9-19-2023

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Arthroplasty Today 23 (2023) 101201

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original research

The Use of Iodophor-Impregnated Drapes in Patients With Iodine-Related Allergies: A Case Series and Review of the Literature

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ARTICLE INFO

Article history:
Received 25 June 2023
Accepted 23 July 2023
Available online 19 September 2023

Keywords:
Iodine allergy
Shellfish allergy
Povidone iodine allergy
Adhesive incise drape
Hip arthroplasty
Knee arthroplasty

ABSTRACT

Background: The use of iodophor-impregnated adhesive drapes have become almost universally incorporated into standard practice of arthroplasty draping technique. Iodine-related allergies in patients planned for joint replacement present a challenge in terms of the best course of action to minimize complications and optimize outcomes.

Methods: This is a retrospective case series of patients that received an iodophor-impregnated drape as part of draping for a total hip or knee arthroplasty at a single orthopaedic-specific hospital with documented iodine-related allergies. From 2015 to 2023, 9816 total hip arthroplasty and total knee arthroplasty cases were reviewed, and 135 were documented to have an iodine-related allergy for a prevalence of 1.38%. Intraoperative and postoperative records were reviewed to screen for an allergic reaction or wound healing issues that may have been related to an adverse reaction to the use of the iodophor-impregnated drape.

Results: Of the 135 patients, 43 had iodine listed as an allergy, 85 had shellfish, 20 had iodinated contrast media, and 3 had povidone iodine. Sixteen patients had a cluster of iodine-related allergies. There were no intraoperative reports of an allergic reaction to this drape. There were four superficial wound problems, none of which were documented to relate to an allergic dermatitis reaction, and none required further surgery.

Conclusions: Patients reporting iodine-related allergies were present in 1.38% of patients undergoing hip or knee arthroplasty in our series. We encountered no allergic reactions or adverse outcomes that could be attributed to the use of iodiphor impregnated drapes in these patients.

Introduction

The use of iodophor-impregnated adhesive drapes have become almost universally incorporated into standard practice of arthroplasty draping technique, primarily related to infection risk reduction [1]. Given the widespread utilization of these drapes, reports of allergic reactions to iodine-impregnated drapes are markedly sparse with only 2 case reports published previously [2,3].

In our experience, reported iodine-related allergies in patients undergoing joint replacement surgery are not uncommon. The prevalence of documented iodine-related allergies is poorly described, and there are no reports on the prevalence of iodine allergies in patients undergoing joint replacement surgery. A true allergic reaction to povidone-iodine has been previously quoted at a prevalence of 0.04% [4]. This lack of clarity is in part due to the nature of iodine-related allergies as clinical entities, which are fraught with confusing nomenclature, a lack of supporting evidence and may lead to a negative impact on patient outcomes due to an alteration in practice in response to a documented allergy [5–11]. Iodine in isolation does not act as an allergen and is an essential nutrient for normal physiological processes [5,7,12]. Allergic reactions to iodine-containing products may occur; however, it is unlikely that iodine is the source of this allergy [9,11,13]. Patients with iodine allergies often have their allergy listed as a cluster of iodine, shellfish, and radiographic contrast media in a variety of combinations. Most commonly, this relates to an underlying food intolerance to shellfish. Less commonly, there may be a history of adverse reaction to iodinated contrast media (ICM) or other iodine-

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https://doi.org/10.1016/j.artd.2023.101201

containing product such as povidone iodine. An examination of the literature published in this area suggests poor correlation between patients documented allergies and the clinical entities that they represent.

So, the issue at hand is what to do about draping when a patient reports an iodine allergy. The manufacturers of the iodophor-impregnated adhesive incise drape recommend against the product in patients 'with a known sensitivity to iodine' [14]. However, this requires using unfamiliar drapes, which may not provide the same level of safety related to infection risk. Occasionally, this allergy may not be identified until the time-out procedure, with the iodophor drape already in place. Further, it is common for surgeons to choose to utilize iodophor drapes, even in the face of a documented iodine allergy, because of a need to prioritize infection risk reduction.

This report describes the use of iodophor-impregnated drapes in the setting of iodine-related allergies (iodine, ICM, shellfish, or povidone iodine) for patients undergoing total hip or total knee arthroplasty. Our hypothesis is that an iodophor-impregnated adhesive incise drape is safe to use in these patients.

