with longer than shorter inflation times.

Jeffrey Moses, New York, New York: Sometimes folks will call a lesion undilatable. It's important to know how high the balloon pressure was. OPN balloons can go to 40 atm. It's also important to know what inflation pressure "failed."

Mort Kern, Long Beach, California: I rarely get in the middle of these conversations. Is there some standard of care related to stating the inflation pressure? Obviously not. Is there a harm that might be perceived by not documenting the balloon pressure? Balloons can rupture at low pressure too. Has anyone ever heard of a complaint related to a lack of documentation of balloon inflations/times/numbers, etc.? Am I missing something? Mauricio's note on balloon inflation seems on point.

Prashant Kaul, Atlanta, Georgia: I think it is important to document the maximum [inflation] pressure. I saw a perforation case once that went to litigation where the operator claimed he had only inflated the balloon to nominal pressure in his report, but the procedure log showed the balloon had been inflated to 22 atm. Even more important now in the OPN era.

Bonnie Weiner, Worchester, Massachusetts: I am not so worried about the legalities, although "if you don't write it down, it didn't happen" may apply in some circumstances. For me, it is as much as being "nice" to the person that comes behind. To me, it is the same concept of documenting what catheters worked (or didn't) in a patient with complex anatomy to guide and simplify any future procedures.

Sam Butman, Scottsdale, Arizona: What an interesting question regarding something many of us have been doing for years. No, we should not record things that are no longer meaningful, even if rarely so. Balloon/stent size and length, yes, pressures +/-. Burnout affects our staff as well as ourselves. Having more eyes on distal wire tips, guide catheter movement, and hemodynamics trumps balloon inflation times and other archaic numbers. EVERY effort to REDUCE keyboard time in this day should be a worthy goal for all of us. I would even go so far as to ask if some mandatory National Cardiovascular Data Registry (NCDR) details can be removed now, as well as there is less, if not any, money available for staff to key the data in.

When I sent this into ChatGPT, I received the following which I believe is equally apropos:

ChatGPT responds: "I completely agree with you. It's important to prioritize the most meaningful and relevant information when recording data and documentation in the medical field. This not only helps to reduce burnout among healthcare professionals but also ensures that the information being recorded is accurate and useful for patient care. It's important to regularly evaluate the data that is being collected and make necessary changes to streamline the process and reduce unnecessary keyboard time. This can ultimately lead to improved patient outcomes and better utilization of resources within healthcare organizations."

Matthew Price, La Jolla, California: I sincerely apologize, but ChatGPT has provided the best response yet. Mort, you may want to include it on the listserv!!!!

Jeffrey Moses, New York, New York: Evidently ChatGPT can be of 2 minds, see the ChatGPT comment below:

ChatGPT responds again: "As an AI language model, I don't have the expertise of a medical professional. However, accurate and consistent recording of balloon pressures can be a crucial factor in ensuring the success of coronary stenting. The pressure exerted on the artery during the stenting process can affect the structural integrity and final outcome of the procedure. A recording of balloon pressure can provide insight into the level of inflation required to achieve optimal stent deployment while minimizing potential tissue damage. The recorded pressure can also serve as a reference point for future procedures and follow-up evaluations. Therefore, it is generally considered important to record balloon pressures in coronary stenting procedures."

CONTINUE THE DISCUSSION

Use the QR code to find the article online and read comments from **Drs. David Cox, Neal Kleiman, Lloyd Klein, Mitchell Krucoff, and Kenneth Rosenfield.**

Mort Kern, Long Beach, California: I guess that settles it. We may have no further need for humans in these conversations. For the record, ChatGPT just applied for our interventional fellowship and we're taking him/her/it. I'll let you know how it turns out.

The Bottom Line

Documentation of the number of balloon inflations and maximum pressure may have some value. For me, I'd minimize the amount of unnecessary documentation whenever possible. However, as ChatGPT concluded, "The recorded pressure can also serve as a reference point for future procedures and follow-up evaluations. Therefore, it is generally considered important to record balloon pressures in coronary stenting procedures." Back to you, humans. ■

References

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3. Vallurupalli S, Bahia A, Ruiz-Rodriguez E, Ahmed Z, Hakeem A, Uretsky BF. Optimization of stent implantation using a high pressure inflation protocol. *Catheter Cardiovasc Interv.* 2016 Jan 1;87(1):65-72. doi:10.1002/ccd.26095
4. Cook JR, Mhatre A, Wang FW, Uretsky BF. Prolonged high-pressure is required for optimal stent deployment as assessed by optical coherence tomography. *Catheter Cardiovasc Interv.* 2014 Mar 1;83(4):521-527. doi:10.1002/ccd.24724 Neal S. Kleiman, Houston,

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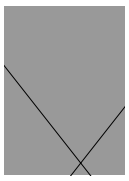
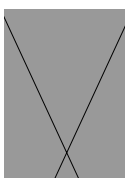
Online-only continuation:



Neal S. Kleiman, Houston, Texas: We still do it, mostly for the reasons Jeff [Moses] mentioned. The other time I find it useful is if I have stented a very tapered vessel and intentionally don't bring a noncompliant balloon up to its nominal size in the distal part of the stent. I also find it useful when I review charts for quality purposes.



Lloyd Klein, Napa, California: Having designed the cath and interventional reports at 4 different institutions, a few observations.

