Benefits of surgeon-controlled fluoroscopy outweigh concerns

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In the study by Setterfield et al, the authors performed a retrospective analysis of patients undergoing fluoroscopy-guided endourological procedures, excluding percutaneous nephrolithotomy, with fluoroscopy being controlled by either a radiation technologist (RT) or the operating surgeon. They found that surgeon control of fluoroscopy did not lead to reduced fluoroscopy times and, in fact, was associated with increased fluoroscopy time during ureteroscopy (URS) with laser lithotripsy, although this difference was not found to be significant on multivariate analysis. We agree with the authors’ premise that reducing patient and surgeon radiation exposure to “as low as reasonably achievable” (ALARA) levels is of paramount importance, and applaud their goals in designing a study to look at this potentially modifiable factor.

While there is no direct evidence demonstrating that patient radiation exposure during endourological procedures is associated with adverse effects, such as risk of secondary malignancy, the literature in other medical fields gives significant cause for alarm. In a study of patients who underwent cardiac imaging after myocardial infarction, five-year risk of malignancy was found to increase by 3% for every 10 mSv of radiation exposure. Ferrandino et al demonstrated a median radiation dose of 29.7 mSv over a one-year period in patients with an acute stone episode, and many patients with nephrolithiasis have multiple stone episodes. As such, any and all approaches to reducing patient radiation exposure should be considered.

While the authors did not show any reduction in fluoroscopy time with surgeon control, this should be interpreted in light of the study’s limitations. The study was retrospective in design and the nature of the intervention being studied precludes blinding, which carries risk of observation bias. It is also difficult to explain why the authors found that RT control of fluoroscopy reduced fluoroscopy time during URS with laser lithotripsy, but had the opposite effect during diagnostic URS. After adjusting for case-based factors that may be markers of more difficult procedures, such as access sheath and guidewire usage, these results were not significant. This suggests that the variation in fluoroscopy time observed during this study was based more on intraoperative factors than on the use of RT- or surgeon-controlled fluoroscopy. Additionally, during the time period in which surgeons controlled fluoroscopy, degree of resident control of fluoroscopy was unknown, which could affect fluoroscopy times. As the authors note, a randomized, controlled trial of surgeon- vs. RT-controlled fluoroscopy is currently accruing at Boston Children’s Hospital, which may help address these questions.

It is important to note that while radiation exposure is an important consideration when deciding whether the surgeon or RT should control fluoroscopy, many other factors must be considered. Direct surgeon control can allow for more precise timing of fluoroscopy during delicate portions of the procedure, such as when attempting to pass an impacted stone or stricture with a wire. Another concern is that a single surgeon is likely to work with multiple RTs of varying degrees of experience and skill. While the effect of RT experience during URS has not been studied, Elkousy et al found that during extracorporeal shock wave lithotripsy (ESWL), different RTs had highly variable fluoroscopy times and stone clearance rates that correlated with RT experience. Surgeon control of fluoroscopy removes RT experience as a source of concern. Finally, many urologists practice using operating tables with built-in C-arms or in settings where dedicated fluoroscopy RTs may not be available; becoming facile with surgeon-controlled fluoroscopy is an important skill. Conversely, the need to manipulate a fluoroscopy pedal could distract the surgeon’s attention from other aspects of the procedure, although this can be partially mitigated by strategically positioning the fluoroscopy pedal in a convenient location at the beginning of the procedure.

At our institution, we feel that the benefits of surgeon control of fluoroscopy outweigh the concerns; however, we acknowledge that this will depend on the comfort level of the individual surgeon.
• Bone Fractures: In patients with bone fractures, stabilization of fractures should be received, stored, used, transferred, administered and disposed of before every dose.

• Spinal Cord Compression: In patients with untreated, imminent or established spinal cord compression (SCC), treatment for SCC should be completed before starting or resuming treatment with Xofigo®.

Other relevant warnings and precautions:

• Gastrointestinal: Patients with inflammatory bowel disease and increased risk of bowel obstruction should be treated with caution. Appropriate monitoring and consideration of additional supportive measures may be required in patients with constipation. Safety and efficacy in patients with Crohn’s disease or ulcerative colitis have not been determined.

• Sexual Function/Reproduction: Because of the potential effects on spermatogenesis associated with radiation, men who are sexually active should be advised to use condoms. Female partners of reproductive potential should use effective contraception during, and for 6 months after their partner’s treatment with Xofigo®. There is a potential risk that radiation from Xofigo® could cause adverse effects on testes.

• Contamination: Caregivers should take precautions to avoid risk of contamination. This includes:
  - wearing gloves and hand-washing when handling bodily fluids
  - promptly cleaning clothing – separately – that has been soiled with Xofigo®, patient fecal matter or urine
  - having the patient use a toilet and flush the toilet twice after use

• Bone Marrow Suppression: Bone marrow suppression has been reported in patients who experience life-threatening complications at baseline and prior to every dose of Xofigo®. Patients with evidence of compromised bone marrow reserve should be monitored closely and provided with supportive care. Xofigo® should be discontinued in patients who experience life-threatening complications despite supportive care. Patients with severely compromised bone marrow reserves at baseline should not receive Xofigo®.

• Contamination: Caregivers should take precautions to avoid risk of contamination. This includes:
  - having the patient use a toilet and flush the toilet twice after use

Most serious warnings and precautions:

Use of Radiopharmaceuticals: Should be used only by those health professionals who are appropriately qualified in the use of radioactive-prescribed substances in or on humans.

Bone Marrow Suppression: Measure blood counts prior to treatment initiation and before every dose.

Other relevant warnings and precautions:

• Xofigo® should be received, stored, used, transferred, administered and disposed of by authorized persons.

• Spinal Cord Compression: In patients with untreated, imminent or established spinal cord compression (SCC), treatment for SCC should be completed before starting or resuming treatment with Xofigo®.

• Bone Fractures: In patients with bone fractures, stabilization of fractures should be performed before starting or resuming Xofigo®.

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