Material and methods

Following institutional review board approval, we performed a retrospective cohort study of patients that received an iodophor-impregnated drape as part of draping for a total hip or knee arthroplasty at a single orthopaedic-specific hospital. Draping technique involved application of a skin preparation solution at the discretion of the treating surgeon with layered draping utilizing nonpermeable, adhesive U drapes, followed by single-use top drapes. The iodophor-impregnated adhesive drape was then applied to the surgical site covering all remaining exposed skin. Patients were identified using an institutional database that contains detailed information from all patients undergoing lower limb total joint arthroplasty at our institution from January 2015 to January 2023. We identified cases of documented iodine related allergies including iodine, ICM, shellfish, or povidone-iodine in patients undergoing hip or knee arthroplasty during this period. In order to calculate an incidence of these allergies, the total number of patients undergoing hip or knee arthroplasty during this timeframe was also sought. The prevalence of iodine allergies, a categorical variable representing the proportion of individuals in the sample diagnosed with an allergy to iodine, was calculated. Medical records of all patients were reviewed to identify patient characteristics, including demographics and details of documented allergies. Intraoperative and postoperative records up until the first postoperative review were reviewed to screen for an allergic reaction or wound healing issues that may have been related to an adverse reaction to the use of the iodophor-impregnated drape. This included any documented presence of rash, delayed wound healing, additional dressing changes, or superficial infection. Furthermore, intraoperative records were reviewed to explore whether noniodine-impregnated adhesive incise drapes were utilized. Draping technique involved the application of an alcohol-based chlorhexidine for skin preparation. Layered draping was then completed utilizing a nonpermeable, adhesive U drape, followed by single-use adhesive top drapes to isolate the surgical field. The iodophor-impregnated adhesive drape was then applied to the surgical site covering all remaining exposed skin.

Study outcomes

Patients are routinely followed up in clinic at multiple times in the first 90 days postoperatively. Outpatient and hospital records were reviewed to determine if any adverse reactions had occurred to the use of iodophor drapes.

Table 1
Demographics.

	Iodine-related allergy (n = 135)
Age (y)	67.11 (39-84)
Joint	
Hip	57 (42.2)
Knee	78 (57.8)
Laterality	
Right	75 (55.5)
Left	60 (44.5)
Sex	
Female	100 (74.1)
Male	35 (25.9)
BMI (kg/m^2)	30.17 (19.66-40.74)

BMI, body mass index.
Values given as mean and range or N (%).

Results

Between 2015 and 2023, 9816 cases of hip or knee arthroplasty were identified. Of these, 135 were documented to have an iodine-related allergy, which provides a prevalence of 1.38% over this time period. The demographics of patients are listed in Table 1. Regarding the breakdown of patient allergies, 43 patients had iodine listed as an allergy, 85 had shellfish, 19 had ICM, and 3 had povidone iodine, which listed as betadine (Table 2). Sixteen patients had a cluster of iodine-related allergies listed with shellfish and iodine being combined in all cases; one patient had a cluster of iodine, iodinated contrast, and shellfish. Of the 135 patients with listed iodine-related allergies, all patients had an iodophor-impregnated drape applied. No noniodine-impregnated adhesive incise drapes were utilized. There were no intraoperative reports of allergic reaction to this drape. Furthermore, there were no documented postoperative rashes consistent with allergic or irritant dermatitis.

Discussion

This is the first series in the hip and knee replacement literature reporting on the use of iodophor-containing adhesive drapes in the setting of patients undergoing total hip and knee arthroplasty with iodine-related allergies. Aside from potential benefit of reducing the chance of infection, these drapes have a very practical advantage in that they provide an excellent method of securing the drapes to ensure complete isolation of the surgical site during surgery. In this series patients did not encounter any adverse reactions that could be attributed to an allergic response. While this is a small series, our data suggest that, for most patients reporting an iodine or iodine-related allergy, this practice may be safe. Patients with documented allergies to povidone-iodine represent a subset of patients that should garner additional scrutiny. In this series, only 4 patients had a documented 'betadine' allergy. There are reports of both anaphylactic reactions as well as contact dermatitis to povidone-iodine, and in this setting, surgeons should consider preoperative patch testing to determine safety of iodophor-impregnated drape use [2,3,15].

Table 2
Details of documented allergies.

Iodine	43
Iodinated contrast media	19
Shellfish	85
Povidone iodine	3
Allergy cluster (2 or more iodine-related allergies listed)	15

It is important to distinguish the spectrum of reactions that can occur with the use of both topical and intravenous iodine-containing products. A true allergic reaction is an immunologically mediated response to a foreign substance known as an antigen. Drug allergies are commonly classified into 4 types: immunoglobulin E (IgE)-mediated (type I); cytotoxic (type II); immune complex (type III); and cellular-mediated (type IV) hypersensitivity [14]. A reaction to topical application of iodine-containing products may lead to contact dermatitis, which can be further divided into allergic contact dermatitis and irritant contact dermatitis. Allergic contact dermatitis is an immune-mediated type IV hypersensitivity reaction [14]. Irritant contact dermatitis is not an immune-mediated response but rather due to exposure to an irritating substance and may be seen particularly where prolonged pooling of a povidone-iodine solution occurs intraoperatively [16,17]. Povidone-iodine may act as both an allergen and an irritant, which makes a definitive diagnosis of an allergy challenging.