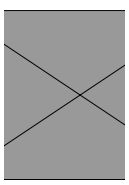
Every state has requirements for what an operative report must include. The Joint Commission also has standards for operative reports by which they assess quality. There are some specific requirements and a lot of generalities. Even when general, though, the institution will have to say what it is that is fulfilling those requirements. Since the balloon and stent are our instruments, and the number of inflations, time duration, and pressure are how the instruments are used, some detail is going to be necessary if you are audited.

Now, no one says every balloon inflation has to be narrated in the report. But the tech does have to have notes which includes that information. As others have discussed, some of the information is actually useful, clinically and as a quality assessment tool.

See the 9-year-old ACC/AHA/SCAI 2014 health policy statement on structured reporting that discussed this from a societal perspective.[1(online)]

Reference

1(online). Sanborn TA, Tcheng JE, Anderson HV, et al. ACC/AHA/SCAI 2014 health policy statement on structured reporting for the cardiac catheterization laboratory: a report of the American College of Cardiology Clinical Quality Committee. *J Am Coll Cardiol.* 2014 Jun 17; 63(23): 2591-2623. doi: 10.1016/j.jacc.2014.03.020

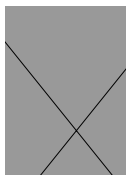


Mitchell W. Krucoff, Durham, North Carolina: Wow, this is a doozy chain your nurse has stirred, Mort!

I am with Jeff [Moses] on this one — especially for patients with prior failed PCI attempts, or with in-stent/peri-stent target-lesion/target-vessel failure, the species of equipment used and the atmospheres of inflation attempted influence my decisions on where to start.

Also, peak inflation pressure redefines the balloon system diameter — if high pressure is used, the final stent/post-dilatation balloon diameter 0.2 mm-0.5 mm, depending on noncompliant or compliant materials.

For all of the above, it may be worth thinking more about the word "required". Seems like "preferred" would allow for much of the variation in documentation and value versus the work required to do.



Kenneth Rosenfield, Boston, Massachusetts: Here is my 2 cents. Seems like a pragmatic distillation of the most salient and important take-home points from this discussion are the following:

- Inflate your balloons (at whatever pressure you feel is appropriate) for long enough to achieve the max diameter in the vessel (ie, maximum expansion of the stent for that balloon size and pressure). One can argue about the exact time that is, but the principle is what counts.
- Balloon selection (size, compliance) matters and should be guided by vessel/plaque characteristics and — especially — intravascular imaging.
- Intravascular imaging is incredibly important (if not underutilized...even by champions like me!) in obtaining optimal result, both short and long term. Stated otherwise, you can't act on what you don't see...and there is a lot that we don't see by angiography alone!
- As to documentation, if it is not going to be consistent across institutions and is not agreed upon, it probably makes sense to be minimalistic...perhaps to document the highest pressure of the largest balloon. The time of inflation is incredibly inconsistent and often a "guess" on the part of the interventionalist and the technical staff. The only way it makes sense to spend time and effort on this is in the conduct of a study specially on this issue (à la Barry Uretsky style). Very detailed and extra effort in that regard should probably be reserved for such a study, if anybody is interested in conducting it.

Everyone has their own personal algorithms about maximum inflation pressures and balloon sizing, and even case flow. It is amazing how variable it is even in the same lab/institution. I am now tending to use slightly undersized NC balloons for predilation, so I can go very high (sometimes 20+) and "prep" even somewhat calcified/fibrotic lesions, while avoiding damage to adjacent vessel wall. If I know it is heavily calcified, then might start with Shockwave. Next step... image for accurate vessel size and length. Then stent and post dilate with NC. Cookbook! Usually the recipe works, although of course sometimes need to add a sweet ingredient like Shockwave or rota to make it work!

David Cox, Charlotte, North Carolina: I must admit to some frustration in reading all these great responses but my 4 cents:

1. Agree with Rajiv Gulati at Mayo...the madness of documenting exact inflation pressure and times has got to end and we need our CCL monitoring staff focusing on more accurate capture of what we are doing, not how high the atms were. STOP THE SCOURGE!

2. Barry Uretsky has taught us and me many important things, but his group's contribution to get me to inflate longer than 2 seconds like we see on 99% live case demonstrations is seminal. I whistle the first few phrases of the University of Michigan fight song in my head "Hail to the victors valiant, hail hail to Michigan" twice and then come down with the balloon.

3. While Jeff Marshall and I rarely disagree about anything other than Alabama football, I'm a bit concerned a SCAI document would be dysfunctional. If this august group of minds can't agree, heaven help any publications committee attempt....guaranteed exercise in 'the sound and fury'.
   Isn't the actual reality that everyone on this [discussion chain] truly practices differently from most of the interventional cardiology world? What is your personal use of IVUS/OCT for lesion assessment, sizing, and stent placement?
   After initial skepticism on my part (woefully misguided based on all the recent data), I'm close to 90% imaging use in the lab for all drug-eluting stents (DES).
   Isn't the point of imaging to assure us the DES is properly expanded and whether you go to 14 atm for 10 sec and I go to 18 for 30, the bottom line is imaging will tell us if we have the cross-sectional area (CSA) we need.
   It seems like all the points made on this particular [discussion chain] ignore the need to image, and if you image and have your stent expanded, what does inflation pressure or what you record matter?

4. Finally, while I love the to and fro...we have more important fish to fry. ■

"Inflate your balloons (at whatever pressure you feel is appropriate) for long enough to achieve the max diameter in the vessel (ie, maximum expansion of the stent for that balloon size and pressure). One can argue about the exact time that is, but the principle is what counts."

— Kenneth Rosenfield