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LETTERS TO THE EDITOR

Major Differences Between Hydrophilic-Coated Radial Sheaths in Regards to Skin Infection and Reaction

With great interest, I read the paper by Rathore et al. (1). In this study, the investigators exclusively used Cook Medical (Bloomington, Indiana) hydrophilic-coated sheaths. They found significantly higher rate of abscess formation and infection in patients randomized to hydrophilic-coated Cook sheaths. This reaction has been described in the literature by many investigators (2-6) and has been exclusively related to the use of coated Cook sheaths but not other coated sheaths. Many centers with similar experience changed their practice by using other coated sheaths eliminating this adverse event. Rathore et al. (1) downplayed this reaction and did not mention that this adverse event has exclusively been reported in association with hydrophilic-coated Cook sheaths. They should have mentioned this painful and costly adverse reaction in their abstract result and conclusion and advised against using hydrophilic-coated Cook sheaths. Making a general statement in their discussion that all coated sheaths may have this problem is misleading and incorrect. Terumo M Coat hydrophilic sheaths (Terumo Interventional Systems, Somerset, New Jersey) may be substituted for coated Cook sheaths as such an adverse event has not been reported with Terumo sheaths. Furthermore, Rathore et al. (1) downplayed the fact that they did not routinely use antispasm medications in their study limiting their results and conclusion. I cannot recall any centers in the U.S. that do not routinely use antispasm medications. It is not clear why the authors avoided routine use of antispasm medications in their patients. Routine use of antispasm medications could have markedly reduced their patient discomfort and the risk of radial artery occlusion.

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Spasm and Occlusion in Contemporary Radial Practice

We congratulate Rathore et al. (1) on their recently published paper. This report confirms, in an adequately powered randomized trial, that hydrophilic coating of radial introducer sheaths is beneficial. This finding, in conjunction with previously published small studies, provides strong evidence that should lead all radial operators to switch practice and use only coated sheaths.

There are other useful data contained in the recent report. The investigators report that puncture failure is very rare (occurring in only 1 in 200 cases) and procedural success rate is high (96%). This is consistent with other contemporary studies (2). The suboptimal rate of puncture failure and procedural success in earlier reports reflects the impact of the learning curve on early adopters. In addition, the excellent results in recent studies are related to the benefits of contemporary equipment specifically designed for use in transradial procedures.

Some of the findings in the study by Rathore et al. (1) are of concern. Spasm was common, occurring in almost 30% of patients. The investigators do not provide any information on operator experience and all the procedures used 6-F sheaths. The use of larger caliber sheaths and catheters, particularly by inexperienced operators, may explain the high rate of spasm in this study. Additionally, vasodilator cocktails were not routinely used despite clear evidence in the literature that these reduce the rate of symptomatic spasm. In contemporary series using vasodilator cocktails, the instance of spasm is <5% (3) when using 5-F catheters and <8% with 6-F catheters (4). Prevention of spasm is important because it is associated with patient discomfort, procedural failure, and based on the Rathore et al. (1) data, radial artery occlusion. We would suggest that appropriate procedural modification would produce better overall results than those reported in this study.

^{1.} Rathore S, Stables RH, Pauriah M, et al. Impact of length and hydrophilic coating of the introducer sheath on radial artery spasm

The rate of radial artery occlusion, at almost 10%, is also troublesome. Of note, radial artery occlusion rates were increased by use of long sheaths. Because the Rathore et al. (1) data indicates no benefit from the use of long sheaths, experienced operators should move to shorter hydrophilic sheaths. The high rate of radial occlusion may also reflect the fact that heparin was not routinely administered to all patients and the rate of spasm in the trial was unusually high. The use of larger caliber sheaths in smaller arm vessels may have also contributed to the risk of occlusion. Utilizing an initial arm angiogram allows operators to identify anatomical variation and select smaller caliber systems where indicated (5). Additionally, no information was provided on the hemostatic technique employed despite significant reductions in radial occlusion with patent hemostasis in previous studies (6). Combining these optimal techniques may result in lower occlusion rates, well below those reported in the current study.

Finally, Rathore et al. (1) report a 3.4% incidence of late local complications. These occur almost exclusively in the hydrophilic-coated sheath group. It is important to note that this is a finding specific to the type of sheath used in the trial and has not been reported as a frequent complication of other hydrophilic sheaths.

Rathore et al. (1) have made an important contribution to the literature, particularly in relation to the value of hydrophilic coating. Some of their other findings do not reflect optimal contemporary transradial practice.

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Reply

We would like to thank Dr. Ratib and colleagues for taking interest in our recently published article (1). We completely agree and have also shown that coated sheaths reduce radial artery spasm and the discomfort experienced by the patient during transradial procedures. Procedural success rates are high with accumulated experience and improvement in equipment.

In our study, clinical evidence of radial artery spasm was observed in 19% of the patients in the coated group and 39% in the uncoated group. We have used a liberal clinical definition to diagnose spasm and avoided the routine use of vasodilators to abolish its potential impact on our end points. This is consistent with the clinical practice of the investigators. All procedures were performed by experienced radial operators using 6-F sheaths.

Spasm resulted in procedural failure in only 17 (2.1%) cases, and in the majority of cases, the procedure was completed successfully via the contralateral radial artery. As suggested, Dham et al. (2) has reported spasm as a cause of procedural failure in 4.8% of patients following the use of 6-F coated sheaths and the routine use of spasmolytic drugs, which is much higher than the failure rate reported in our study. Similarly and more recently, De-an et al. (3) has reported spasm in 7.8% of the patients, using a combination of clinical and angiographic definitions following use of 6-F coated sheaths. Among the patients experiencing spasm, one-third resulted in procedural failure (overall procedural failure in 2.9%), which is slightly worse than in our study. The incidence of spasm is very much dependent on the definition used. Spasm leading to procedural failure, a much "harder" end point, is lower in our study than other contemporary studies (2,3).

Slightly higher rates of radial artery occlusion are seen in our study as heparin was not routinely administered during some purely diagnostic procedures. The occlusion rate was 7.2% in patients receiving heparin during transradial procedures, which is similar to that reported in the literature (4,5). We did employ patent hemostasis, using either the TR band (Terumo Interventional Systems, Somerset, New Jersey) or RadiStop (RADI Medical Systems–St. Jude Medical, St. Paul, Minnesota) after removal of the sheath, and did not observe any difference in occlusion rates between the 2 devices (6). We agree that initial arm angiogram could be helpful in some cases (7).

We would also like to thank Dr. Movahed for expressing interest in our article (1). We agree that there was significantly higher occurrence of inflammatory reactions with the use of coated sheaths in our study, similar to the data reported by other investigators (8,9). In an attempt to standardize as much as possible in our sheaths, apart from the investigated qualities of length and hydrophilic coating, we used 4 different types of sheaths from the same manufacturer. We agree that prophylactic use of intra-arterial spasmolytic drugs reduce radial artery spasm in contemporary practice. Although these inflammatory reactions do seem to be related to the hydrophilic coating used by Cook, it should be noted that Cook has, since this trial was performed, changed the composition of their coating and, in our experience, does seem to have overcome this problem.