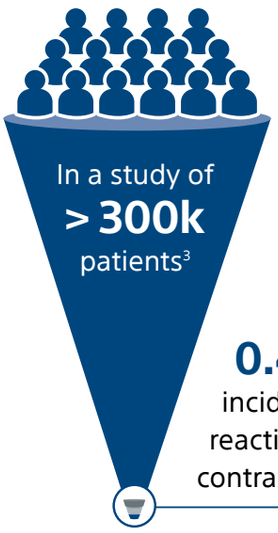
Boston Scientific
Advancing science for life™

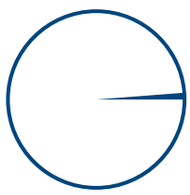
Iodinated Contrast Media Reactions = Low Risk

Radiocontrast agents used to improve imaging studies often contain iodine. Patients with contrast agent reactions often do not undergo necessary procedures that involve imaging. Yet, prevalence and incidence of reactions to iodinated contrast media are actually rare, particularly severe reactions.[1]

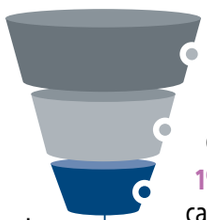


Prevalence: Rare

In a study population of 200,000 patients, iodinated contrast media reactions occured in **less than 1% of the population,** with few or no symptoms.[1]



Types of Reactions* of the 0.48%:



91.1% were mild such as hives, itching, limited skin edema, nasal congestion, sneezing, conjunctivitis or throat itching[3]

7.9% were moderate such as diffuse urticaria, diffuse erythema, wheezing or mild bronchospasm[3]

1% were severe such as profound laryngeal edema, cardiopulmonary arrest or anaphylactoid shock3

Iodine Formulations, Dosage and Location Injected Matter

Forms of Iodine

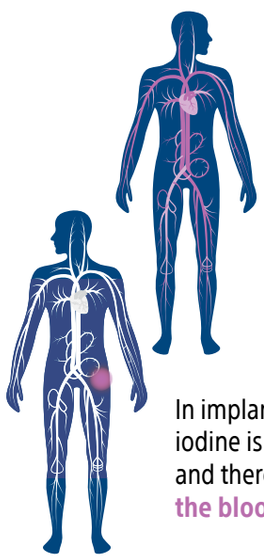
Iodine is an essential element. There is no generic allergy to all forms of iodine. Pegylated iodine is among the safest forms of ionic iodine.[8]

Adverse reactions can be falsely considered as an allergy to iodine because contrast materials are iodine based. IgE-mediated anaphylaxis is rare but may be one of the possible mechanisms of severe adverse reactions to contrast material.[4]

96 patients who had an anaphylactoid response to contrast media were tested for an allergy using 4 types of contrast media, and **only 4 patients' tests strongly** suggested IgE-mediated allergy to the contrast. **None were allergic to all.** The majority of the positive allergy responses were to the non-ionic contrast media.[4]

Doses of Iodine

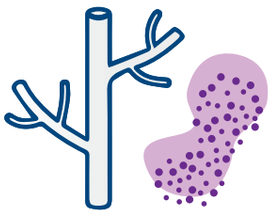
The body's reaction to different doses of iodine may be different.



For imaging, contrast agents are low molecular weight compounds with iodine bound to a benzene ring that creates radiopacity. **The contrast agent usually contains 200-400 mg of iodine per mL** which enters the bloodstream and the material is eventually absorbed by the body or eliminated through urine or bowel movements.[4,8]

In implantable products with iodine, the iodine isn't inserted into the bloodstream and therefore the **iodine concentration in the blood is much lower.**[8]

Location of Iodine Injection on the Body



Contrast agents outside the vascular space

Although contrast agents are most frequently administered via intravascular injection,[6] there has been experience with administration of these contrast agents outside the vascular space with:

0 serious adverse events

0 reports of systemic reactions

Minimal mild adverse events are all related to local inflammation to contrast agents and usually occur only when large volumes of contrast medium are involved.[7]

Conclusion: Minimal Overall Risk of "Iodine Sensitivity"

An allergic-like reaction to non-ionic iodine contrast media is an extremely rare event that presents as a mild acute reaction without significant clinical consequences.[3] As with any medical procedure, there are risks involved in using iodine in the body. Treatment decisions should be at the discretion of the physician. Any known risks should be explained to the patient.

SpaceOAR Vue™ Hydrogel**

SpaceOAR Vue System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue System to reduce the radiation dose delivered to the anterior rectum.
The SpaceOAR Vue System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.[3]

Products such as SpaceOAR Vue Hydrogel are not contraindicated for patients with iodine sensitivity as the iodine is covalently bound to the PEG molecule and does not present in the body in the same way as free-flowing iodine contrast that is typically used in imaging.[8] In fact, SpaceOAR Vue Hydrogel contains about 100 mg of PEGylated Iodine in a 10 mL injection, and is bound for three months, after which it is slowly released. Consequently, the blood concentration of PEGylated Iodine "is vanishingly small."[8]

Dr. Michael A. Bettmann contributed to the research, analysis and design of this infographic.

*Study evaluated both iodinated contrast media and gadolinium-based contrast media.
** SpaceOAR Vue Hydrogel has not been studied in patients and the decision to use the product is left to the physician's discretion.

1. Mammarappallil JG, Hiatt KD, Vincent W, et al. How accurate is the label "allergic to iodinated contrast agents"? Acta Radiol. 2016 Jan;57(1):47-50.
2. Cha MJ, Kang DY, Lee W, et al. Hypersensitivity reactions to iodinated contrast media: A multicenter study of 196 081 patients. Radiology. 2019 Oct;293(1):117-24.
3. Sodagari F, Mozaffary A, Wood CG 3rd, et al. Reactions to both nonionic iodinated and gadolinium-based contrast media: Incidence and clinical characteristics. AJR Am J Roentgenol. 2018 Apr;210(4):715-9.
4. Trcka J, Schmidt C, Seitz CS, et al. Anaphylaxis to iodinated contrast material: Nonallergic hypersensitivity or IgE-mediated allergy? AJR Am J Roentgenol. 2008 Mar;190(3):666-70.
5. Veronese FM, Harris JM. Introduction and overview of peptide and protein pegylation. Adv Drug Deliv Rev. 2002 Jun 17;54(4):453-6.
6. Kaller MO, An J. Contrast agent toxicity. In: StatPearls. Treasure Island (FL): StatPearls Publishing; May 25, 2020.
7. Wang CL, Cohan RH, Ellis JH, et al. Frequency, management, and outcome of extravasation of nonionic iodinated contrast medium in 69,657 intravenous injections. Radiology. 2007 Apr; 243(1):80-7.
8. Data on file at Boston Scientific.