As previously discussed, allergies to iodine-containing products can occur and can have serious adverse outcomes for patients if exposed to these products inadvertently; however, it is unlikely that iodine is the allergen for these reactions [9,11,13,15,18]. This is brought into focus by the recognition that iodine is essential for normal endocrine physiology and is involved in thyroid hormone synthesis. Iodine in its elemental form is an essential nutrient with recommended daily intakes of 150 ug per day for adults [19]. People with documented iodine allergies are not excluded from this requirement. Therefore, it is the compounds that iodine is bound to rather than the elemental iodine that will act as an allergen in the setting of an allergy.

Multiple reports have shown that allergies to iodine-containing products do not cross over to other unrelated iodine-containing products. This has been shown in the setting of iodine-containing pharmaceuticals, iodine-containing contrast agents, and products such as PVP-1 [5,8,20–22]. The most commonly occurring cluster of allergies in our series were iodine and shellfish allergies. Shellfish allergies are caused by proteins called tropomyosin, which have no relationship to iodine [5]. How the myth began linking shellfish allergies to iodine-based compounds is unclear, but it may relate to early investigations seeking to identify risk factors for an adverse reaction to contrast media [5]. While seafood may contain relatively high levels of iodine compared with other foods, the allergenic proteins are not iodinated, and seafood allergy does not depend on the iodine content of the seafood. The American College of Radiology recently published guidelines on the phenomenon of seafood allergies as they relate to iodinated contrast, which state that there is no cross-reaction between iodine-containing contrast medium and iodine or seafood allergies [23].

Given a lack of cross-reactivity to iodine-containing products, in the setting of utilizing an iodophor-impregnated incise drape, documented allergies to iodophors such as povidone iodine (betadine) pose the greatest risk of an adverse reaction. Of significance is the small number of patients in this series with documented allergies to povidone iodine. The most common incise drape utilizes an iodophor in the adhesive agent to provide antimicrobial properties. An iodophor is iodine complexed with a solubilizing agent such as a surfactant. Povidone iodine and iodine povacrylex are the 2 most common examples of iodophors used as antiseptic agents [24]. The exact preparation of iodine utilized in incise drapes is often a proprietary trade secret and not freely available. This makes interpreting the potential for allergic cross-reaction challenging. Product information recommends avoiding use where patients have 'sensitivity to iodine'. This advice is ambiguous and further complicates the decision of when to use these products. The incidence of allergic contact dermatitis (type IV hypersensitivity reaction) to povidone iodine is poorly described in spite of its widespread use. An early report into the use of povidone-iodine found allergic contact dermatitis to occur with an incidence of 0.04% in 5000 normal subjects [25]. Type 1 allergic reactions leading to anaphylaxis due to povidone exposure may occur, but they are even rarer with only nine cases reported in the literature [15]. Anaphylactic reactions have been documented to occur both with topical application of povidone iodine for skin prep as well as using lavage of wounds but not incise drapes [15]. In spite of their rare occurrence, the consequences can be important, and the use of iodophor incise drapes should be avoided where a documented anaphylactic reaction to povidone iodine exists [16]. In patients with a history of an allergic reaction to povidone-iodine, patch testing has been suggested to avoid an anaphylactic reaction to intraoperative exposure.

There are several limitations to this study. Firstly, this is a retrospective case series, and as such, it is possible that reactions to the use of an iodophor impregnated drape were missed due to inaccuracies in documentation. Secondly, due to the limitations of documentation utilized by our institution, while we can be sure that iodophor-impregnated drapes were opened for all patients in this series, it is possible that some patients did not have these drapes applied following a late recognition of a patient's allergies. Thirdly, given the rare occurrence of allergies to povidone-iodine, our series is likely not large enough to provide a definitive answer regarding the safety of using iodophor-impregnated drapes in these patients. The nature of the documented allergies in this series is limited to the level of documentation in a patient's file. Prospective studies could more accurately identify the exact nature of the allergy and the inciting event. Given the rare occurrence of true allergic reactions to povidone-iodine, further prospective large studies are required to further clarify the safety of using iodophor-impregnated adhesive drapes in these patients.

Conclusions

Patients reporting iodine-related allergies were present in 1.38% of patients undergoing hip or knee arthroplasty in our series. We encountered no allergic reactions or adverse outcomes that could be attributed to the use of iodophor-impregnated adhesive drapes in these patients. Patients with documented allergies to povidone-iodine, as distinct from 'iodine', shellfish, or ICM should be considered for patch testing prior to proceeding with the utilization of iodophor incise drapes until further research can confirm safety in these patients.

Conflicts of interest

The authors declare there are no conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2023.101201.

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